DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
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Bethesda, Maryland 20892-2107
phone: (301) 496-5633
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Via Email: porfanedes@judicialwatch.org

April 22, 2022

Ramona Cotca
Judicial Watch, Inc.
425 Third Street SW, Suite 800
Washington, DC 20024

Re: NIH FOIA Case No.: 54052; Judicial Watch v. HHS, Case No. 21-cv-00696

Dear Mr. Orfanedes:

This is an additional response to the Freedom of Information Act (FOIA) request that is the subject of the complaint filed in *Judicial Watch v. HHS*, 21-cv-00696, now pending in the U.S. District Court for the District of Columbia. Your FOIA request, dated April 22, 2020, was received by the National Institutes of Allergy and Infectious Diseases (NIAID) on the same day.

You requested the following:

1. All internal NIAID communications regarding the Wuhan Institute of Virology in Wuhan, China.
2. All agreements, contracts and related documents between NIAID and the Wuhan Institute of Virology.
3. All records, including agreements, funds disbursement records and related NIAID communications regarding a reported $3.7 million in grants provided by NIH to the Wuhan Institute of Virology.

The date range for the records request is January 1, 2013 to April 22, 2020.

In accordance with the Court's order dated March 16, 2021, we have processed an additional 1651 pages of records this month. The information being withheld is protected from release pursuant to Exemptions 4, 5, and 6 of the FOIA, 5 U.S.C. § 552 (b)(4), (b)(5) and (b)(6); and sections 5.31 (d), (e) and (f) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. Exemption 5 permits the withholding of internal government records which are predecisional and contain staff advice, opinion, and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making. Exemption 6 exempts from disclosure records the release of which would cause a clearly unwarranted invasion of personal privacy.

Please direct any questions regarding this response to Derek Hammond of the Department of Justice, who can be reached at derek.hammond@usdoj.gov, or (202) 252-2511.

Sincerely,

for Gorka Garcia-Malene
Freedom of Information Act Officer, NIH

From: Aleksei Chmura
To: Stemmy, Erik (NIH/NIAID) [E]; Gratton, Shaun (NIH/NIAID) [E]
Cc: Peter Daszak; Hongying Li
Subject: 5 R01 AI110964 (Interim Report)
Date: Tuesday, August 3, 2021 1:42:44 PM
Attachments: 5R01AI110964-05 Interim Report as submitted.pdf

Dear Erik and Shaun,

We have submitted our interim report in the eRA commons system for our "Understanding the Risk of Bat Coronavirus Emergence" award (5 R01 AI110964-05).

Please let us know, if there is anything further required for this.

Many thanks,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff &
Authorized Organizational Representative

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

A. COVER PAGE

Project Title: Understanding the Risk of Bat Coronavirus Emergence	
Grant Number: 5R01AI110964-05	**Project/Grant Period:** 06/01/2014 - 05/31/2019
Reporting Period: 06/01/2018 - 05/31/2019	**Requested Budget Period:** 06/01/2018 - 05/31/2019
Report Term Frequency: Annual	**Date Submitted:** 08/03/2021
Program Director/Principal Investigator Information: PETER DASZAK , PHD BS **Phone Number:** (b) (6) **Email:** (b) (6)	**Recipient Organization:** ECOHEALTH ALLIANCE, INC. ECOHEALTH ALLIANCE, INC. 520 EIGHTH AVENUE NEW YORK, NY 100181620 **DUNS:** 077090066 **EIN:** 1311726494A1 **RECIPIENT ID:**
Change of Contact PD/PI: NA	
Administrative Official: ALEKSEI CHMURA 460 W 34th St., 17th Floor New York, NY 10001 **Phone number:** (b) (6) **Email:** (b) (6)	**Signing Official:** ALEKSEI CHMURA 460 W 34th St., 17th Floor New York, NY 10001 **Phone number:** (b) (6) **Email:** (b) (6)
Human Subjects: Yes **HS Exempt:** NA **Exemption Number:** **Phase III Clinical Trial:** NA	**Vertebrate Animals:** NA
hESC: No	**Inventions/Patents:** No

B. ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002, and the recent emergence Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then hundreds of novel bat-CoVs have been discovered (including >260 by our group). These, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating a largescale human-wildlife interface, and high risk of future emergence of novel CoVs. To understand the risk of zoonotic CoV emergence, we propose to examine 1) the transmission dynamics of bat-CoVs across the human-wildlife interface, and 2) how this process is affected by CoV evolutionary potential, and how it might force CoV evolution. We will assess the nature and frequency of contact among animals and people in two critical human-animal interfaces: live animal markets in China and people who are highly exposed to bats in rural China. In the markets we hypothesize that viral emergence may be accelerated by heightened mixing of host species leading to viral evolution, and high potential for contact with humans. In this study, we propose three specific aims and will screen free ranging and captive bats in China for known and novel coronaviruses; screen people who have high occupational exposure to bats and other wildlife; and examine the genetics and receptor binding properties of novel bat-CoVs we have already identified and those we will discover. We will then use ecological and evolutionary analyses and predictive mathematical models to examine the risk of future bat-CoV spillover to humans. This work will follow 3 specific aims:

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces. We will examine if: 1) wildlife markets in China provide enhanced capacity for bat-CoVs to infect other hosts, either via evolutionary adaptation or recombination; 2) the import of animals from throughout Southeast Asia introduces a higher genetic diversity of mammalian CoVs in market systems compared to within intact ecosystems of China and Southeast Asia; We will interview people about the nature and frequency of contact with bats and other wildlife; collect blood samples from people highly exposed to wildlife; and collect a full range of clinical samples from bats and other mammals in the wild and in wetmarkets; and screen these for CoVs using serological and molecular assays.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk. We propose two competing hypotheses: 1) CoV host-range in bats and other mammals is limited by the phylogenetic relatedness of bats and evolutionary conservation of CoV receptors; 2) CoV host-range is limited by geographic and ecological opportunity for contact between species so that the wildlife trade disrupts the 'natural' co-phylogeny, facilitates spillover and promotes viral evolution. We will develop CoV phylogenies from sequence data collected previously by our group, and in the proposed study, as well as from Genbank. We will examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes. We will predict host-range in unsampled species using a generalizable model of host and viral ecological and phylogenetic traits to explain patterns of viral sharing between species. We will test for positive selection in market vs. wild-sampled viruses, and use data to parameterize mathematical models that predict CoV evolutionary and transmission dynamics. We will then examine scenarios of how CoVs with different transmissibility would likely emerge in wildlife markets.

Specific Aim 3: Testing predictions of CoV inter-species transmission. We will test our models of host range (i.e. emergence potential) experimentally using reverse genetics, pseudovirus and receptor binding assays, and virus infection experiments in cell culture and humanized mice. With bat-CoVs that we've isolated or sequenced, and using live virus or pseudovirus infection in cells of different origin or expressing different receptor molecules, we will assess potential for each isolated virus and those with receptor binding site sequence, to spill over. We will do this by sequencing the spike (or other receptor binding/fusion) protein genes from all our bat-CoVs, creating mutants to identify how significantly each would need to evolve to use ACE2, CD26/DPP4 (MERS-CoV receptor) or other potential CoV receptors. We will then use receptor-mutant pseudovirus binding assays, in vitro studies in bat, primate, human and other species' cell lines, and with humanized mice where particularly interesting viruses are identified phylogenetically, or isolated. These tests will provide public health-relevant data, and also iteratively improve our predictive model to better target bat species and CoVs during our field studies to obtain bat-CoV strains of the greatest interest for understanding the mechanisms of cross-species transmission.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Year 5 NIAID CoV Report Accomplishments Final.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

File Uploaded : B4 Training.pdf

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

1. Conference and University Lectures: PI Daszak and Co-investigators Shi, Epstein, Olival, and Zhang gave invited conference and university lectures at The US-China Dialogue on the Challenges of Emerging Infections, Laboratory Safety and Global Health Security in Galveston, US; the US-China Workshop on Frontiers in Ecology and Evolution of Infectious Diseases in Berkeley, US and Shenzhen, China; the Sino-Germany symposium "Globalization-Challenge and Response for Infectious Diseases" in Hamburg, Germany; the 8th International Symposium on Emerging Viral Diseases in Wuhan, China; the Global Virome Project meeting, Bangkok, Thailand; the Western Asia Bat Research Network (WAB-Net) workshop, Tbilisi, Georgia; the International Conference on Emerging Infectious Diseases (ICEID), Atlanta, US; the North American Society for Bat Research (NASBR) Conference, Puerta Vallerta, Mexico; and the 3rd Symposium of Biodiversity and Health in Southeast Asia, Chiayi, Taiwan

2. Agency and other briefing: PI Daszak and Co-investigators Shi, Olival presented this project at the Cary Institute for Ecosystem Studies, New York, US; the National Institute for Viral Disease Control and Prevention, China CDC; the Chinese Academy of Sciences; and the Chinese Academy of Medical Sciences

3. Public outreach: PI Daszak and Co-investigator Shi, Epstein, Olival, have presented this work to the general public in a series of meetings over Year 5 including at a Cosmos Club briefing that EcoHealth Alliances hosts in Washington DC, multiple meetings of the China National Virome Project and the Global Virome Project in China, Europe, Australia, Southeast Asia and Latin America. As in Year 4, Co-Investigator Zhu introduced this work to the conservation and ecological research community in China through field training workshops.

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Not Applicable

The results of the 5th year of our R01 work are detailed below. They include:

Specific Aim 1: Assessment of CoV spillover potential at high-risk human-wildlife interfaces

During Year 5, we finalized the analysis of both quantitative and qualitative data from human surveillance in three provinces in Southern China: Yunnan, Guangxi, and Guangdong provinces.

1.1 High-risk human-animal interaction increase bat coronavirus spillover potential among rural residents in southern China

We conducted a cross-sectional biological behavioral surveillance in Yunnan, Guangxi, and Guangdong provinces from 2015 to 2017. From 8 study sites, a total of 1,596 residents were enrolled, of these, 1,585 participants completed the questionnaires and 11 participants withdrew from the questionnaire interview due to personal schedule reasons. After the interviews, 1,497 participants provided biological samples for lab analysis (**Fig. 1**).

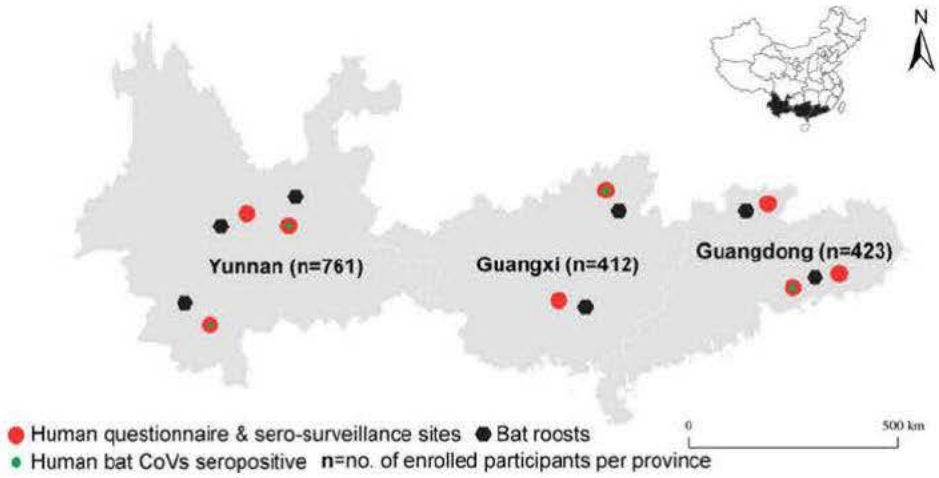

Fig. 1: Eight field surveillance sites for human questionnaire & sero-surveillance with concurrent bat sampling in Yunnan, Guangxi, Guangdong provinces in Southern China. Bat coronavirus sero-positivity were detected in human population in four sites in this study

1.1.1 Demographics

There were more female (62%) than male (38%) from the communities participated in this study. Most participants were adults over 45 years old (69%) and had been living in the community for more than 5 years (97%) with their family members (95%). A majority relied on a comparatively low family annual per capita income less than 10,000 RMB (86%), which is below the national level of per capita disposable income of rural households from 2015 to 2017. Most participants (98%) had not received a higher education from college and were making a living on crop production (76%). 9% of the participants frequently traveled outside the county as migrant laborers.Some participants were working in sectors where frequent human-animal contacts occur, such as the animal production business (1.7%), wild animal trade (0.5%), slaughterhouses or abattoirs (0.5%), protected nature reserve rangers (0.4%) or in wildlife restaurants (0.3%). It was common for participants to have multiple part-time jobs as income sources **(Table 1)**.

Variable	Total	
	N	Valid %
Gender (n= 1,574)		
Female	968	61.5
Male	605	38.4
Other	1	0.1
Age (n=1,582)		
Under 18 years	71	4.5
18 to 44 years	420	26.5
45 to 64 years	780	49.3
Age 65 or older	311	19.7
Province (n=1,585)		
Guang Dong	420	26.5
Guang Xi	412	26.0
Yun Nan	753	47.5
Time of residence (n=1,568)		
< 1 month	4	0.3
1 month – 1 year	12	0.8
1 year – 5 years	26	1.7
> 5 years	1,526	97.3
Family annual per capita income (RMB) (n=1,565)		
<1000	271	17.3
1001-10000	1067	68.2
>10000	227	14.5
Activities to earn livelihood since last year		
Extraction of minerals, gas, oil, timber (n=1,566)	5	0.3
Crop production (n=1,569)	1,196	76.2
Wildlife restaurant business (n=1,564)	5	0.3
Wild/exotic animal trade/market business (n=1,566)	8	0.5
Rancher/farmer animal production business (n=1,566)	27	1.7
Meat processing, slaughterhouse, abattoir (n=1,567)	8	0.5
Zoo/sanctuary animal health care (n=1,565)	1	0.1
Protected area worker (n=1,567)	7	0.4
Hunter/trapper/fisher (n=1,565)	3	0.2
Forager/gatherer/non-timber forest product collector (n=1,566)	4	0.3
Migrant laborer (n=1,567)	144	9.2
Nurse, doctor, healer, community health worker (n=1567)	7	0.4
Construction (n=1,564)	41	2.6
Other (n=1,568)	293	18.7
Highest level of education you completed (n=1,570)		
None	428	27.3
Primary School	632	40.3
Secondary school/Polytechnic school	479	30.5
College/university/professional	31	2.0
Live with family (n=1,564)		
No	73	4.7
Yes	1491	95.3

Table 1: Demographics of study participants. Total counts differ due to missing responses.

1.1.2 Animal contact and exposure to bat coronaviruses

Serological testing of serum samples from 1,497 local residents revealed 9 individuals (0.6%) were positive for bat coronavirus, indicating exposure at any point in their life to bat-born SARS-related Coronavirus (n=7, Yunnan) and HKU10 Coronavirus (n=2, Guangxi), or other coronaviruses that are phylogenetically closely related to these two coronaviruses (Table 2). All individuals who tested positive (male=6, female=3) were over 45 years old, and most (n=8)

were making a living from crop production.None of those participants reported any symptoms in the preceding 12 months in the interview.

Site	# tested	Bat CoV + (%)	SARSr-CoV Rp3 + (%)	HKU10 + (%)	HKU9 + (%)	MERS-CoV+ (%)
Jinning, Yunnan	209	6 (2.87)	6 (2.87)	-	-	-
Mengla, Yunnan	168	1 (0.6)	1 (0.6)	-	-	-
Jinghong, Yunnan	212	-	-	-	-	-
Lufeng, Yunnan	144	-	-	-	-	-
Guangdong	420	-	-	-	-	-
Guangxi	412	2 (0.48)	-	2 (0.48)	-	-

Table 2: ELISA testing of human sera for 4 bat CoVs

Due to the low rate of sero-positivity, we did not conduct statistical comparisons of animal-contact behavior by coronavirus outcome. Figure 2 shows animal contact rates among the survey population (n= 1,585) and among sero-positive individuals (n=9).Participants reported common contact with poultry and rodents/shrews, and most animal contact occurred in domestic settings through raising animal or food preparation activities.

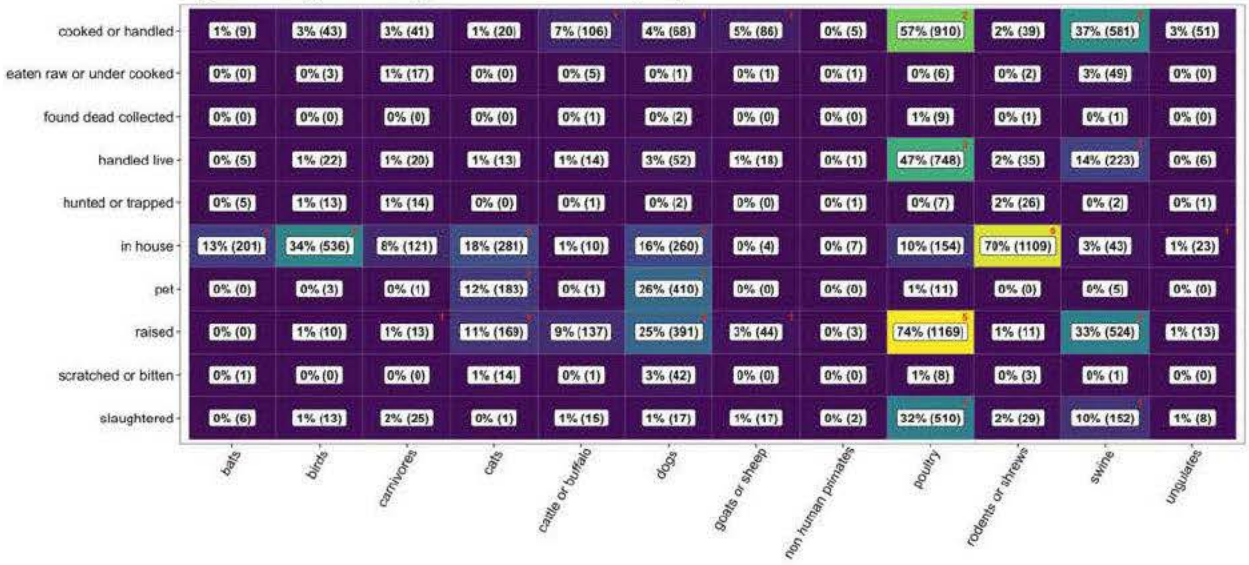

Fig. 2: Animal contact by taxa and activities. Values and shading represent survey population; red numbers in upper-right corners of cells indicate the number of sero-positive individuals with the given contact.

1.1.3 Self-report SARI/ILI symptoms and animal contact

Among the 1,565 participants who responded, 17% (n=265) had experienced fever with cough and shortness of breath or difficulty breathing (38, 14%), indicative of severe acute respiratory infection (SARI), or fever with muscle aches; cough, or sore throat (192, 72%), indicative of influenza like illness (ILI), or both symptoms (35, 13%) in the past 12 months.

LASSO analyses of the associations between animal contact and self-report SARI or ILI symptoms showed that eating raw or undercooked carnivores (OR = 1.6; bootstrap support = 0.67) was the most salient predictor of experiencing SARI or ILI symptoms, followed by slaughtering poultry as a resident of Guangxi province (OR = 1.4; support = 0.68); having an income below 10,000 as a resident of Guangxi province (OR = 1.3; support = 0.84); domestic

contact with bats (OR = 1.3 ; support = 0.63) and domestic contact with rodents or shrews as a resident of Guangdong province (OR = 1.2; support = 0.63) **(Fig. 3)**.

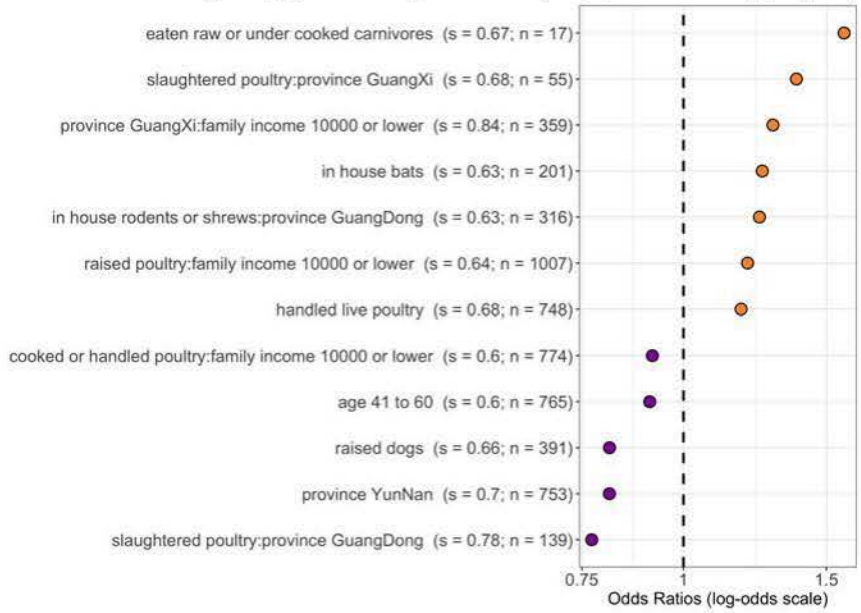

Fig. 3: Most salient predictors of self-reported ILI and/or SARI symptoms in the last year (s = bootstrap support; n = count positive out of 1585 respondents). Bootstrap support values = 0.6 are demonstrated here meaning they were identified as associated with the outcome for 60% or more of the bootstrap iterations. Odds ratios > 1 (orange) are positively associated with the outcome, and odds ratios <1 (purple) are negatively associated with the outcome.

This study provides serological evidence of subclinical or asymptomatic bat-born SARS-related Coronavirus and HKU10 Coronavirus spillover event(s) in rural communities in Southern China, highlights the associations between human-animal interaction and zoonotic spillover risk. The rate of seropositivity observed in this study is clearly lower than would be seen for established human infections. However it has important implications for predicting and preventing pandemics:

1. It indicates that spillover of novel bat-CoVs is detectable if populations that live within areas inhabited by likely bats hosts are targeted. **This provides a pathway to identify spillover events rapidly, perhaps even before a SARS-like disease can become established in people**;
2. It allows us to calculate the likely number of people infected by novel bat SARSr-CoVs annually in this region. Our preliminary analyses suggest that if similar seroprevalence occurs in human populations across the region bat SARSr-CoV hosts inhabit, **there may be as many as the low hundreds of thousands to over a million people infected each year in South China and Southeast Asia.** We aim to conduct a detailed analysis of this in the future.
3. It highlights ways to refine surveillance that could help prevent pandemics, by targeting populations where seroprevalence suggests that they are **at higher risk due to behavioral preferences (e.g. wildlife hunting, farming, or trading)** or where **early-stage SARS-like illnesses could be identified using syndromic surveillance of clinics**.

Contact with poultry and rodents/shrews were commonly reported among participants and associated with self-reported ILI and/or SARI symptoms, which suggests that domestic animals, in addition to wildlife, are an important link in understanding the coronavirus transmission from bat to human populations, indirect exposure might occur through contact with live domestic animals in house or market when the animals had prior exposure to bat coronavirus.

When clinical evidence is limited, undiagnosed or subclinical symptoms similar to SARI and ILI in a population should be brought to our attention as indicators in monitoring zoonotic pathogen spillover events, and considered for prevention strategies. This is particularly important in rural community settings, where people have a higher level of exposure to both domestic and wild animals, but may not seek diagnosis or treatment in a timely fashion, thus slowing the processes of early detection and response.

1.2 Qualitative Approach to Developing Zoonotic Risk Mitigation Strategies in Southern China

To explore the potential drivers of zoonotic exposure and the opportunities for intervention, we conducted field observation and semi-structured ethnographic interviews among 88 community members who have frequent exposure to wildlife and domestic animals and/or have extensive local knowledge in 9 sites in Yunnan, Guangdong, and Guangxi provinces.

The majority of participants in this study were adults between 31 to 50 years of age, residing in rural or suburban areas. Most earned their livelihoods from multiple sources, primarily in crop production, subsistence animal farming, small business, and other temporary jobs as migrant workers. Risk and protective factors were identified at the individual, community, and policy levels regarding potential zoonosis exposures, recommending risk-mitigation strategies with the strengthened policy enforcement and multi-sectoral collaboration among human, animal, and environment health programs **(Fig. 4)**.

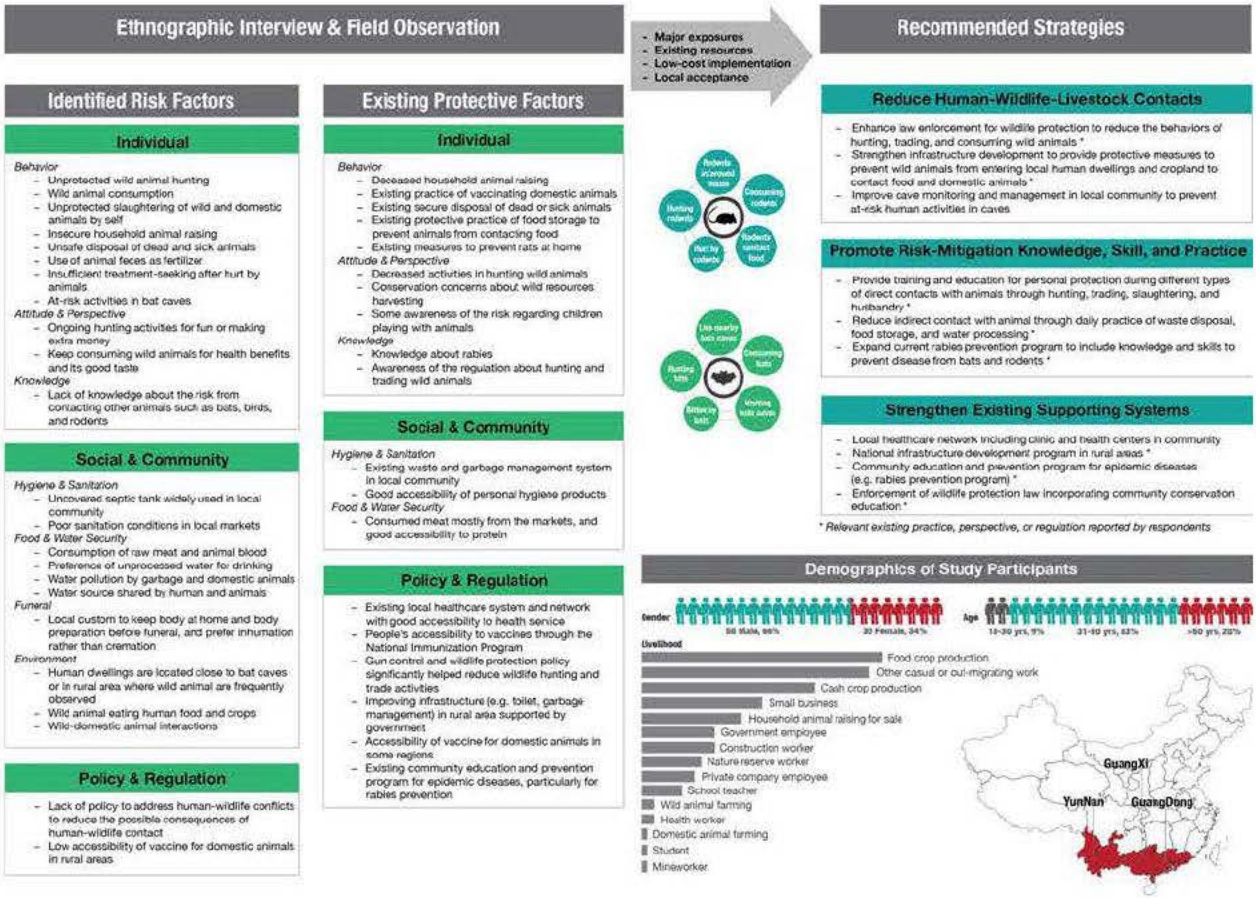

Fig. 1: Community Zoonosis Exposure Risk Mitigation Strategy Development Process. Leveraging ethnographic interview and observational research data to identify risk and protective factors and develop risk-mitigation recommendations

This demonstrated a qualitative approach to understand the zoonotic risks in community, and provided guidance for future research and interventions with focused potential zoonotic risks for disease control and prevention in southern China and a broader area with similar ecological, culture, and demographic contexts.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk

2.1 Bat CoV PCR detection and sequencing from live-sampled bat populations

From May to October 2018, we collected 1,697 rectal swabs, oral swabs, and feces specimens from 26 bat species in Hubei, Shandong, Yunnan and Guangdong Provinces across southern, central and northern China in Year 5, all specimen were tested for CoV RNA and 109 (6.4%) were positive. SARS-related coronaviruses were discovered in *Rhinolophus sinicus* samples from Yunnan and Hubei provinces while HKU2-related coronaviruses were detected in *R.sinicus* from Hubei. HKU5-related and HKU10-related coronaviruses were identified in *Pipistrellus abramus* from Shandong and *Hipposideros larvatus* from Guangdong, respetively. *Scotophilus* coronavirus 512 was detected in Guangdong. Addtionally, two novel *Pipistrellus* alphacoronaviruses were found in Shandong province in northern China **(Fig. 5)**.

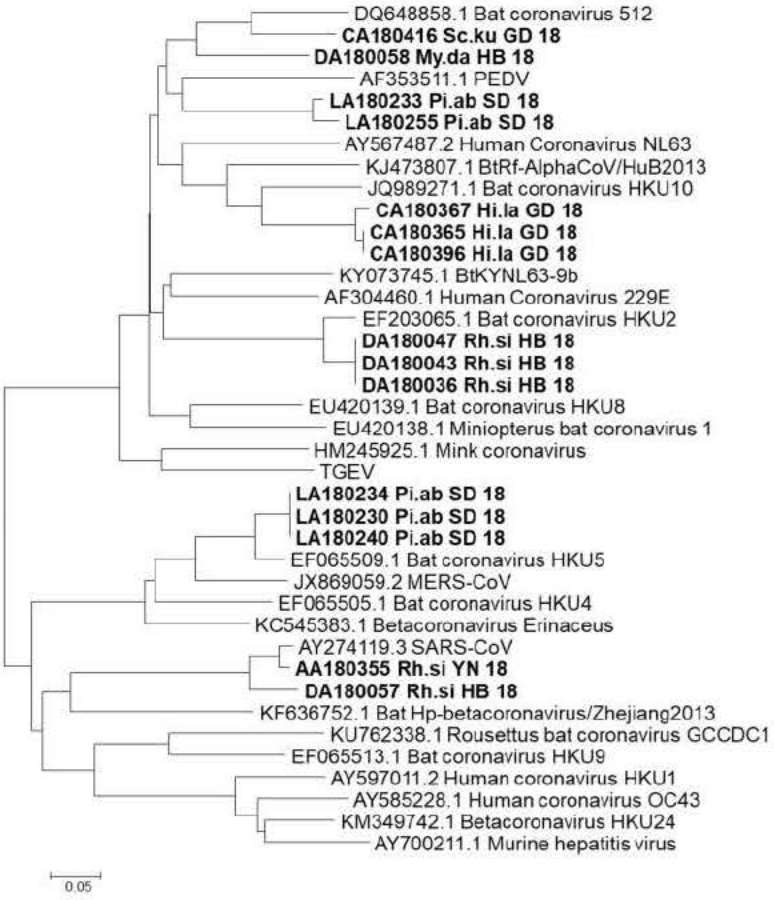

Fig. 2: Phylogenetic analysis of partial RdRp gene of CoV (440-nt partial sequence)

2.2 Bat coronavirus host-virus phylogeography in China

Our dataset includes all CoV RdRp sequences isolated from bat specimens collected by our team from 2008-2015 (Alpha-CoVs: n = 491 – Beta-CoVs: n = 326), including those collected under prior NIAID funding (1 R01 AI079231), and funding from Chinese Federal Agencies. All Chinese bat CoV RdRp sequences available in GenBank were also added to

our dataset (Alpha-CoVs: n = 226 – Beta-CoVs: n = 206). Phylogenetic trees were reconstructed for Alpha- and Beta-CoVs separately using Bayesian inference (BEAST 1.8).

2.2.1 Ancestral hosts and cross-species transmission

We used ancestral character state reconstruction and a Bayesian stochastic search variable selection (BSSVS) to identify host switches between bat families **(Fig. 6)** and genera **(Fig. 7)** that occurred along the branches of the phylogenetic tree and calculated BF to estimate the significance of these non-zero transition rates. We identified nine and three highly supported (BF > 10) **inter-family** host transition rates for alpha- and beta-CoVs, respectively **(Figs. 6A and 6B)**. To quantify the intensity of these host switches, we estimated the number of state changes (Markov jumps) along the significant inter-family transition rates **(Figs. 6C and 6D)**. The total estimated number of inter-family host jump events was more than eight times higher in the evolutionary history of alpha- (n = 90) than beta-CoVs (n = 11) in China. Host transition events from Rhinolophidae and Miniopteridae were greater than from other families for alpha-CoVs while Rhinolophidae were the highest donor family for beta-CoVs. Rhinolophidae and Hipposideridae were the families receiving the highest numbers of transition events for alpha- and beta-CoVs, respectively **(Figs. 6C and 6D)**.

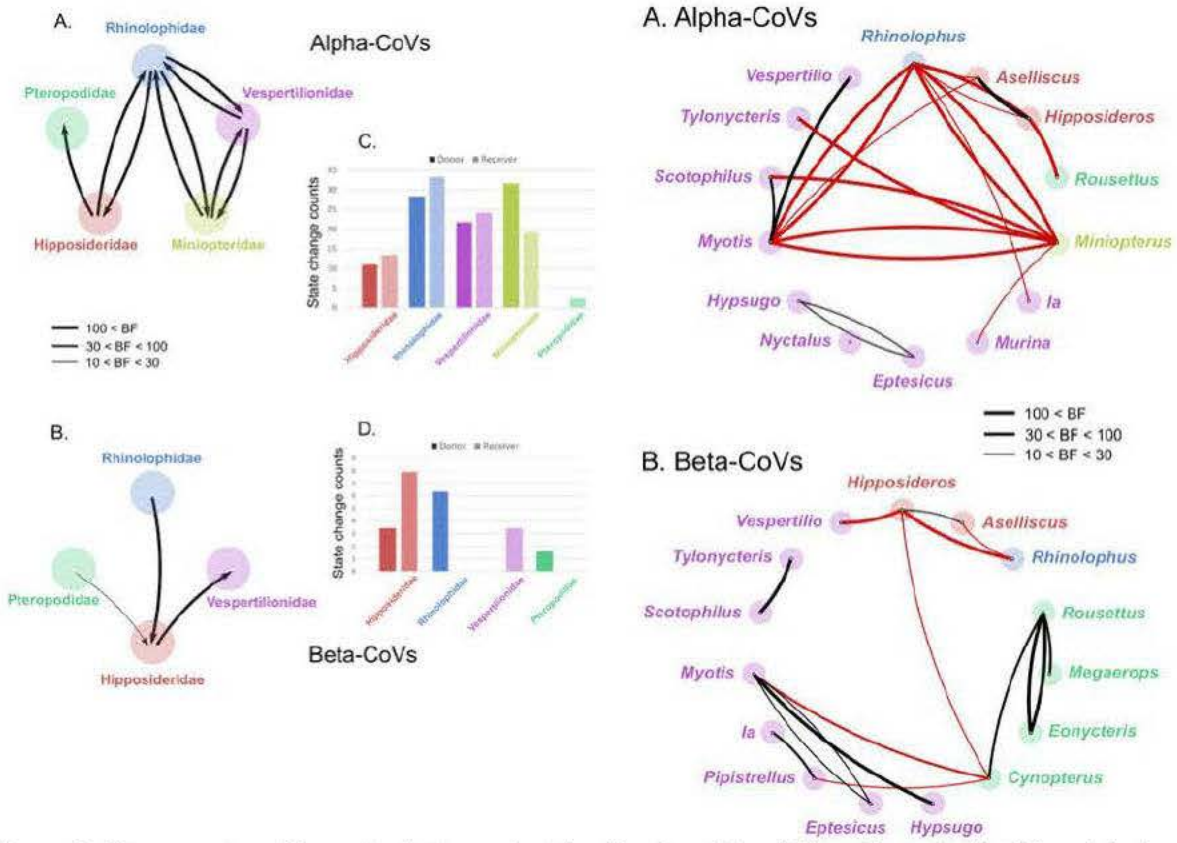

Figure 3: Non-zero transition rates between bat families for alpha- **(A)** and beta-CoVs **(B)** and their significance level (Bayes factor, BF), BF < 10 are considered as non-significant. Arrows indicate the direction of the transition; arrow thickness is proportional to the transition significance level. Histograms show total number of state changes (Markov jumps) from/to each bat family along the significant inter-family transition rates for alpha- **(C)** and beta-CoVs **(D)**.

Figure 4: Non-zero transition rates between bat genera for alpha- **(A)** and beta-CoVs **(B)** and their significance level (Bayes factor, BF), BF < 10 are considered as non-significant. Lines with a rightward curvature depict transitions from that bat genus, while lines with leftward curvature depict transition to that bat genus. Inter-family transitions are highlighted in red.

At the genus level, we identified 20 highly supported inter-genus host transition rates for alpha-CoVs **(Fig. 7A)**. *Rhinolophus* and *Myotis* were the donor genera in four of these transitions while *Miniopterus* and *Rhinolophus* were each the recipients of four of these transitions **(Fig. 7A)**. Sixteen highly supported inter-genus transition rates were identified for beta-CoVs **(Fig.7B)**. Four of these 16 host switches originated in *Cynopterus* while three of them ended in *Myotis* **(Fig. 7B)**. Fifteen out of the 20 significant pairwise host transitions (75%) for alpha-CoVs involved two genera belonging to different bat families, while this proportion is only 6/16 (37.5%) for beta-CoVs. This confirmed the highest number of inter-family host transitions for alpha-CoVs. The estimated total number of inter-genus host switches was almost two times higher for alpha- (n = 123) than beta-CoVs (n = 70).

These findings indicate that alpha-CoVs were able to switch hosts more frequently and between more distantly related taxa during their evolution and suggest that phylogenetic distance among hosts represents higher constraint on host switches for beta- than alpha-CoVs.

2.2.2 CoV spatiotemporal dispersal in China

We also used our Bayesian discrete phylogeographic model using zoogeographic regions as character states to reconstruct the spatiotemporal dynamics of CoV dispersal in China. Eleven and seven highly significant (BF > 10) dispersal routes within China were identified for alpha- and beta-CoVs, respectively **(Fig. 8A and 8B)**. The Rhinacovirus lineage that includes HKU2 and SADS-CoV likely originated in SO region while all other alpha-CoV lineages likely arose in SW China and spread to other regions before several dispersal events occurred from SO and NO in all directions **(Fig. 8A)**.

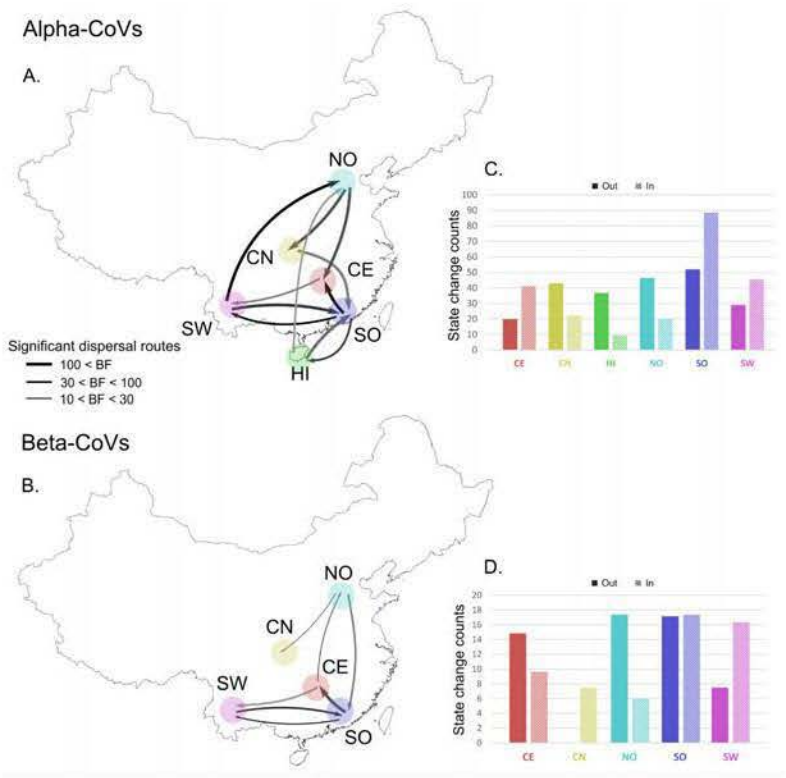

Fig. 8: Significant dispersal routes among China zoogeographic regions for alpha- **(A)** and beta-CoVs **(B)**. Arrows indicate the direction of the transition; arrow thickness is proportional to the transition significance level. Darker arrow colors indicate older dispersal events. **Fig. 8 (C & D)** Histograms of total number of state changes (Markov jumps) from/to each region along the significant dispersal routes for alpha- **(C)** and beta-CoVs **(D)**. NO, Northern region; CN, Central northern region; SW, South western region; CE, Central region; SO, Southern region; HI, Hainan island.

The oldest inferred dispersal movements among beta-CoVs occurred among SO and SW regions **(Fig. 8B)**. SO region is the likely origin of Merbecovirus (Lineage C, including HKU4 and

HKU5) and Sarbecovirus subgenera (Lineage B, including HKU 3 and SARS-related CoVs) while Nobecovirus (lineage D) and Hibecovirus (lineage E) subgenera originated in SW China. Then several dispersal movements likely originated from SO and CE **(Fig. 8B)**. More recent southward dispersal from NO was observed.

The estimated total number of migration events along these significant dispersal routes is four times higher for alpha- (n = 227) than beta-CoVs (n = 57). SO has the highest number of outbound and inbound migration events for alpha-CoVs **(Fig. 8C)**. For beta-CoVs, the highest numbers of outbound migration events have been estimated from NO and SO while SO and SW have the highest numbers of inbound migration events **(Fig. 8D)**.

Our Bayesian ancestral reconstructions revealed the high importance of South western and Southern China as centers of diversification for both alpha- and beta-CoVs. These two regions are clearly hotspots of CoV phylo-diversity, harboring evolutionary old and phylogenetically diverse lineages of alpha- and beta- CoVs.

2.2.3 Phylogenetic diversity

In order to quantitatively evaluate the diversity and the clustering process in our phylogenies, the Mean Phylogenetic Distance (MPD) and the Mean Nearest Taxon Distance (MNTD) statistics and their standardized effect size (SES) were calculated for each zoogeographic region, bat family and genus. The SES corresponds to the difference between the phylogenetic distances in the observed communities versus null communities built by randomly reshuffling tip labels 1000 times along the entire phylogeny. Low and negative SES values denote phylogenetic clustering, high and positive values indicate phylogenetic over-dispersion while values close to 0 show random dispersion.

Significant negative SES MPD values ($p < 0.05$), indicating basal phylogenetic clustering, were observed within all bat families and genera for both alpha- and beta-CoVs, except within *Aselliscus* and *Tylonycteris* for alpha-CoVs **(Figs. 9A & B)**. Negative and mostly significant SES MNTD values, reflecting phylogenetic structure closer to the tips, were also observed within most bat families and genera for alpha- and beta-CoVs but we found non-significant positive SES MNTD value for Vespertilionidae and *Pipistrellus* for beta-CoVs (Fig. 4A and 4B). In general, we observed lower phylogenetic diversity for beta- than alpha-CoVs within all bat families and most genera when looking at SES MPD, while similar level of diversity are observed when looking at SES MNTD **(Figs. 9A & B)**. These results suggest stronger basal clustering (at the deeper nodes) for beta-CoVs than alpha-CoVs.

Chinese zoogeographic regions don't harbor a random set of CoVs as alpha- and beta-CoV strains within most regions are more closely related than expected by chance as denoted by negative and mostly significant values of MPD and MNTD **(Fig. 9C)**. However, positive SES MPD value for alpha-CoVs in SW indicate wider evolutionary diversity in that region **(Fig. 9C)**.

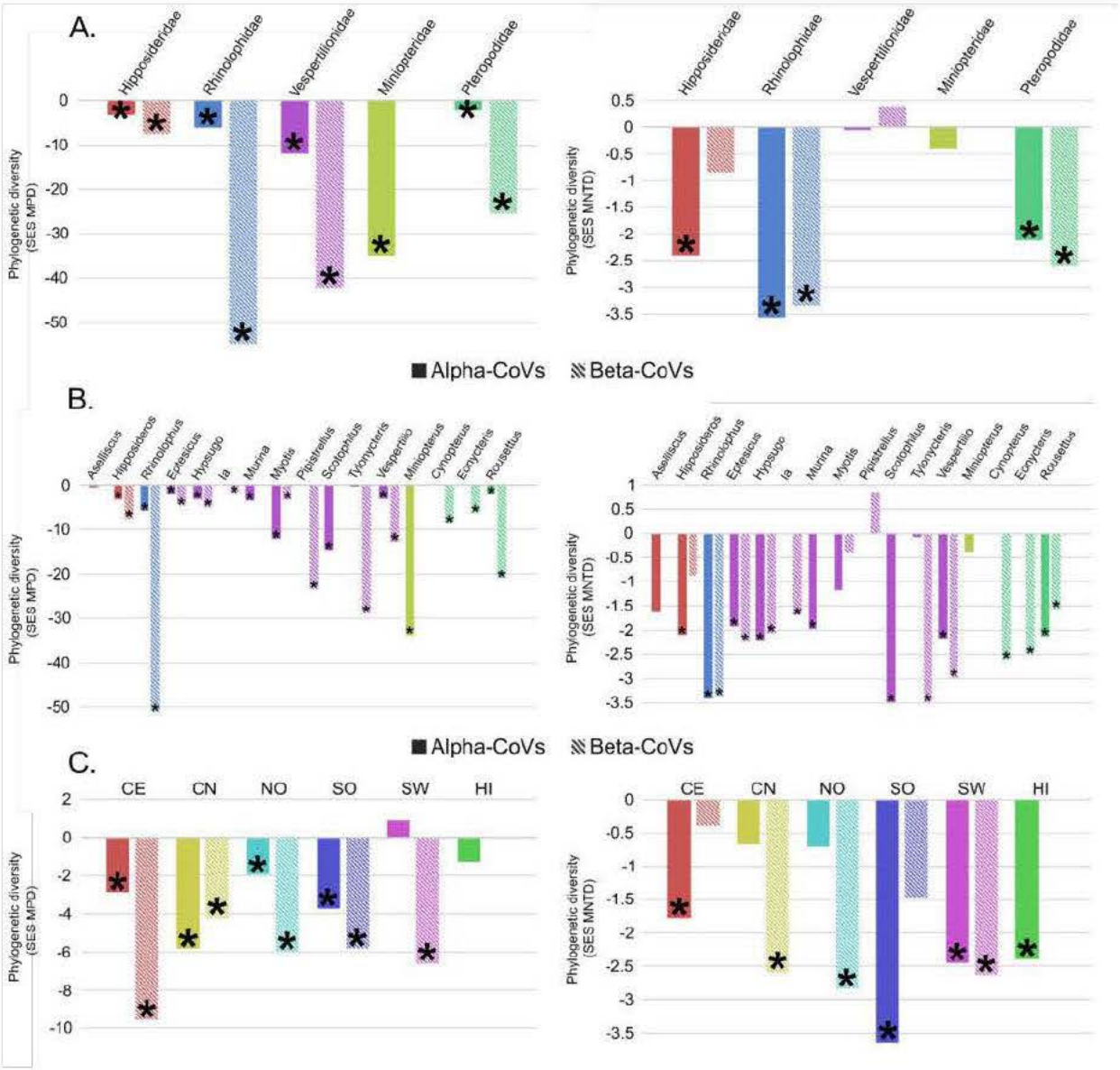

Fig. 9: CoV phylogenetic diversity bat families **(A),** genera **(B),** and zoogeographic regions **(C)**: SES MPD, standardized effect size of Mean Phylogenetic Distance **(Left)**; and SES MNTD, standardized effect size of Mean Nearest Taxon Distance **(Right)**. Values departing significantly from null model (p-value < 0.05) indicated with an asterisk. NO, Northern region; CN, Central northern region; SW, South western region; CE, Central region; SO, Southern region; HI, Hainan island.

2.3 Characterization of SADSr-CoV coronaviruses diversity and distributions

In previous project years, our team identified and characterized Swine Acute Diarrheal Syndrome coronavirus (SADS-CoV), a novel swine virus causing outbreaks in farms in multiple Chinese provinces.In this year, we were able to identify SADS-related CoVs in bats from our wild bat sampling.In >17,000 bat and other mammals at 47 sites across southern China, we found 78 new SADSr-CoVs[11], all in 9 bat species, with mean prevalence of 0.1 to 37.5%.

Our phylogenetic analysis suggests that pig SADS-CoV recently spilled over from *R. sinicus* or *R. affinis* bats **(Fig. 10 Left)** However, analysis of full pig viral genomes from 4 initially infected

farms suggests that either the virus evolved as it circulated or that multiple spillover events occurred (**Fig. 10 Right**).

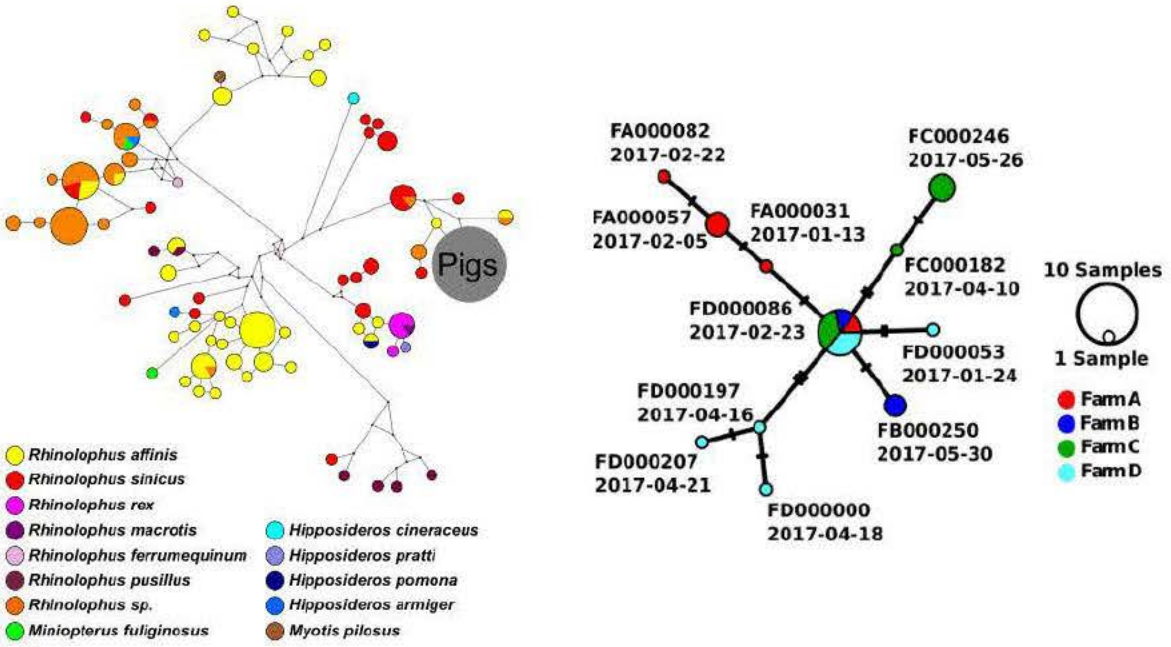

Fig. 10: Left: Median joining network of conserved RdRp gene fragment of 198 unique SADSr-CoV sequences discovered in China under our previous funding. Size of circle proportional to the number specimens with identical viral sequences. **Right:** Median joining network of SADS-CoV full genome sequence data from 4 infected pigs farms in S. China.

We built species distribution models of the major bat species hosts of SADSr-CoVs across southeast Asia to determine the areas where their ranges intersect with large swine operations similar to those of the original outbreak.We found that these are Southern China (including Taiwan), throughout Vietnam, the Philippines, and Thailand. Compared to other countries, China had the largest area of bat-pig overlap with 329,847 km2 (3.4% of total country area) and 2,127,006 pigs located within predicted bat distributions. By Chinese province, the largest area of overlap was found in Jiangsu (35,226 km2 amounting to 34.3% of the province's area and 242,299 pigs within this area). Sichuan had the largest pig population at risk (the pig population within an area that intersects with predicted bat occurrence), at 274,353 heads over 26,015 km2 (5.4% of the total area of the province) (**Figs. 11 & 12**).

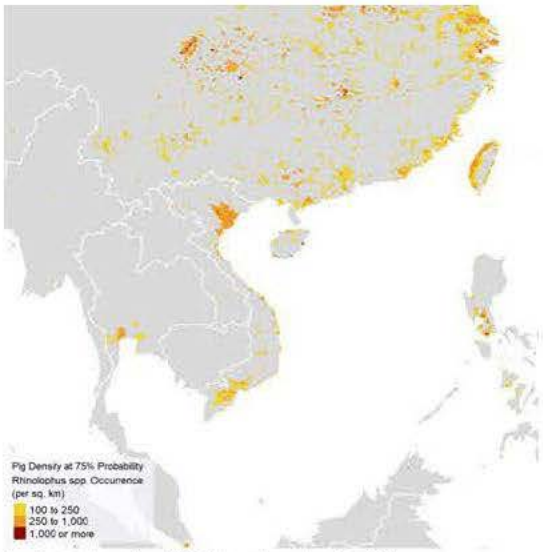

Fig. 5: Areas of bat-pig overlap where probability of SADS-CoV Rhinolophus spp. reservoir occurrence is high (>75%) and pig densities are indicative of intensive pig farming (>100 heads per km2).

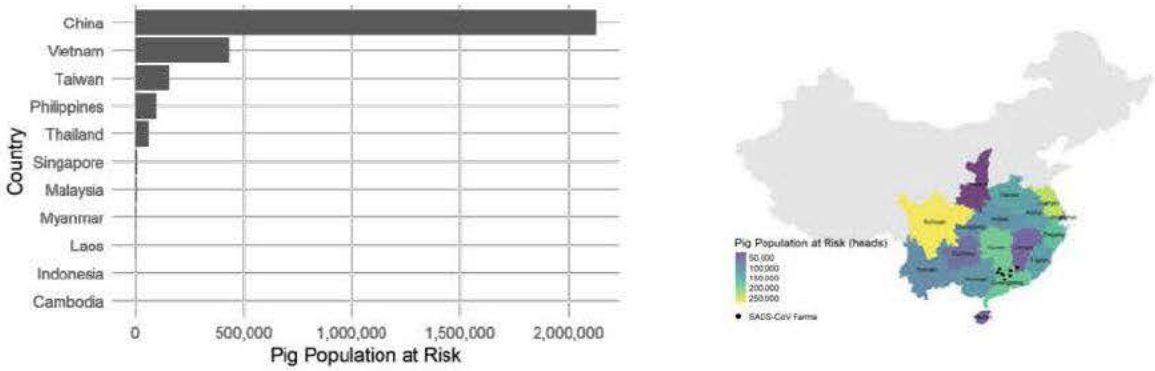

Fig. 6: Top: Country-level, and **Bottom:** province-level estimate of swine populations at-risk based on overlap between modeled populations of bat species known to be SADSr-CoV hosts and large swine operations.

Specific Aim 3: Testing Predictions of CoV Inter-Species Transmission

3.1 *In vivo* infection of Human ACE2 (hACE2) expressing mice with SARSr-CoV S protein variants

In Year 5, we continued with *in vivo* infection experiments of diverse bat SARSr-CoVs on transgenic mice expressing human ACE2. Mice were infected with 4 strains of SARSr-CoVs with different S protein, including the full-length recombinant virus of SARSr-CoV WIV1 and three chimeric viruses with the backbone of WIV1 and S proteins of SHC014, WIV16 and Rs4231, respectively. Pathogenicity of the 4 SARSr-CoVs was evaluated by recording the survival rate of challenged mice in a 2-week course. All of the 4 SARSr-CoVs caused lethal infection in hACE2 transgenic mice, but the mortality rate vary among 4 groups of infected mice **(Fig. 13a)**. 14 days post infection, 5 out of 7 mice infected with WIV1 remained alive (71.4%), while only 2 of 8 mice infected with rWIV1-SHC014 S survived (25%). The survival rate of mice infected with rWIV1-WIV16S and rWIV1-4231S were 50%. Viral replication was confirmed by quantitative PCR in spleen, lung, intestine and brain of infected mice. In brain, rWIV1, rWIV1-WIV16S and rWIV1-4231S cannot be detected 2 days or 4 days post infection. However, rWIV1-SHC014 was detected at all time points and showed an increasing viral titer after infection. The viral load reached more than 10^9 genome copies/g at the dead point **(Fig. 13b)**. We also conducted histopathological section examination in infected mice. Tissue lesion and lymphocytes infiltration can be observed in lung, which is more significant in mice infected with rWIV1-SHC014 S **(Fig. 13d)** than those infected with rWIV1 **(Fig. 13c)**. These results suggest that the pathogenicity of SHC014 is higher than other tested bat SARSr-CoVs in transgenic mice that express hACE2.

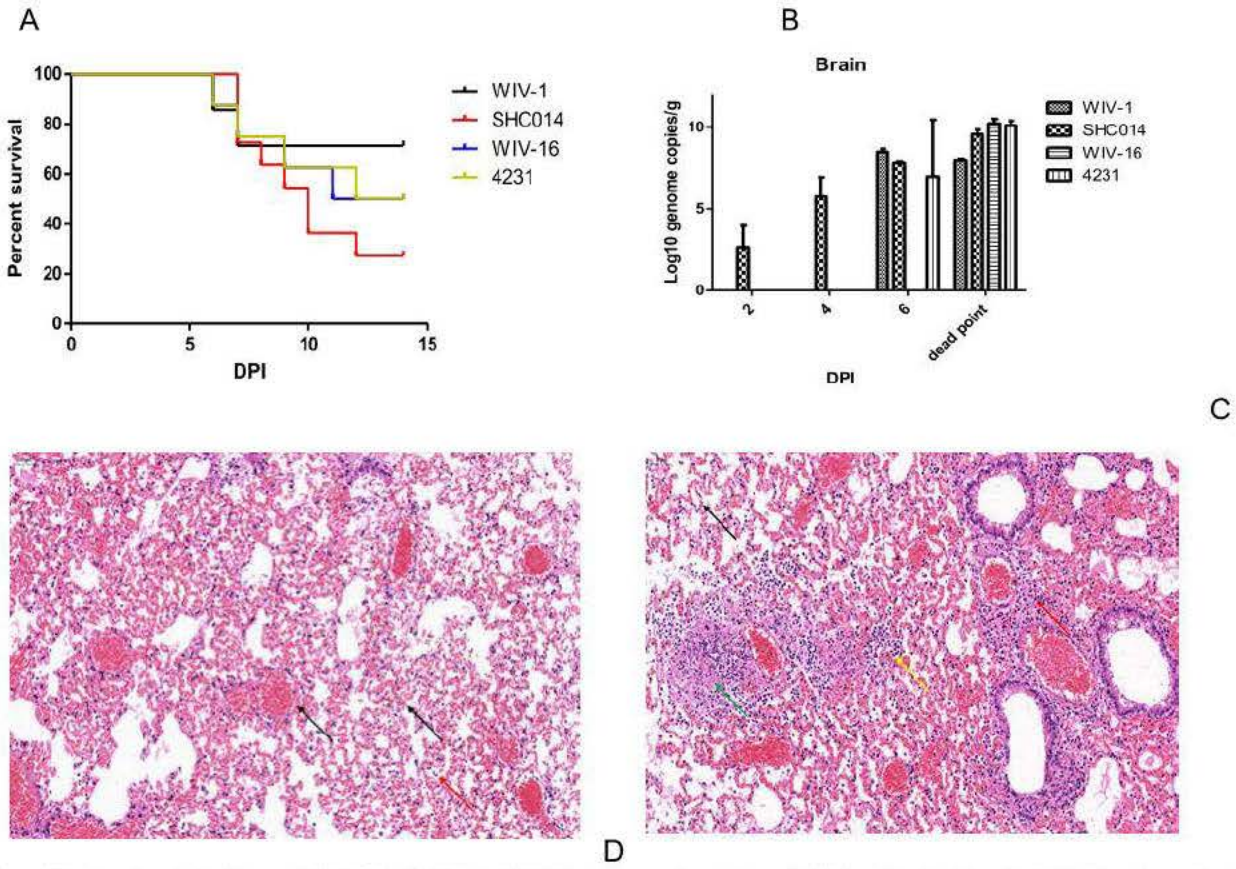

Fig. 13: *In vivo* infection of SARSr-CoV in hACE2-expressing mice. **(A)** Survival rate of hACE2_mice after infection **(B)** Viral load in brains of infected hACE2-expressing mice. **(C)** Histopathological section of lung tissue of mice infected with rWIV1. **(D)** Histopathological section of lung tissue of mice infected with rWIV1-SHC014 S.

3.2 Assessment of interspecies transmission risk of bat HKU4-related coronaviruses

Taking a similar reverse genetics strategy that we used in SARSr-CoV studies, we constructed the full-length infectious clone of MERS-CoV, and replaced the RBD of MERS-CoV with the RBDs of various strains of HKU4-related coronaviruses previously identified in bats from different provinces in southern China. The full-length MERS-CoV and chimeric viruses with RBDs of HKU4r-CoVs were then rescued. Immunofluorescence assay showed that these chimeric MERS-HKU4rRBD coronaviruses were able to infect human cells from different tissues including lung, liver, intestine and kidney **(Fig. 14 Left)**. Moreover, efficient replication of the chimeric HKU4r-CoVs were detected by real-time PCR in HeLa cells that expressed human DPP4 receptor **(Fig. 14 Right)**. The results suggest potential risk of the bat HKU4r-CoVs for cross-species infection in humans.

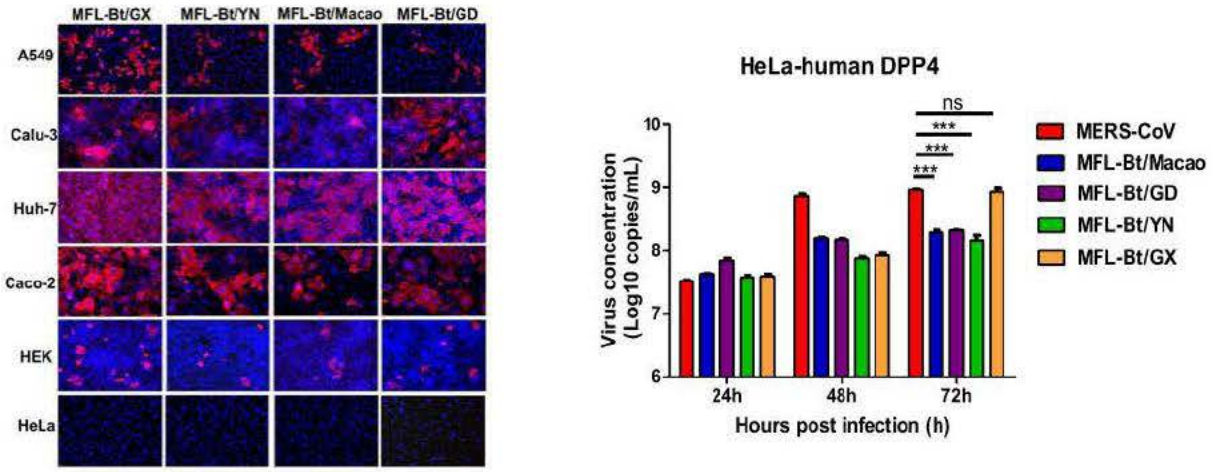

Fig. 7: Left: Immunofluorescence assay confirms Infection of 4 chimeric viruses with the backbone of MERS-CoV and RBD of bat HKU4r-CoVs in different cell lines derived from human tissues. **Right:** Replication of MERS-HKU4rRBD CoVs in HeLa cells expressing human DPP4 was determined by real-time PCR.

1. Conference and University lectures: We continued to provide human subject research trainings to chief physicians and nurses at local clinics, staff from Yunnan Institute of Endemic Diseases Control and Prevention, students from Dali College and Wuhan University for both qualitative and quantitative research.
2. Agency and other briefing: Dr. Guangjian Zhu provided training to 18 field team members from the Dali College and 4 Wuhan Insitute of Virology laboratory team members regarding biosafety and PPE use, bats and rodents sampling.
3. Public outreach: PI Daszak, and Co-investigators Shi, Epstein, and Olival presented the Year 5 results of this project to the public via interviews with national central and local television, social media, newspaper and journals in China and the US.

C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

No

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
(b) (6)	Y	DASZAK, PETER	BS,PHD	PD/PI	(b) (4), (b) (6)					NA
	N	KE, CHANGWEN	PHD	Co-Investigator				Center for Disease Control and Prevention of Guangdon g Province	CHINA	NA
	N	ZHANG, YUNZHI	PHD	Co-Investigator				Yunnan Provincial Institute of Endemic Diseases Control & Prevention	CHINA	NA
	N	ZHU, GUANGJIAN	PHD	Co-Investigator				East China Normal University	CHINA	NA
(b) (6)	N	Chmura, Aleksei	BS,PHD	Non-Student Research Assistant						NA
(b) (6)	N	Ross, Noam Martin	PhD	Co-Investigator						NA
(b) (6)	N	Olival, Kevin J.	PHD	Co-Investigator						NA
(b) (6)	N	Zhang, Shu-yi	PHD	Co-Investigator				East China Normal University	CHINA	NA
(b) (6)	N	SHI, ZHENGLI	PhD	Co-Investigator				Wuhan Institute of Virology	CHINA	NA
	N	GE, XINGYI	PHD	Co-Investigator				Wuhan Institute of Virology	CHINA	NA
(b) (6)	N	EPSTEIN, JONATHAN H	MPH,DVM,BA,PHD	Co-Investigator						NA

Glossary of acronyms:
S/K - Senior/Key
DOB - Date of Birth
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RE - Reentry Supplement
DI - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Not Applicable
D.2.b New Senior/Key Personnel Not Applicable
D.2.c Changes in Other Support Not Applicable
D.2.d New Other Significant Contributors Not Applicable
D.2.e Multi-PI (MPI) Leadership Plan Not Applicable

E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Dollar Amount	Country
$66,500	CHINA

G. SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Sub-Project ID	Study ID	Study Title	Delayed Onset	Clinical Trial	NCT	NIH-Defined Phase 3	ACT
	58010	Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001	NO	NO		NO	

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Organization Name: Wuhan Institute of Virology
Country: CHINA

Description of Foreign Component:
Principal Laboratory for all Research in China and detailed in our Specific Aims

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

Section 1 - Basic Information (Study 58010)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	○ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	○ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	○ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 58010)

2.1. Conditions or Focus of Study		
2.2. Eligibility Criteria		
2.3. Age Limits	Min Age:	Max Age:
2.3.a. Inclusion of Individuals Across the Lifespan		
2.4. Inclusion of Women and Minorities		
2.5. Recruitment and Retention Plan		
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline		
2.8. Enrollment of First Participant (SEE SECTION 6.3)		

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
IER 58010	Foreign	

Inclusion Enrollment Report 58010

1. Inclusion Enrollment Report Title* : China Study Report

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ❍ Domestic ● Foreign

4. Enrollment Country(ies): CHN: CHINA

5. Enrollment Location(s):

6. Comments:

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	1230	1230	0	0	2460
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	1230	1230	0	0	2460

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	980	616	0	0	0	0	0	0	0	1596
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	980	616	0	0	0	0	0	0	0	1596

Section 3 - Protection and Monitoring Plans (Study 58010)

3.1. Protection of Human Subjects

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site? ❍ Yes ❍ No ❍ N/A

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study? ❍ Yes ❍ No

3.5. Overall structure of the study team

Section 4 - Protocol Synopsis (Study 58010)

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

Type	Name	Description

4.1.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ● No

4.1.e. Intervention Model

4.1.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

4.3. Statistical Design and Power

4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? (SEE SECTION 6.6)

4.7. Dissemination Plan

I. OUTCOMES

I.1 What were the outcomes of the award?

The aims of our grant (R01AI110964) were to: 1) Analyze the risk that there could be a repeat of the SARS outbreak, due to bat coronaviruses still circulating in China; 2) Work out how we can predict which bat viruses would be most likely to emerge, so that we can prevent new outbreaks; 3) Using lab tests, find out if any of the coronaviruses still present in bat populations in China have the potential to infect people. The overall goal of this work is to help design vaccines and therapeutics against future potentially emerging viruses, work out which communities are on the frontline of a new potential outbreak, and reduce the risk of them being infected by analyzing their risk behavior. During this 5-year period of work, we made significant discoveries leading to 18 peer-reviewed scientific papers, including in some of the world's foremost scientific journals.

Overall, our work shows that bats in China harbor a high number and diversity of coronaviruses, some closely related to SARS-CoV (the virus that caused the SARS pandemic in 2003). We sampled over 16,000 individual bats and found evidence of hundreds of different SARS-related coronavirus genetic sequences. We found out that bats across China harbor these viruses, and that they are common, with 6.7% of bats sampled being positive. Many of these bats are found across China, Southeast Asia, South Asia and beyond, suggesting viruses with zoonotic potential may exist in those regions also. Many of these bats are abundant, and roost and feed close to people and livestock, suggesting high potential for future viral spillover. We also dentified one cave system in Yunnan Province with horseshoe bats that had diverse SARSr-CoVs, including some with S proteins able to use human ACE2 as entry receptors. Bats in this cave carried SARSr-CoVs with all unique genetic elements of the SARS-CoV outbreak virus, suggesting that this site may be a potential public health risk.

To analyze which viruses were a potential public health risk, we managed to culture three strains of SARSr-CoVs from bat feces: WIV1, WIV16 and Rs4874. We used the genetic codes of some of the other viruses we found in bats and inserted the spike protein genes of those viruses (the proteins that attach to cells) into the cultured viruses. By doing this experiment we showed that other viruses may also be able to infect human cells, and were able to do this safely without the need to culture large amounts of virus. We also showed that some of these viruses cause SARS-like illness in mice that are adapted to have similar cell surface receptors to people. This work proves that there is a clear and present danger for future emergence of novel SARS-like viruses in people. We also demonstrated that outbreaks can happen in livestock. In 2016-17, we analyzed fecal samples from pigs at 5 farms in South China affected by a fatal diarrheal disease. We discovered a new coronavirus, Swine Acute Diarrheal Syndrome coronavirus (SADS-CoV), and showed that it originates in bats, caused the death of more than 20,000 pigs, but also is able to infect human cells in the lab.

Our work has produced predictive algorithms to map hotspots of viral risk so that public health measures can be taken to protect communities at the frontline of potentially the next SARS pandemic. We have produced new reagents and viral cultures that can be used by labs across the world to design novel vaccines and therapeutics against SARS-CoV and other related viruses that might emerge in the future. Finally, our work has been used directly by the WHO to list SARS-related coronaviruses as one of the highest priority group of pathogens with pandemic potential, so that efforts can be taken to stop a future pandemic before it happens.

From:	era-notify@mail.nih.gov
To:	Stemmy, Erik (NIH/NIAID) [E]
Subject:	eRA Commons: The Interim Research Performance Progress Report for Grant R01AI110964-05 has been submitted to the NIH
Date:	Tuesday, August 3, 2021 12:44:20 PM

*** This is an automated notification - Please do not reply to this message. ***

The Interim Research Performance Progress Report has been submitted to the NIH for Grant R01AI110964-05 in the eRA Commons by: Aleksei Chmura.

Contact PI for this Grant: DASZAK, PETER.

You may access the Acceptance page by clicking here IRPPR Acceptance Page and also review the report at the same location.

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact.
Please access Commons at http://public.era.nih.gov/commonsplus.
For more information please visit http://era.nih.gov/

From:	Mulach, Barbara (NIH/NIAID) [E]
To:	Hauguel, Teresa (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Bozick, Brooke (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Dixon, Dennis M. (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]
Cc:	NIAID BUGS
Subject:	RE: Action by 10a tomorrow (8/3): GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)
Date:	Tuesday, August 3, 2021 10:10:30 AM
Attachments:	FY21_ALL_STAFF-#803376-v3-105051__COORDINATED_HHS_QUESTIONS_ACCOMPANYING_PPP_v2_toDivisions_TH blm.docx

HI Andrew,
I've included a few additional edits for consideration.
Thanks!
Barbara

From: Hauguel, Teresa (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, August 3, 2021 9:56 AM
To: Post, Diane (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Degrace, Marciela (NIH/NIAID) [E] (b) (6); Dixon, Dennis M. (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS (b) (6)
Subject: RE: Action by 10a tomorrow (8/3): GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

One edit and one comment attached.

Teresa M. Hauguel, Ph.D.
Acting Chief, Respiratory Diseases Branch
COR, Collaborative Influenza Vaccine Innovation Centers (CIVICs)
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Rockville, MD 20852
Phone: (b) (6)
Email: (b) (6)

From: Post, Diane (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, August 3, 2021 9:46 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6); Degrace, Marciela (NIH/NIAID) [E] (b) (6); Dixon, Dennis M. (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS (b) (6)

Subject: RE: Action by 10a tomorrow (8/3): GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

Hi Andrew,

I have reviewed, nothing new to add.

Thank you
Diane

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, August 3, 2021 9:33 AM
To: Bozick, Brooke (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6); Degrace, Marciela (NIH/NIAID) [E] (b) (6); Dixon, Dennis M. (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Post, Diane (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS (b) (6)
Subject: RE: Action by 10a tomorrow (8/3): GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

No edits from me either.

From: Bozick, Brooke (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, August 3, 2021 9:30 AM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6); Degrace, Marciela (NIH/NIAID) [E] (b) (6); Dixon, Dennis M. (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Post, Diane (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS (b) (6)
Subject: RE: Action by 10a tomorrow (8/3): GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

Hi Andrew- I reviewed, no additional edits from me.

Brooke

From: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Sent: Monday, August 2, 2021 5:07 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6); Degrace, Marciela (NIH/NIAID) [E] (b) (6); Dixon, Dennis M. (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Post, Diane

(NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS (b) (6)
Subject: FW: Action by 10a tomorrow (8/3): GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

Dear All,

Attached for another round of review are draft responses to follow-up questions from GAO regarding the RFI on gain-of-function research.

Please review the attached version and send any comments/edits to BUGS by 10:00am tomorrow, Tuesday, August 3, 2021; BUGS will also review.

Thanks,
Andrew

From: "Dunivin, Taylor (NIH/OD) [E]" (b) (6)
Date: Monday, August 2, 2021 at 4:42 PM
To: NIAID DEA DART (b) (6), NIAID BUGS (b) (6)
Cc: NIAID OCGR Leg (b) (6)
Subject: Action by 10a tomorrow (8/3): GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

Hi BUGS and DEA,

Background
Thank you for your help with the request for information (RFI) on potential pandemic pathogens for the GAO engagement 105051. Using your input, OCGR-Leg has prepared the attached response and would appreciate your review and additional input.

Action
By 10 a.m. tomorrow, Tuesday, August 3rd, please provide any edits or additional information to the attached RFI using tracked changes.

Let me know if you have any questions. We appreciate your continued assistance with this engagement.

Thanks,
Taylor

From: Dunivin, Taylor (NIH/OD) [E]
Sent: Tuesday, July 27, 2021 5:50 PM
To: Fenton, Matthew (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6); NIAID DEA DART (b) (6); NIAID BUGS (b) (6)

Cc: NIAID OCGR Leg (b) (6)
Subject: Action by 12p Thursday (7/29): GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

Hello,

Background
As you know, NIH is participating in the GAO engagement "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051) related to research involving potential pandemic pathogens.

NIAID recently contributed to a request for information for this engagement and has now received several follow-up questions from GAO (attached).

This request also was sent to NIH OSP and NIH OER.

Action
By 12 p.m. Thursday, July 29th, please provide responses to the attached questions from GAO as appropriate for your Division.

Let us know if you have any questions.

Thanks,
Taylor

From: Dunivin, Taylor (NIH/OD) [E] (b) (6)
Sent: Wednesday, July 14, 2021 6:06 PM
To: Embry, Alan (NIH/NIAID) [E] (b) (6); NIAID DEA DART (b) (6); NIAID BUGS (b) (6)
Cc: NIAID OCGR Leg (b) (6)
Subject: Action by 3p tomorrow (7/15): OSP draft responses - GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

Hello,

Background
As you know, NIH is working to respond to a request for information (RFI) from the GAO engagement "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051) related to research involving potential pandemic pathogens.

OSP has the lead for responding to this information request and has asked NIAID to review and contribute to the draft responses to questions 3-6 of the RFI.

Action
By 3 p.m. tomorrow, Thursday, July 15th, please provide any edits or additional information as appropriate to the attached responses.

Note that NIAID already has contributed to responses to questions 1-2 of the RFI. No action is needed on questions 1-2 at this time.

Let me know if you have any questions.

Thanks,
Taylor

From: Arms, Erin (NIH/NIAID) [E] (b) (6)
Sent: Thursday, July 8, 2021 11:22 AM
To: Embry, Alan (NIH/NIAID) [E] (b) (6); NIAID BUGS (b) (6); NIAID DEA DART (b) (6)
Cc: Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg (b) (6)
Subject: Action ASAP: Review NIAID edits to OSP draft responses - GAO RFI: "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051)

Hello,

-

Background

As you are aware, NIH recently received a request for information (RFI) on research involving potential pandemic pathogens. GAO is requesting this information as part of their ongoing congressionally mandated engagement "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic" (105051).

OSP has the lead for responding to this information request, and has asked NIAID to review the draft responses to questions 1 and 2 of the RFI. The attached version of these responses includes edits in tracked changes from DMID, as well as additional edits from OCGR-Leg to reflect language prepared for recent Congressional correspondence.

Action

As soon as possible, please review NIAID's edits to OSP's draft responses to questions 1 and 2 and provide any additional comments or edits in tracked changes. No action is needed for questions 3 - 6.

Please let me know if you have any questions.

Thanks,
Erin

Erin Arms, Ph.D.

Public Health Analyst
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
31 Center Drive
Bldg. 31, Room 7A17H, MSC 2520
Bethesda, MD 20892-2080
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(b) (5)

From:	Ford, Andrew (NIH/NIAID) [E]
To:	Dunivin, Taylor (NIH/OD) [E]; NIAID BUGS; NIAID DAIDS WOCRB; NIAID DAIT-OPA; NIAID DIR-OCGR; NIAID DCR-OCGR; NIAID VRC-OPA; NIAID DEA DART; Fenton, Matthew (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; Nealy, Michael (NIH/NIAID) [E]; Vandalen, Kaci (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Mulach, Barbara (NIH/NIAID) [E]; Johnson, Martin S. (NIH/NIAID) [E]; Gent, Laura (NIH/NIAID) [E]; Grifka, Michelle (NIH/NIAID) [E]
Cc:	Billet, Courtney (NIH/NIAID) [E]; NIAID OCGR Leg
Subject:	Re: URGENT Action by COB TODAY (8/2): GAO SOF - Monitoring and Oversight of Response to Coronavirus 2019 Pandemic – October(105051)
Date:	Monday, August 2, 2021 5:05:07 PM
Attachments:	FY21_ALL_STAFF-#859193-v1-105051__HHS_Statement_of_Facts_v2_toDivisions AQF.docx

Hey Taylor,

A few edits/comments from me.

Thanks,
Andrew

From: "Dunivin, Taylor (NIH/OD) [E]" (b) (6)
Date: Monday, August 2, 2021 at 3:22 PM
To: NIAID BUGS (b) (6), NIAID DAIDS WOCRB (b) (6), NIAID DAIT-OPA (b) (6), NIAID DIR-OCGR (b) (6), NIAID DCR-OCGR (b) (6), NIAID VRC-OPA (b) (6), NIAID DEA DART (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6), "Nealy, Michael (NIH/NIAID) [E]" (b) (6), "Vandalen, Kaci (NIH/NIAID) [E]" (b) (6), Emily Erbelding (b) (6), "Embry, Alan (NIH/NIAID) [E]" (b) (6), Teresa Hauguel (b) (6), "Stemmy, Erik (NIH/NIAID) [E]" (b) (6), "Mulach, Barbara (NIH/NIAID) [E]" (b) (6), "Ford, Andrew (NIH/NIAID) [E]" (b) (6), "Johnson, Martin S. (NIH/NIAID) [E]" (b) (6), "Gent, Laura (NIH/NIAID) [E]" (b) (6), "Grifka, Michelle (NIH/NIAID) [E]" (b) (6)
Cc: "Billet, Courtney (NIH/NIAID) [E]" (b) (6), NIAID OCGR Leg (b) (6)
Subject: URGENT Action by COB TODAY (8/2): GAO SOF - Monitoring and Oversight of Response to Coronavirus 2019 Pandemic – October(105051)

Hello,

Background
Thank you for your assistance with the Statement of Facts (SOF) on potential pandemic pathogens for the GAO engagement 105051. Using your input, OCGR-Leg has prepared the attached edits/comments to submit to GAO and would appreciate your review.

Urgent Action

By COB today, Monday, August 2nd, please review OCGR-Leg's proposed edits/comments to GAO in the attached SOF and let us know if you have any edits or recommend additional edits/comments.

Let us know if you have any questions.

Thanks,
Taylor

From: Dunivin, Taylor (NIH/OD) [E]
Sent: Tuesday, July 27, 2021 4:47 PM
To: NIAID BUGS (b) (6); NIAID DAIDS WOCRB (b) (6); NIAID DAIT-OPA (b) (6); NIAID DIR-OCGR (b) (6); NIAID DCR-OCGR (b) (6); NIAID VRC-OPA (b) (6) (b) (6); NIAID DEA DART (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6) Nealy, Michael (NIH/NIAID) [E] (b) (6); Vandalen, Kaci (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Mulach, Barbara (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Johnson, Martin S. (NIH/NIAID) [E] (b) (6); Gent, Laura (NIH/NIAID) [E] (b) (6); Grifka, Michelle (NIH/NIAID) [E] (b) (6)
Cc: Billet, Courtney (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg (b) (6)
Subject: Action by 3p Friday (7/30): GAO SOF - Monitoring and Oversight of Response to Coronavirus 2019 Pandemic – October(105051)

Hello,

Background

NIAID has been asked to review the attached Statement of Facts (SOF) for the GAO engagement "Monitoring and Oversight of Response to Coronavirus 2019 Pandemic – October" (105051). This SOF includes discussion of research involving potential pandemic pathogens, NIH cybersecurity information, COVID-19 Other Transaction Authority (OTA), and budgetary information. The engagement is being conducted under GAO's oversight responsibilities under the CARES Act.

NIH is mentioned in the following sections:

- HHS COVID-19 Funding (pages 30-35)
- HHS Cybersecurity (pages 37-39)
- Federal Contracts and Agreements for COVID-19 (pages 40-49)
- Gain-of-Function Research Involving Potential Pandemic Pathogens (pages 57-64)

OCGR-Leg notes that some sections of this SOF may be misleading or incorrect and is requesting a

careful review of this SOF as appropriate for your Division, especially pages 57-64.

Action

By 3 p.m. Friday, July 30th, please provide any edits or comments to the attached SOF using tracked changes.

Let me know if you have any questions.

Thanks,
Taylor

Taylor K. Dunivin, Ph.D.
Health Scientist – AAAS S&T Policy Fellow
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
Office #: (b) (6)
Cell #: (b) (6)
(b) (6)

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, August 2, 2021 6:00:46 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
(b) (4), (b) (6)						
R01AI159182-02	Wang	2021-08-01	Not Recvd	N	35	Reilly-Weedon
R01AI110700-07	Baric	2021-09-01	2021-07-20	Y	35	Khandjian
F31AI147560-02	Gribble	2021-09-01	2021-07-06	Y	35	Champagne
R01AI157827-02	Haselton	2021-09-01	2021-07-14	Y	35	Ceron
R01AI157253-02	Heise	2021-09-01	2021-07-19	Y	35	Chacon
R01AI157155-02	Diamond	2021-09-01	2021-07-14	Y	35	Steele

From:	Selgrade, Sara (NIH/NIAID) [E]
To:	Embry, Alan (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]; Mulach, Barbara (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]
Cc:	NIAID OCGR Leg; Billet, Courtney (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; NIAID BUGS
Subject:	URGENT for ASF: Must-change review of draft congressional letters on COVID-19
Date:	Tuesday, July 27, 2021 7:39:05 AM
Attachments:	Johnson 5.20 draft response (7-27).docx Cole draft response (7-27).docx Grassley 5.26 draft response (7-27).docx Johnson 5.20.pdf Grassley 5.26.pdf Grassley 3.8.pdf Comer Jordan 5.28.pdf Comer Jordan 6.9.pdf Comer Jordan 5.28 & 6.9 Draft Response (7-27).docx

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Hello all,

We have been asked to quickly review the attached draft letters of response to Congress regarding COVID-19. These letters are based on previously cleared language and will be sent to Congress ASAP. Limited changes from previously cleared language are marked in tracked changes.

Please review and identify any must-change edits or typos ASAP (no later than 12pm today). If we do not hear from you, we will assume you have no comment.

Please note that we will not be able to put forward any editorial comments unless the information is incorrect. Dr. Collins or Dr. Tabak will be the signatory, and NIH Exec Sec will adjust the formatting to conform to their style guide, so there is no need for you to suggest any formatting changes.

Thank you for your help with this quick turnaround request for Dr. Fauci. Please let me know if you have any questions.

Thanks,
Sara

Sara Selgrade, Ph.D.
Section Chief for Legislative Activities
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
Bldg. 31, Room 7A17, MSC 2520
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Phone: (b) (6)
(b) (6)

DEPARTMENT OF HEALTH &. HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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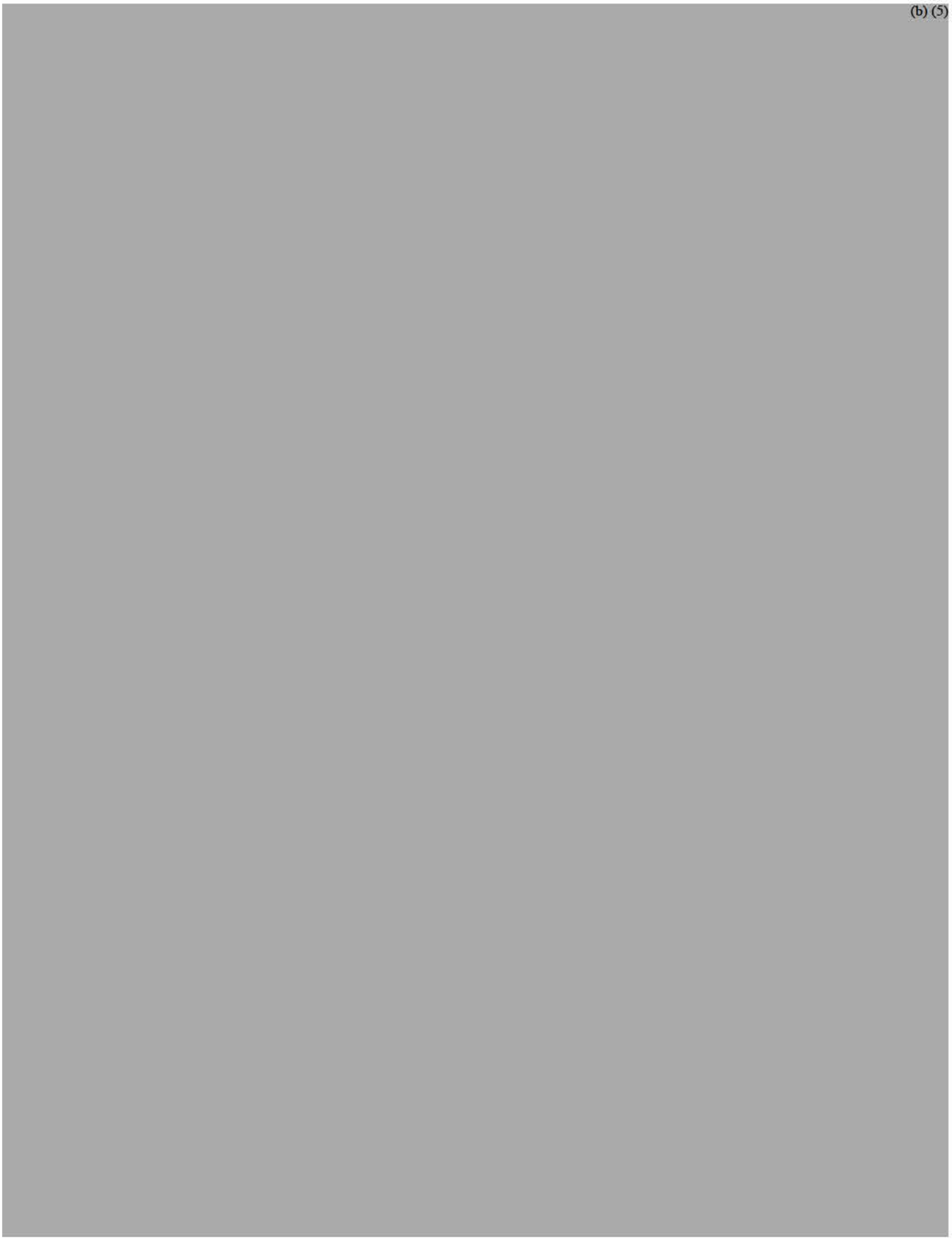

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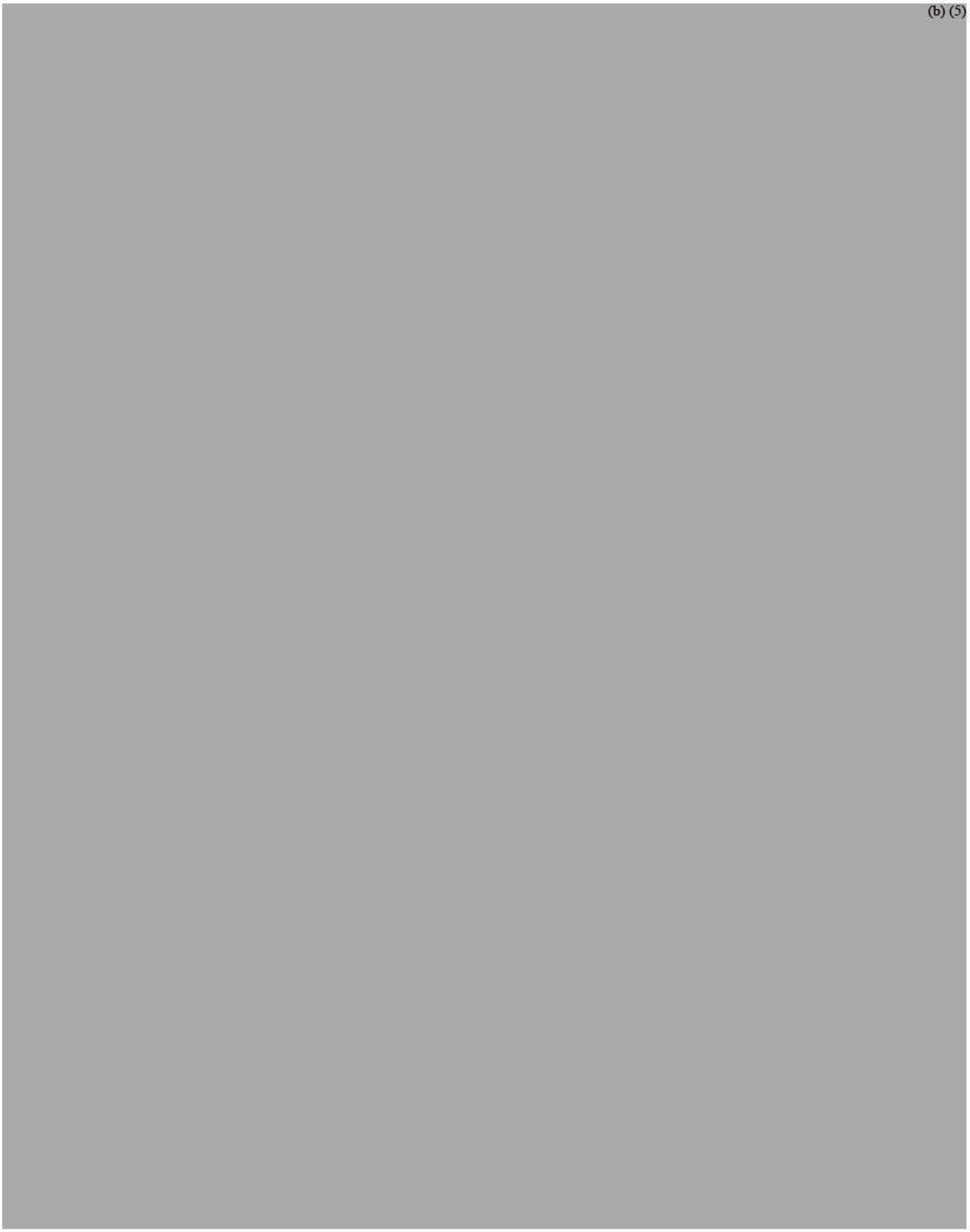

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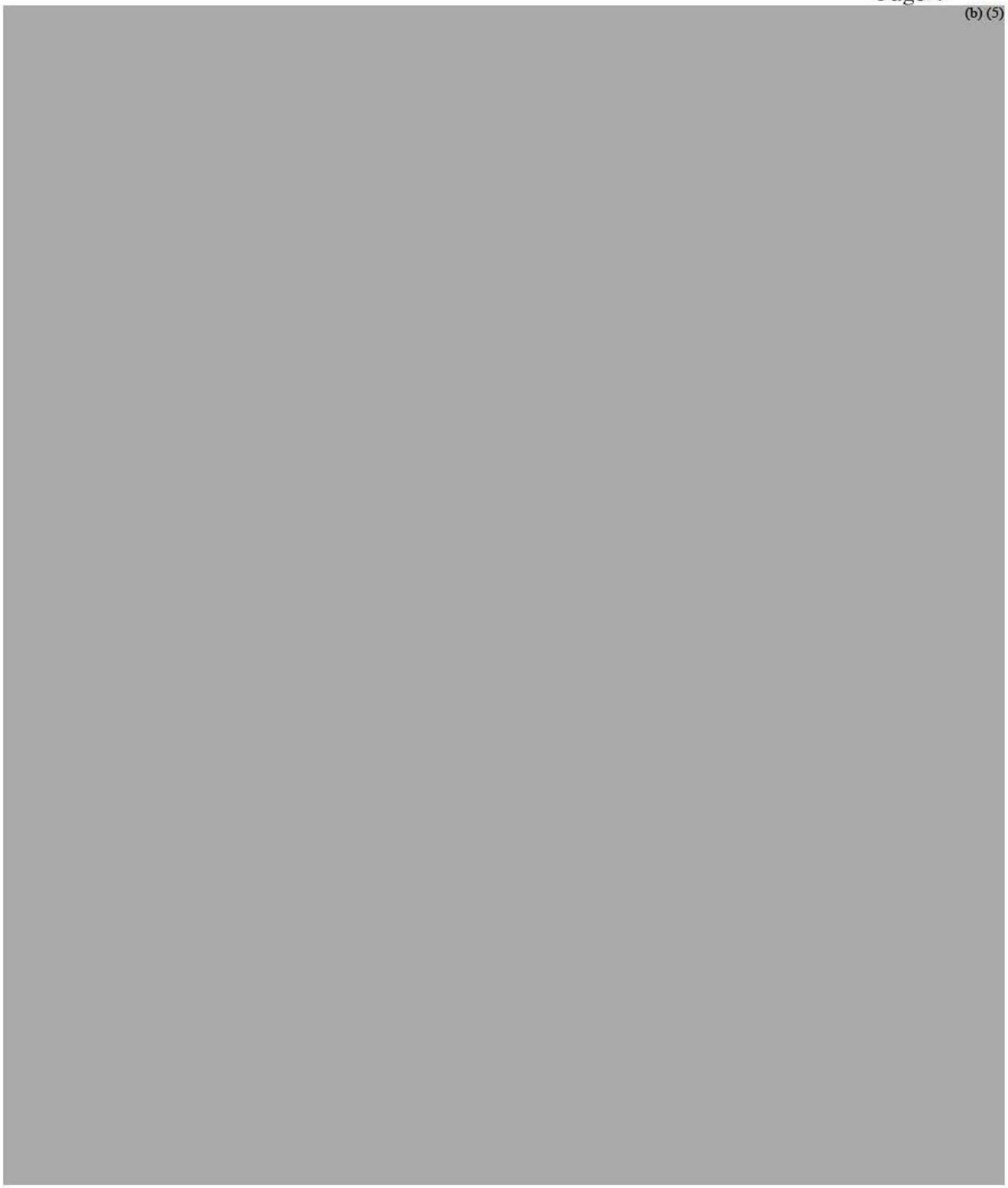

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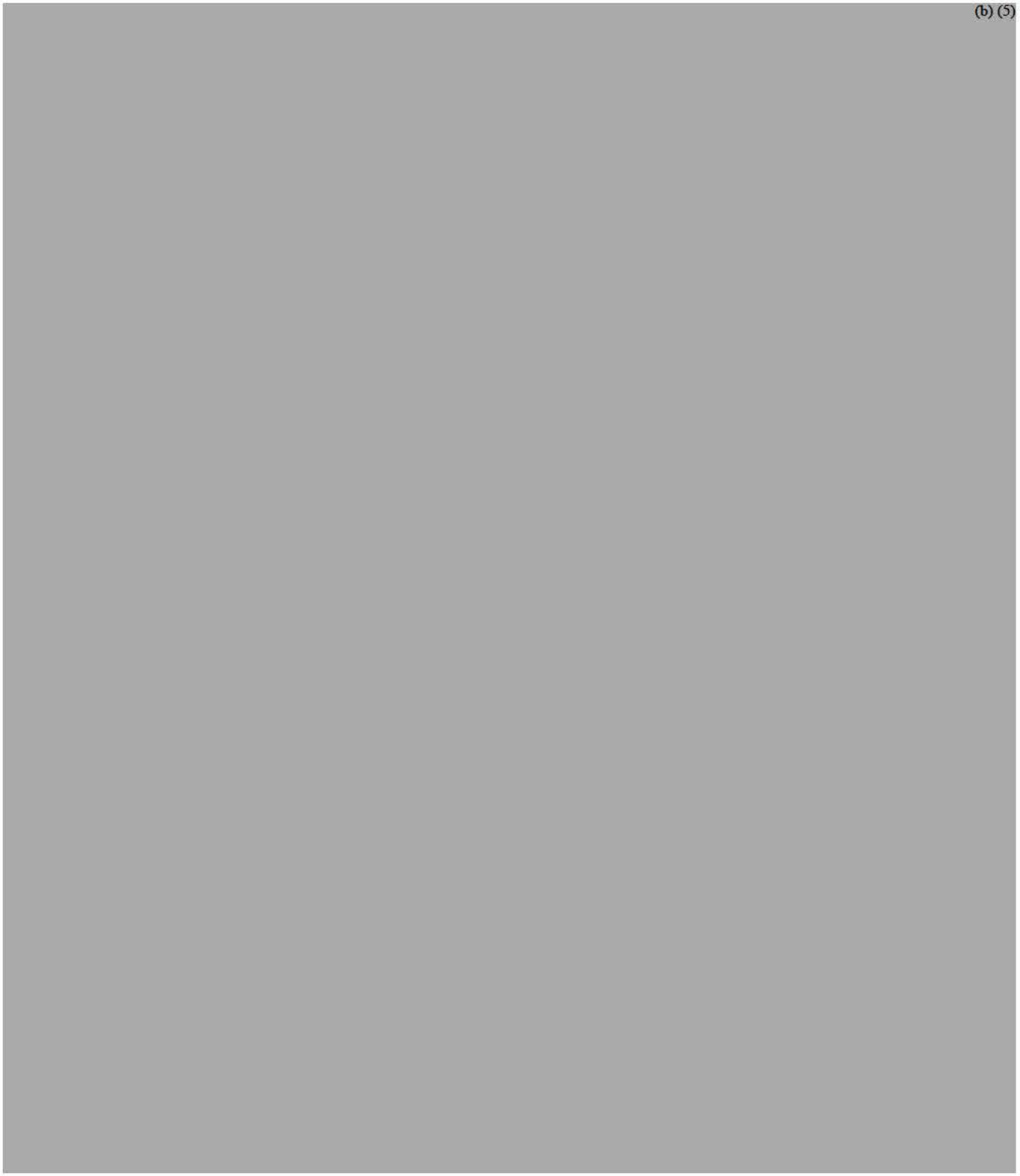

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DEPARTMENT OF HEALTH &. HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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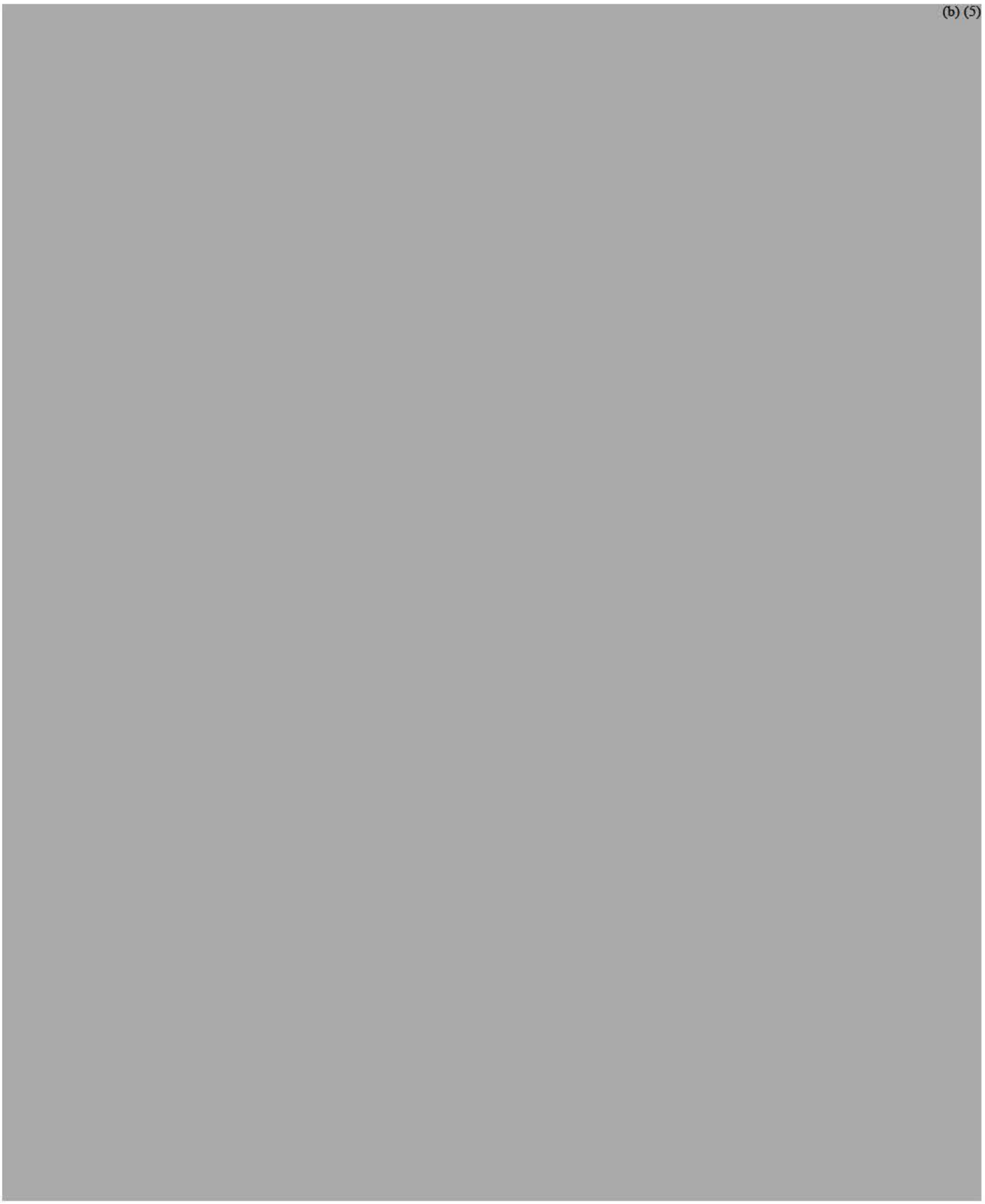

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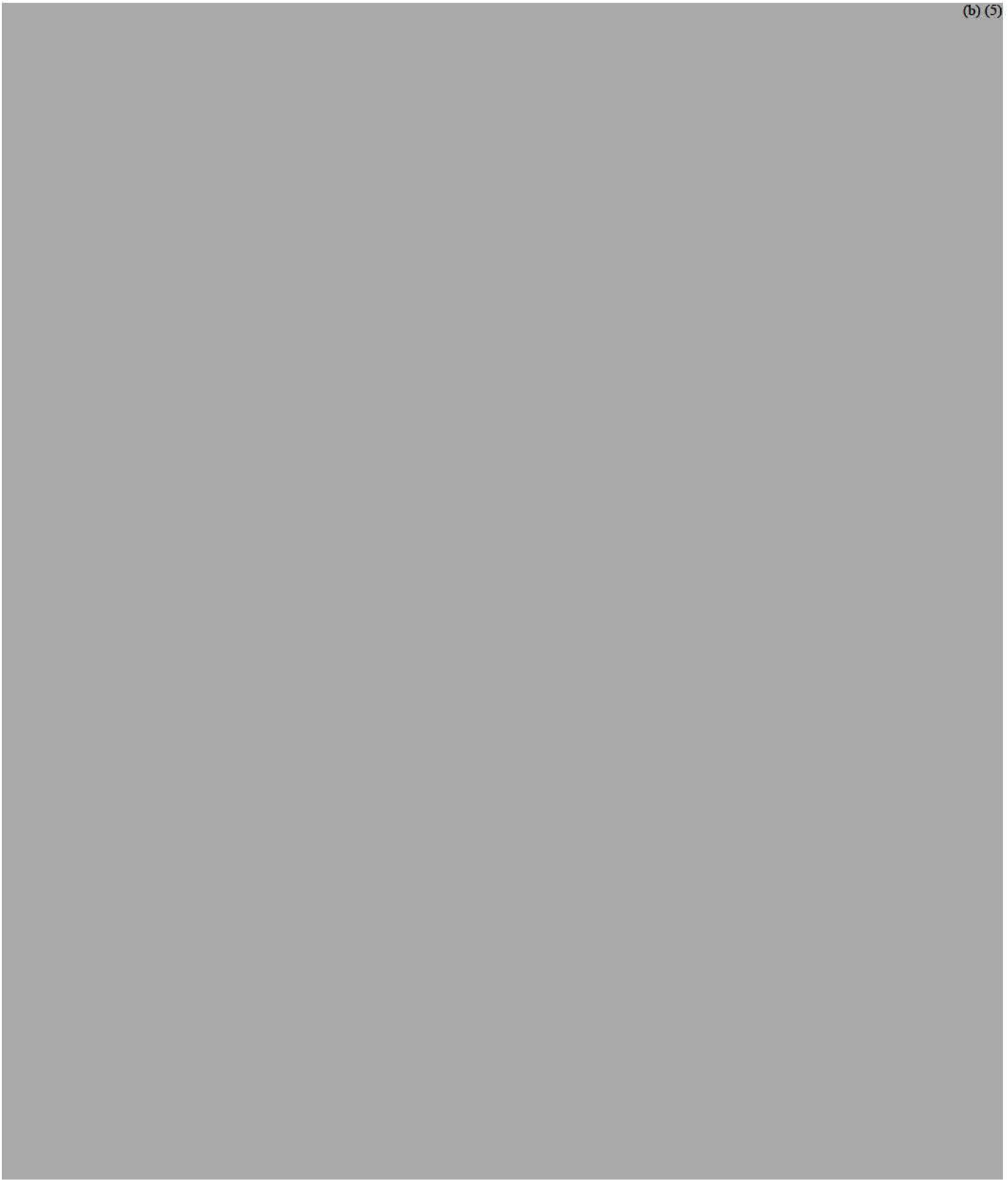

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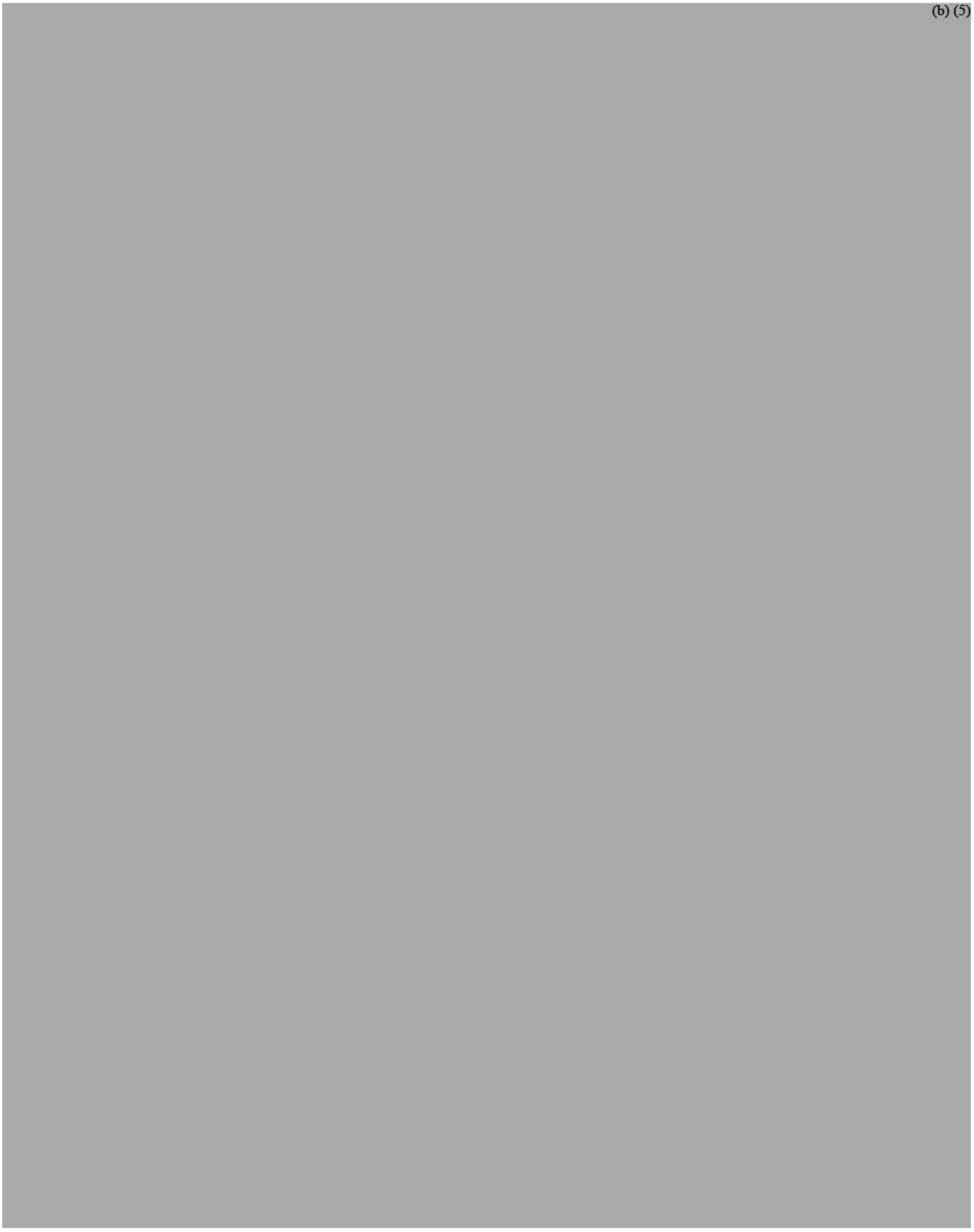

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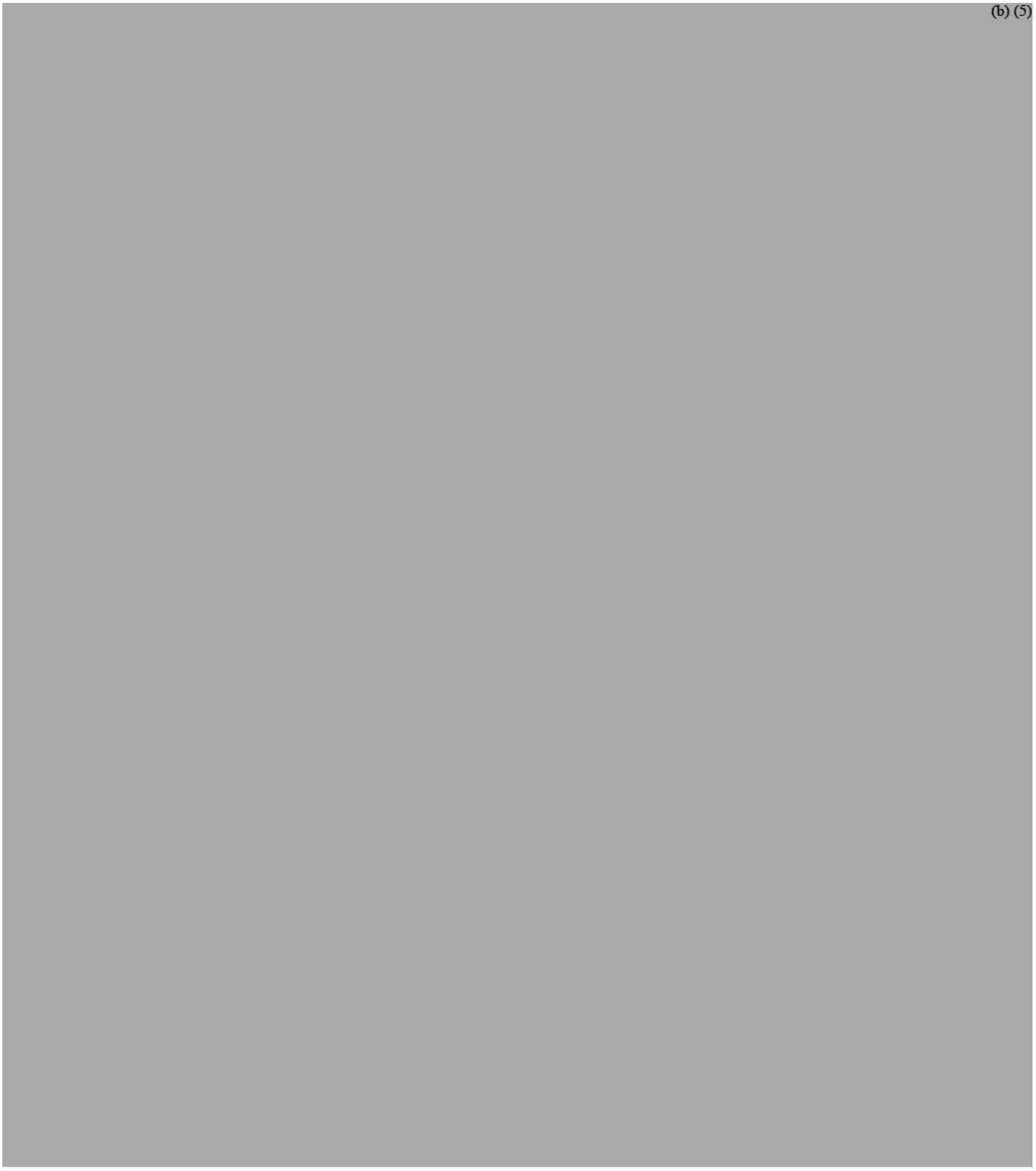

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DEPARTMENT OF HEALTH &. HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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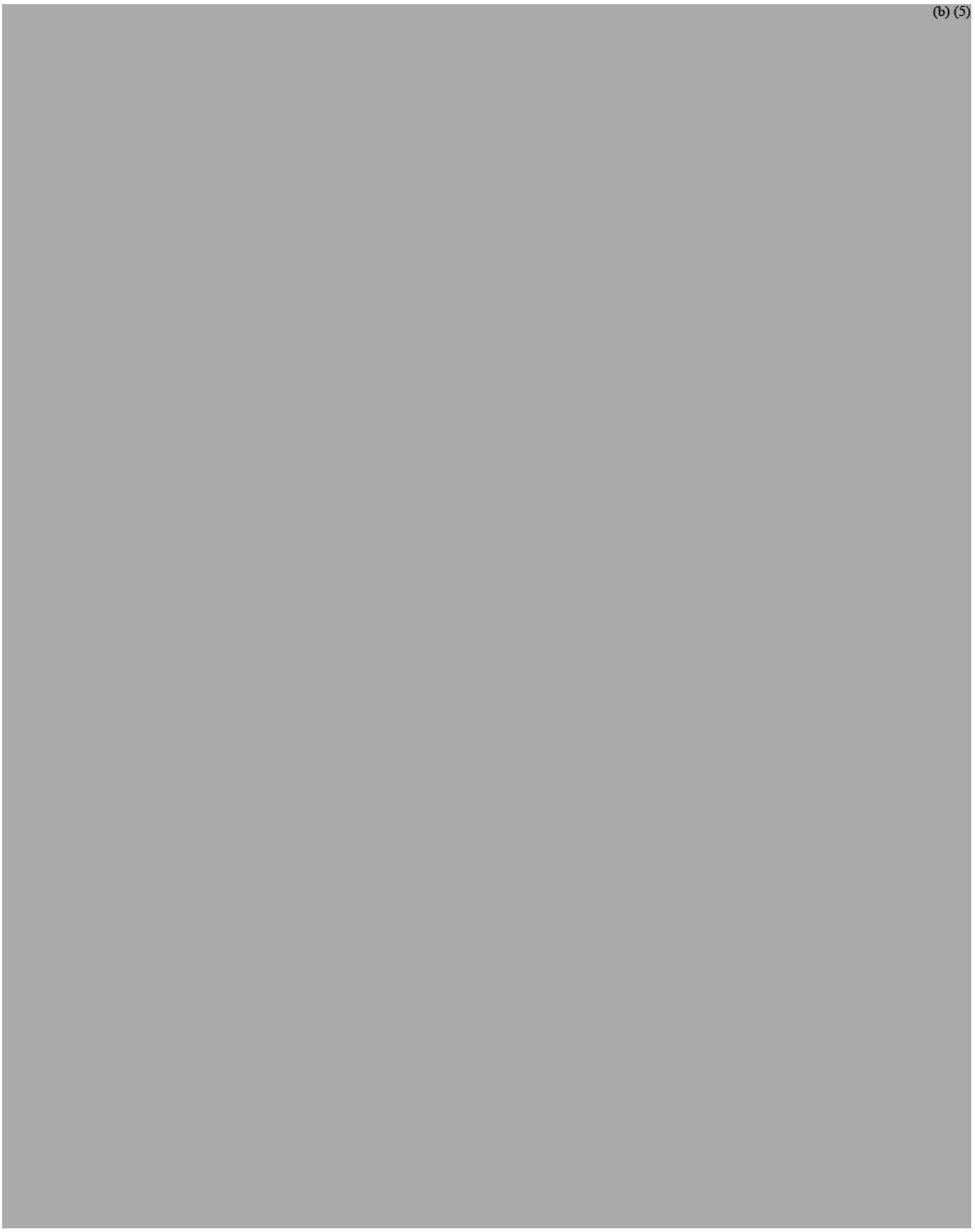

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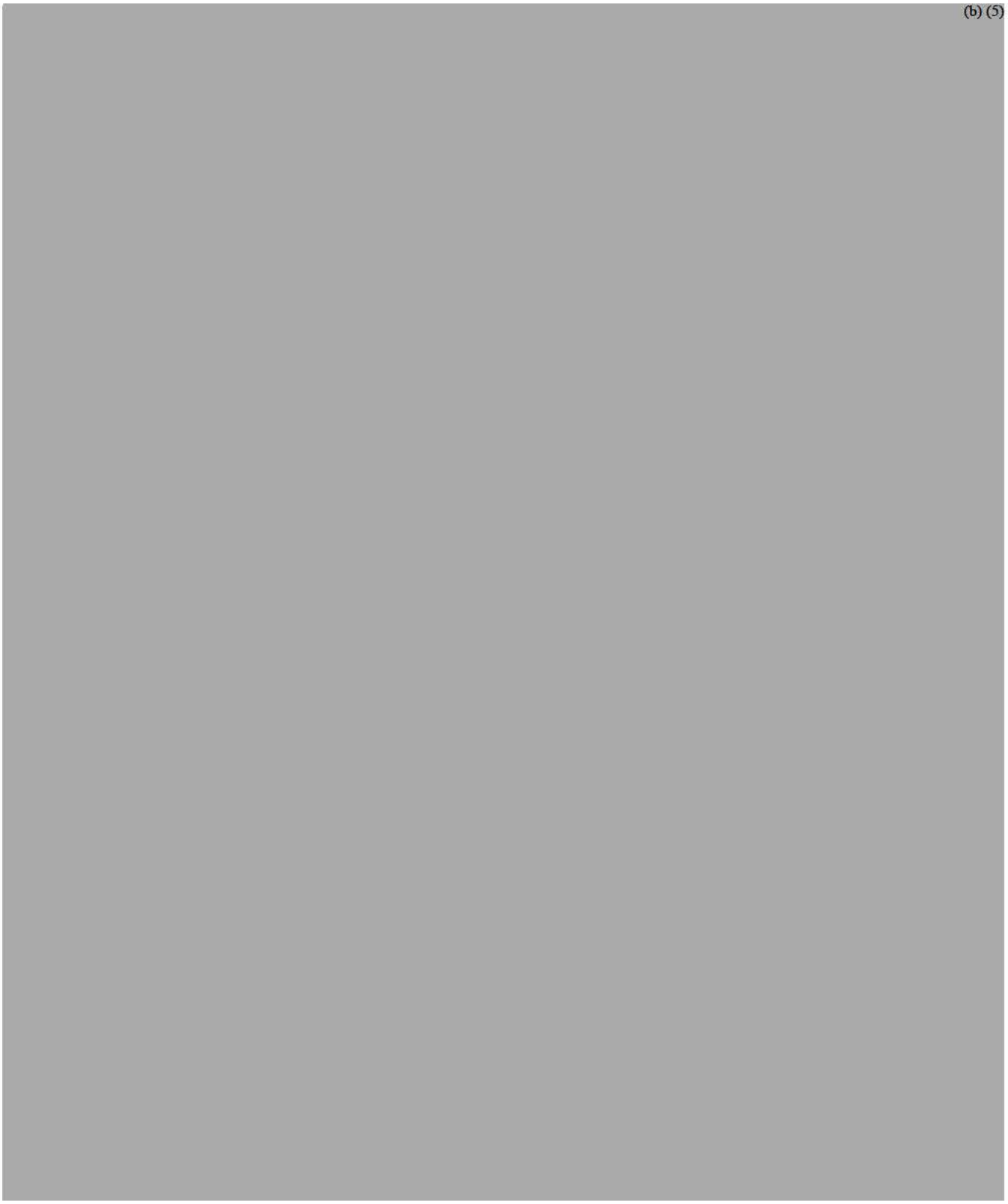

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Congress of the United States
Washington, DC 20510

May 20, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Rockville, MD 20892

Dear Director Collins,

Since the beginning of the pandemic, the exact origin of SARS-CoV-2 has remained elusive. Recently, in response to the World Health Organization's study of SARS-CoV-2's origins, a group of eighteen scientists published a letter in Science Magazine stating that a leak of the virus from a lab is a "viable" theory and should be thoroughly investigated.[1] Yet, obtaining information about the research on bat coronaviruses conducted at China's Wuhan Institute of Virology has been very difficult. Such information, including if and when gain of function experiments occurred at the lab, is crucial in determining the viability of the laboratory introduction theory. In light of the many unanswered questions regarding the origins of the SARS-CoV-2, we write to seek information regarding the National Institutes of Health's (NIH) 2014 funding pause on gain of function research (also referred to as the moratorium), exceptions NIH may have granted from that pause to allow gain of function research to continue, and the lifting of that pause in 2017.

In October 2014, following several high profile biosafety incidents at labs, as well as public scrutiny of gain of function research studies, the Department of Health and Human Services and NIH instituted a pause on funding research of gain of function experiments "involving influenza, SARS, and MERS viruses."[2] The U.S. government (USG) noted, though, that "[a]n exception from the research pause may be obtained if the head of the USG funding agency determines that the research is urgently necessary to protect the public health or national security."[3] This pause did not apply to currently-funded research at the time, but the moratorium did urge "the USG and non-USG funded research community to join in adopting a voluntary pause."[4]

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[1] Jeese Bloom et al., *Investigate the origins of COVID-19*, Science Magazine, May 14, 2021, https://science.sciencemag.org/content/372/6543/694.1.
[2] *NIH lifts funding pause on gain-of-function research*, National Institutes of Health, Dec. 19, 2017, https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-lifts-funding-pause-gain-function-research; *Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function* Research, President Barack Obama White House Archives, Oct. 17, 2014, https://obamawhitehouse.archives.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research; Sarah Reardon, *White House suspends enhanced pathogen* research, Nature, Oct. 17, 2014, http://blogs.nature.com/news/2014/10/white-house-suspends-enhanced-pathogen-research.html.
[3] *U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-function Research Involving Influenza, MERS, and SARS Viruses*, Dep't of Health and Human Services, Oct. 17, 2014, https://www.phe.gov/s3/dualuse/documents/gain-of-function.pdf.
[4] *Id.*

One of the notable NIH-funded studies that was already underway prior to the funding moratorium was Dr. Ralph Baric's work on a "lab-made coronavirus related to SARS."[5] In this 2015 study, researchers reportedly created a chimeric virus "related to SARS [that] can infect human cells."[6] Dr. Zhengli-Li Shi, "China's leading expert on bat viruses" from the Wuhan Institute of Virology, contributed to this research.[7] An article noted that NIH allowed this study "to proceed while it was under review by the agency."[8] Baric reportedly added that "NIH eventually concluded that the work was not so risky as to fall under the [gain of function] moratorium."[9] It is unclear why NIH apparently concluded that this study was not "risky" enough to fall under the moratorium.

In addition to Baric's apparent gain of function research in 2015, NIH and the National Institute of Allergy and Infectious Diseases (NIAID) also reportedly funded similar coronavirus research conducted by EcoHealth Alliance, which subcontracted with Shi.[10] Because of Shi's research and her connection to the Wuhan lab, Dr. Richard Ebright, a molecular biologist and infectious disease expert, stated, "[i]t is clear that the Wuhan Institute of Virology was systematically constructing novel chimeric coronaviruses and was assessing their ability to infect human cells and human-ACE2-expressing mice."[11] In fact, Dr. Peter Dasazk, the president of EcoHealth Alliance, spoke about changing coronaviruses in a lab. In an interview Dasazk stated, "Well I think . . . coronaviruses—you can manipulate them in the lab pretty easily."[12]

In December 2017, NIH lifted the funding pause and established a multi-disciplinary review process, known as the P3CO Framework, to ensure that federally funded gain of function experiments are "conducted responsibly."[13] It is unclear whether EcoHealth Alliance or any of its subcontractors was granted an exception to the moratorium or whether NIH reviewed those studies in connection with the P3CO Framework.[14]

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[5] Declan Buter, *Engineered bat virus stirs debate over risky research*, Nature, Nov. 12, 2015, https://www.nature.com/news/engineered-bat-virus-stirs-debate-over-risky-research-%201.18787.
[6] *Id.*
[7] Nicholas Wade, *The origin of COIVD: Did people or nature open Pandora's box at Wuhan*, Bulletin of the Atomic Scientists, May 5, 2021, https://thebulletin.org/2021/05/the-origin-of-covid-did-people-or-nature-open-pandoras-box-at-wuhan/; Ralph Baric et al., *A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence*, Nature Medicine, Nov. 9, 2015, https://www.nature.com/articles/nm.3985.
[8] Declan Buter, *Engineered bat virus stirs debate over risky research*, Nature, Nov. 12, 2015, https://www.nature.com/news/engineered-bat-virus-stirs-debate-over-risky-research-%201.18787.
[9] *A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence*, Nature, Nov. 9, 2015, https://www.nature.com/articles/nm.3985.
[10] Nicholas Wade, *The origin of COIVD: Did people or nature open Pandora's box at Wuhan*, Bulletin of the Atomic Scientists, May 5, 2021, https://thebulletin.org/2021/05/the-origin-of-covid-did-people-or-nature-open-pandoras-box-at-wuhan/.
[11] *Id*; Fred Guterl, Naveed Jamali, and Tom O'Connor, *The Controversial Experiments and Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, Newsweek, Apr. 27, 2020, https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503.
[12] *Peter Daszak of EcoHealth Alliance*, YouTube, May 19, 2020 at 29:53, https://www.youtube.com/watch?v=IdYDL_RK--w.
[13] *NIH lifts funding pause on gain-of-function research*, National Institutes of Health, Dec. 19, 2017, https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-lifts-funding-pause-gain-function-research.
[14] It appears based on an April 4, 2021 Daily Caller article that an NIH spokesperson confirmed to the Daily Caller News Foundation that the EcoHealth grants were not subjected to the P3CO review process. *See* Andrew Kerr, *US Grant To Wuhan Lab To Enhance Bat-Based Coronaviruses Was Never Scrutinized By HHS Review Board, NIH*

Given the unanswered questions surrounding SARS-CoV-2's origin, as well as both the 2014 moratorium on gain of function research and the 2017 P3CO Framework, we request that NIH provide the following information as well as all records responsive to Representative Cathy McMorris Rodgers' March 18, 2021 letter to NIH by June 3, 2021:

1. The 2014 moratorium defines gain of function research as "research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have *enhanced pathogenicity and/or transmissibility in mammals via the respiratory route*."[15] Is Dr. Baric's research that reportedly created a chimeric virus related to SARS that could infect human airway cells[16], or research that is "systematically constructing novel chimeric coronaviruses and [is] assessing their ability to infect human cells"[17] considered gain of function research under the 2014 moratorium definition? If not, please explain why not.

2. Please explain what prompted the establishment of a moratorium on gain of function research in 2014.

3. Who was involved in drafting the moratorium document?

4. Who gave final approval of the moratorium document?

5. Please explain why the moratorium stated that, "[a]n exception from the research pause may be obtained if the head of the USG funding agency determines that the research is urgently necessary to protect the public health or national security."[18]

6. Who requested that the moratorium include this exception?

7. How many studies received an exception during the moratorium period (2014-2017)?

8. Please list all requests for exceptions and indicate what exceptions NIH granted.

9. Who approved these exceptions?

Says, Daily Caller, Apr. 4, 2021, https://dailycaller.com/2021/04/04/nih-gain-of-function-anthony-fauci-review-board-wuhan-lab/.

[15] *U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-function Research Involving Influenza, MERS, and SARS Viruses*, Dep't of Health and Human Services, Oct. 17, 2014, https://www.phe.gov/s3/dualuse/documents/gain-of-function.pdf. (emphasis added)

[16] Declan Buter, *Engineered bat virus stirs debate over risky research*, Nature, Nov. 12, 2015, https://www.nature.com/news/engineered-bat-virus-stirs-debate-over-risky-research-%201.18787.

[17] Nicholas Wade, *The origin of COIVD: Did people or nature open Pandora's box at Wuhan*, Bulletin of the Atomic Scientists, May 5, 2021, https://thebulletin.org/2021/05/the-origin-of-covid-did-people-or-nature-open-pandoras-box-at-wuhan/.

[18] *U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-function Research Involving Influenza, MERS, and SARS Viruses*, Dep't of Health and Human Services, Oct. 17, 2014, https://www.phe.gov/s3/dualuse/documents/gain-of-function.pdf.

10. Please explain whether research connected to EcoHealth Alliance or Dr. Shi required an exception? If so, was an exception: a) requested; b) granted or denied? If so, who was involved in those evaluations and decisions?

11. Was any EcoHealth Alliance grant ever forwarded for review pursuant to the P3CO Framework? If not, why not?

12. Please explain whether NIH reviewed Dr. Baric's 2015 study[19], as reported in the November 12, 2015 *Nature* article.[20] If NIH reviewed this study, please explain how NIH evaluated the study's risk level and how NIH reportedly determined the study was not "so risky as to fall under the moratorium."[21]

13. Did NIH request that Dr. Baric voluntarily comply with the 2014 moratorium? Please explain.

14. Were any of Dr. Baric's grant proposals ever forwarded for review pursuant to the P3CO Framework? If not, why not?

15. After the moratorium went into effect, how many studies, which were already funded at the time, adopted a "voluntary pause on research"?[22] Please provide a list of those studies.

16. Provide the total number of grant proposals or projects that have been forwarded for review pursuant to the P3CO Framework since its establishment? How many of those grants have been approved?

17. Provide an explanation of what processes or procedures NIH used to ensure that a grant recipient was complying with the moratorium, including voluntary compliance.

Thank you for prompt attention to this matter.

Sincerely,

Ron Johnson
United States Senator

Rand Paul
United States Senator

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[19] *A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence*, Nature Medicine, Nov. 9, 2015, https://www.nature.com/articles/nm.3985.
[20] Declan Buter, *Engineered bat virus stirs debate over risky research*, Nature, Nov. 12, 2015, https://www.nature.com/news/engineered-bat-virus-stirs-debate-over-risky-research-%201.18787.
[21] *Id.*
[22] *U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-function Research Involving Influenza, MERS, and SARS Viruses*, Dep't of Health and Human Services, Oct. 17, 2014, https://www.phe.gov/s3/dualuse/documents/gain-of-function.pdf.

James Lankford
United States Senator

Rick Scott
United States Senator

Tom Cotton
United States Senator

Roger Marshall
United States Senator

Mike Gallagher
Member of Congress

United States Senate
WASHINGTON, DC 20510

May 26, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services

Dr. Francis Collins
Director
National Institutes of Health

Dear Secretary Becerra and Dr. Collins:

On March 8, 2021, I wrote to the Department of Health and Human Services and the Director of National Intelligence requesting records relating to the efforts undertaken by both agencies to determine the origins of SARS-CoV-2 ("coronavirus"). In response, I received intelligence product that causes very serious concern and further supports my belief that the Biden administration must engage in an all-hands-on-deck investigation with respect to the origins of the coronavirus. We must also get to the bottom of the communist Chinese government's potential role. Although I received intelligence product, the Director of National Intelligence failed to provide a full and complete response.

On May 21, 2021, I received a letter response from the Department of Health and Human Services. Your letter also failed to provide a full and complete response; namely it failed to provide any data relating to scientific research performed by the government to better understand the origins of the coronavirus; failed to describe the steps the Department of Health and Human Services has taken to further incorporate itself into the Intelligence Community; and failed to describe the steps the Department of Health and Human Services took to oversee the research done at the Wuhan Institute of Virology in light of it being funded by the taxpayer. If your agencies are not privy to certain intelligence information that you require to answer my questions, Congress needs to know.

Furthermore, your letter noted that the National Institutes of Health awarded a grant to EcoHealth Alliance, which made sub-awards to the Wuhan Institute of Virology and "other

institutions based in East Asia" where coronaviruses are prevalent.[1] The project was called "Understanding the Risk of Bat Coronavirus Emergence."[2] Your letter also noted that the project was intended to study several coronavirus characteristics:

> The research proposed in the grant application sought to understand how bat coronaviruses evolve naturally in the environment to become transmissible to the human population. This included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other jobs with high exposure to wildlife for evidence of bat-coronavirus infection, and analyzing data to predict which newly discovered viruses pose the greatest threat to human health.[3]

According to the link provided in your letter, the project dates to 2014 and the administering agency was the National Institute of Allergy and Infectious Diseases. The project ended in 2019 and total spending was $3,748,715.[4] However, your letter failed to note what steps were taken to oversee that spending and research.

It's been well-understood for many years that the communist Chinese government is a bad actor and cannot be trusted. With millions of dollars sent to the Chinese government, the taxpayer and Congress expects you to perform aggressive oversight of that spending and its resulting research projects to ensure that they are not used for malign activities, especially when the funded research involves highly infectious and deadly viruses. Furthermore, if no oversight was performed, then that would call into question the government's confidence that no gain of function research was supported by taxpayer dollars.

Over 500,000 Americans have lost their lives and the federal government has spent trillions of dollars due to the pandemic. If the National Institute of Allergy and Infectious Diseases failed to perform any oversight of the grants used to study bat coronaviruses and similar viruses – money that was given to the Wuhan Institute of Virology – the American people have a right to know.

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[1] Understanding the Risk of Bat Coronavirus Emergence, Project Number 2R01AI110964-06. https://reporter.nih.gov/project-details/9819304
[2] Understanding the Risk of Bat Coronavirus Emergence, Project Number 2R01AI110964-06. https://reporter.nih.gov/project-details/9819304
[3] *Id.*
[4] *Id.* It's been reported that the Wuhan Institute of Virology received approximately $600,000 of this funding. *See* Samuel Chamberlain, *Fauci admits 'modest' NIH funding of Wuhan lab but denies 'gain of function'*, New York Post (May 25, 2021).

In light of your failure to fully respond to my March 8, 2021, letter please provide a more detailed response no later than June 9, 2021. Specifically, I request that you address each question with a corresponding answer with an emphasis on what, if any, oversight was done on the relevant grants to track where the money went and the type of research that was performed.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

United States Senate
WASHINGTON, DC 20510

March 8, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Avril Haines
Director of National Intelligence

Mr. Norris Cochran
Acting Director
Department of Health and Human Services

Dear Director Haines and Acting Director Cochran:

On February 4, 2020, my oversight and investigations staff received a classified briefing from the Department of Health and Human Services (HHS), Office of National Security regarding the SARS-CoV-2 (hereinafter "coronavirus") threat and the status of the U.S. government's efforts to combat the spread of the deadly virus.[1] From the beginning, my goal has been to ensure a robust federal response to the threat and to better understand the origins of the virus. For example, there is still considerable debate about whether the coronavirus is a naturally occurring virus, a naturally occurring virus that escaped from a lab, or a laboratory manipulated virus that escaped from a lab.

In December 2020, a team of World Health Organization (WHO) researchers and scientists traveled to Wuhan, China to investigate the origins of coronavirus. However, according to recent reports, China refused to grant WHO researchers access to anonymized raw data from the earliest days of the outbreak which would help pinpoint the origins of the virus.[2] Instead, China produced self-generated summaries and analyses of the data which could have been manipulated by the communist Chinese government, effectively preventing a real review.[3]

In early February last year, I warned about China's reluctance to share data regarding the coronavirus outbreak.[4] I also noted that China's failure to cooperate made it more important for the Intelligence Community and HHS to work together to ensure information is efficiently

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[1] Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.
[2] Jeremy Page et al., *China Refuse to Give WHO Raw Data on Early COVID-19 Cases*, WALL ST. J. (Feb. 12, 2021), https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580.
[3] *Id.*
[4] Press Release, Grassley Urges More Information Sharing Between Health, Intelligence Agencies (Mar. 24, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-urges-more-information-sharing-between-health-intelligence-agencies; Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.

shared between them. The Trump administration ensured that federal health agencies had a seat at the table within the Intelligence Community and access to information relating to the pandemic. That cooperation and access must continue and be built upon to better combat the virus and determine its origins.

More than 500,000 Americans have died as a result of the coronavirus pandemic and trillions of taxpayer dollars have been spent to shore up our economy and take care of our citizens. Congress and the American public have a right to know and understand what work the government has done to determine the origins of the coronavirus. Accordingly, in light of your agency's role with respect to the pandemic, no later than March 22, 2021, please provide the following:

1. All information disseminated to the National Intelligence Council relating to the coronavirus pandemic.

2. All records relating to detailed genomic sequencing analyses for SARS-CoV-2 and related coronaviruses, including all records relating to research about the receptor binding domain of pangolin origin coronavirus and furin-cleavage site insertion.

3. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and any previous published and/or unpublished work by the Wuhan Institute of Virology on coronavirus chimeras.

4. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and genomic sequencing analyses on miners that were hospitalized in Yunnan Province in and around 2012.

5. All records relating to all analyses with respect to the capabilities of the Wuhan Institute of Virology to manipulate bat coronaviruses using reverse genetic technologies.

6. All records relating to illnesses at the Wuhan Institute of Virology among its personnel and scientific staff during the Fall of 2019. In your answer, please describe the type of work these employees were engaged in.

7. All records relating to work conducted at the Wuhan Institute of Virology by Chinese government agencies prior to and during Fall of 2019.

8. Please describe the steps you have taken to continue to incorporate the Department of Health and Human Services into missions involving threats to the nation's health care, including access to Intelligence Community information, and the steps you have taken to improve upon the information access provided by the Trump administration.

9. In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.

Please send all unclassified material directly to the Committee. In keeping with the requirements of Executive Order 13526, if any of the responsive documents do contain classified information, please segregate all unclassified material within the classified documents, provide all unclassified information directly to the Committee, and provide a classified addendum to the Office of Senate Security. Although the Committee complies with all laws and regulations governing the handling of classified information, it is not bound, absent its prior agreement, by any handling restrictions.

Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

Congress of the United States

Washington, DC 20515

May 28, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Rockville, M.D. 20892

Dr. Anthony Fauci
Director
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane, MSC 9806
Bethesda, M.D. 20892

Dear Directors Collins and Fauci:

House Republicans are investigating the origins of COVID-19. We are particularly interested in a National Institutes of Health (NIH) grant awarded to EcoHealth Alliance (EcoHealth), which subsequently awarded funds to the Wuhan Institute of Virology (WIV).[1] Under this grant, EcoHealth and the WIV conducted studies on emerging coronaviruses—like COVID-19, their potential for human-to-human transmission, and the risk of a new pandemic.[2] There is mounting evidence the COVID-19 pandemic started in the WIV, and the Chinese Communist Party (CCP) covered it up.[3] If U.S. taxpayer money was used to develop COVID-19, conduct gain of function research, or assist in any sort of cover-up, EcoHealth must be held accountable.

EcoHealth has awarded almost $600,000 dollars to the WIV and another $200,000 to the Wuhan University School of Public Health. On July 8, 2020, NIH Deputy Director for Extramural Research Dr. Michael Lauer sent a letter to EcoHealth expressing concern over its relationship with the WIV and suspended EcoHealth's grant pending answers to several routine

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[1] Grant from U.S. Dep't of Health & Human Servs., Nat'l Inst. Of Allergy and Infectious Diseases, to EcoHealth Alliance Inc., R01AI110964 (June 1, 2014), https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529.

[2] Josh Rogin, *State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses,* THE WASH. POST (Apr. 14, 2020), https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

[3] Michael R. Gordon, Warren P. Strobel, and Drew Hinshaw, *Intelligence on Sick Staff at Wuhan Lab Fuels Debate on Covid-19 Origin,* WALL ST. J. (May 23, 2021), https://www.wsj.com/articles/intelligence-on-sick-staff-at-wuhan-lab-fuels-debate-on-covid-19-origin-11621796228.

questions.[4] The questions posed by Dr. Lauer raise serious concerns and suggest COVID-19 was spreading worldwide by October 2019. Specifically, Dr. Lauer asked EcoHealth to:

1. Explain the disappearance of Huang Yanling, a scientist who worked in the WIV but whose online presence has since been deleted;

2. Disclose and explain out-of-ordinary restrictions on laboratory facilities, such as diminished cell-phone traffic in October 2019 and roadblocks surrounding the WIV from October 14-19, 2019;

3. Explain the 2012 deaths of three Chinese mine workers from a viral illness, in the WIV collection, with symptoms remarkably similar to COVID-19; and

4. Allow a U.S. government-led inspection of lab facilities and lab records at the WIV regarding COVID-19, including collection of animals.[5]

These questions suggest that EcoHealth knew of the CCP's attempts to cover-up the origins of the COVID-19 pandemic and failed to act or inform the U.S. government. When asked if EcoHealth and WIV could have lied to the government, Dr. Fauci, you said, "I cannot guarantee that . . . because you never know."[6] The actions of both EcoHealth and the CCP must be thoroughly investigated.

This investigation is more urgent now considering the recent report that, according to U.S. intelligence sources, three researchers from the WIV became ill and sought hospital care in November 2019.[7] Dr. Lauer's letter suggests that the first cases of COVID-19 occurred even earlier—in October 2019. However, the CCP did not report any COVID-19 cases until December 2019. Based on this new timeline, it is likely COVID-19 was circulating worldwide three months before anyone outside of China was informed of its existence.

Despite U.S. intelligence concerns about the ability of the WIV to properly contain the deadly diseases—including the virus that causes COVID-19—they study, EcoHealth still awarded U.S. taxpayer grant funds to the WIV.[8] Intelligence reports stated, "during interactions with scientists at the WIV laboratory, [U.S. officials] noted the new lab has a serious shortage of

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[4] Letter from Dr. Michael Lauer, Deputy Director for Extramural Research, U.S. Nat'l Inst of Health, to Drs. Aleksei Chmura & Peter Daszak, EcoHealth Alliance Inc. (July 8, 2020).
[5] *Id.*
[6] *National Institutes of Health's FY22 budget and the State of Medical Research: Hearing Before Subcomm. On Labor, Health and Human Services, Education and Related agencies, S. comm. On Appropriations,* 117th Cong. (May 26, 2021)(statement by Dr. Anthony Fauci).
[7] Gordon, *supra* note 3.
[8] Grace Panetta, *US officials were reportedly concerned that safety breaches at a Wuhan lab studying coronaviruses in bats could cause a pandemic*, BUSINESS INSIDER (Apr. 14, 2020), https://www.businessinsider.com/us-officials-raised-alarms-about-safety-issues-in-wuhan-lab-report-2020-4; Sarah Owermohle, *Trump cuts U.S. research on bat-human virus transmission over China ties*, POLITICO (Apr. 27, 2020), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.

appropriately trained technicians and investigators needed to safely operate this high-containment laboratory."[9] This is alarming.

To prevent future pandemics, Congress is obligated to conduct robust oversight of grant recipients, both current and historic. It is incumbent upon grant recipients to ensure their work is performed within the scope of the grant, advances our national interest, and protects our national security. It is vital to understand if U.S. taxpayer funds were at all affiliated with a pandemic that has taken the lives of nearly 600,000 Americans so we can prevent similar future catastrophes.

To help us better understand the relationship between the U.S. government and EcoHealth and EcoHealth's ties to the WIV, please provide the following information as soon as possible, but no later than June 11, 2021:

1. All documents and communications between NIH and EcoHealth regarding grant R01AI110964.

2. All documents and communications between NIH and WIV regarding grant R01AI110964.

3. All documents and communications pertaining to or resulting from any U.S. government-led inspection of the WIV arranged by EcoHealth.

4. All documents and communications regarding Potential Pandemic Pathogen Care and Oversight Committee review of R01AI110964.

5. All documents and communications regarding gain of function research funded by EcoHealth or any other U.S. entity.

In addition to these documents, please provide a staff-level briefing as soon as possible but no later than June 4, 2021. To schedule the briefing or ask any follow-up or related questions, please contact Committee on Oversight and Reform staff at (202) 225-5074.

The Committee on Oversight and Reform is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you in advance for your cooperation with this inquiry.

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[9] *Id.*

Sincerely,

James Comer
Ranking Member
Committee on Oversight and Reform

Jim Jordan
Ranking Member
Committee on the Judiciary

cc: The Honorable Carolyn B. Maloney, Chairwoman
Committee on Oversight and Reform

The Honorable Jerrold Nadler, Chairman
Committee on the Judiciary

Enclosure: Letter from Dr. Michael Lauer to EcoHealth Alliance on July 8, 2020.

Congress of the United States

Washington, DC 20515

June 9, 2021

Dr. Anthony Fauci
Director
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane, MSC 9806
Bethesda, M.D. 20892

Dear Dr. Fauci:

House Republicans remain concerned about the origins of COVID-19, including the increasing possibility it originated and subsequently leaked from the Wuhan Institute of Virology (WIV) in China.

At a 2012 conference entitled "Gain-of-Function Research on HPA1 H5N1 Viruses," you said, "[w]hat historically investigators have done is to actually create gain-of-function by making mutations, passage adoption, or other genetic techniques, such as ***reverse genetics***."[1]

In 2014, you, through the National Institutes of Health (NIH) awarded EcoHealth Alliance, Inc. (EcoHealth) a grant entitled "Understanding the Risk of Bat Coronavirus Emergence."[2] This grant allowed EcoHealth to "[t]est predictions of [coronavirus]…transmission…using ***reverse genetics***…"[3] Funds from this grant were subsequently awarded to the WIV.[4] Using your own definition, it appears the NIH funded gain-of-function research at the WIV.

On May 11, 2021, while testifying under oath, you stated, "[t]he NIH has not ever and does not now fund gain-of-function research in the [WIV]."[5] This appears to contradict your 2012 statement regarding gain-of-function research and the WIV.

Can you please confirm the authenticity of the 2012 video accessible on the YouTube platform? Further, please verify that the 2014 grant description is accurate and explain the apparent discrepancy in your recent testimony?

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[1] *Gain-of-Function Research on HPAI H%N1 Viruses: Welcome and Introductory Remarks,* YouTube (Mar. 20, 2013), https://www.youtube.com/watch?v=BACqqgRpktA&t=1257s *(emphasis added).*
[2] Understanding the Risk of Bat Coronavirus Emergence, R01AI110964 (last accessed June 7, 2021), https://reporter.nih.gov/search/PbfOIYYqDU28xKp7OMp5vg/project-details/8674931.
[3] *Id (emphasis added).*
[4] *Id.*
[5] Zachary Basu, *Fauci and Rand Paul clash over NIH funding for Wuhan Institute of Virology,* Axios (Mar. 11, 2021), https://www.axios.com/fauci-rand-paul-wuhan-lab-coronavirus-eff1bb08-f6c7-4d63-b170-c49e87c2e3dd.html.

The Committee on Oversight and Reform is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you in advance for your cooperation with this inquiry.

Sincerely,

James Comer
Ranking Member
Committee on Oversight and Reform

Jim Jordan
Ranking Member
Committee on the Judiciary

cc: The Honorable Carolyn Maloney, Chairwoman
Committee on Oversight and Reform

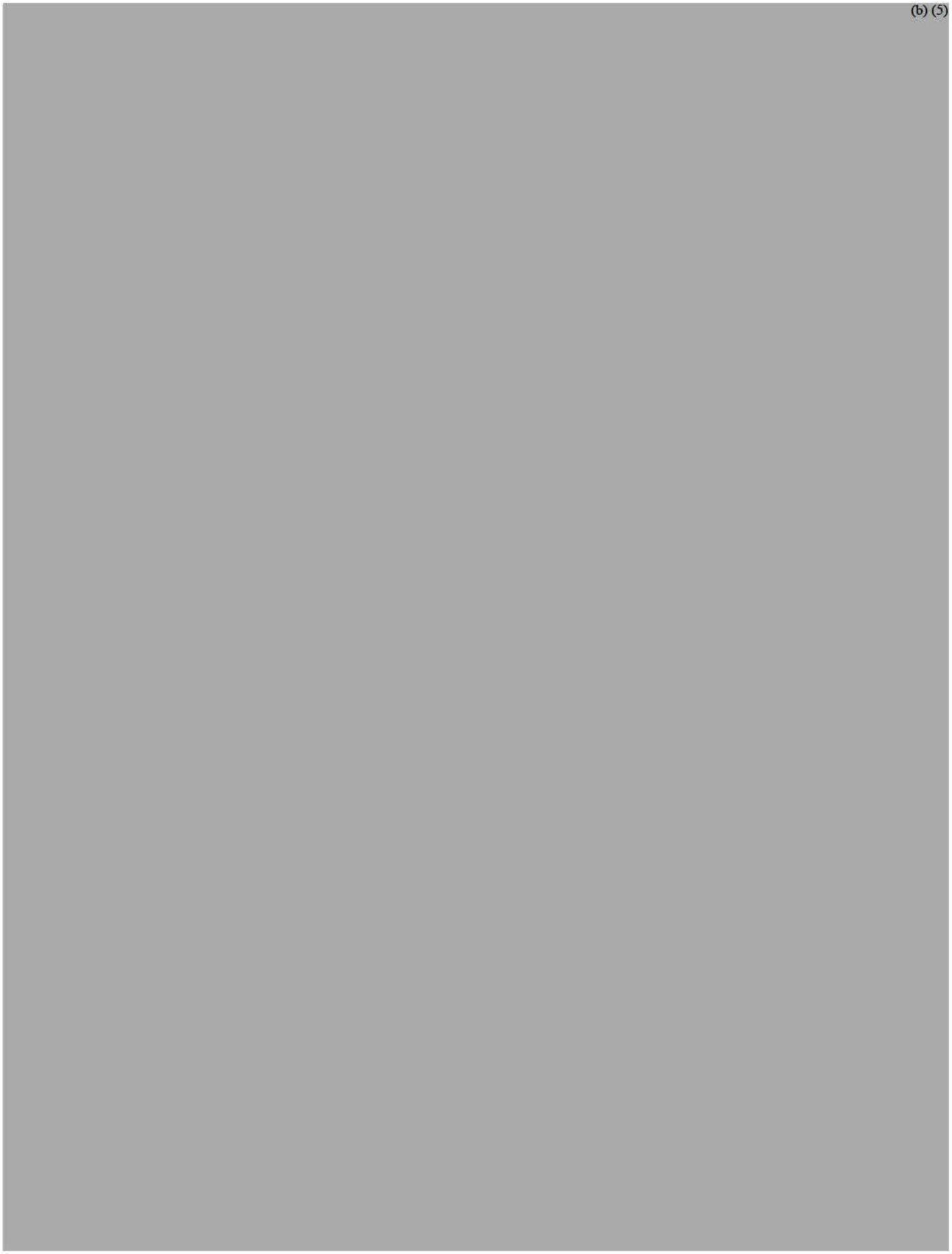
The Honorable Jerrold Nadler, Chairman
Committee on the Judiciary

DEPARTMENT OF HEALTH &. HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

(b) (5)



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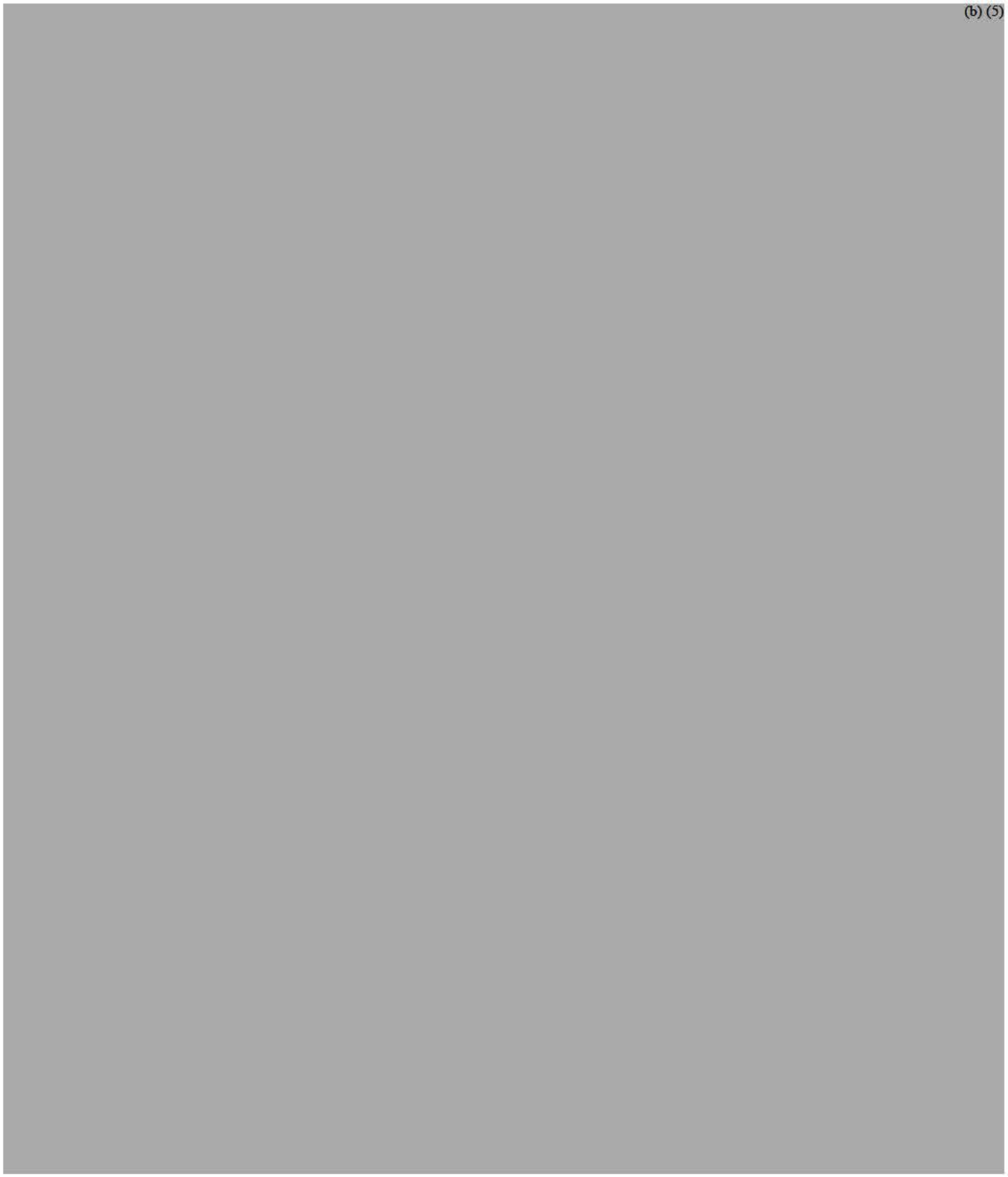
(b) (5)



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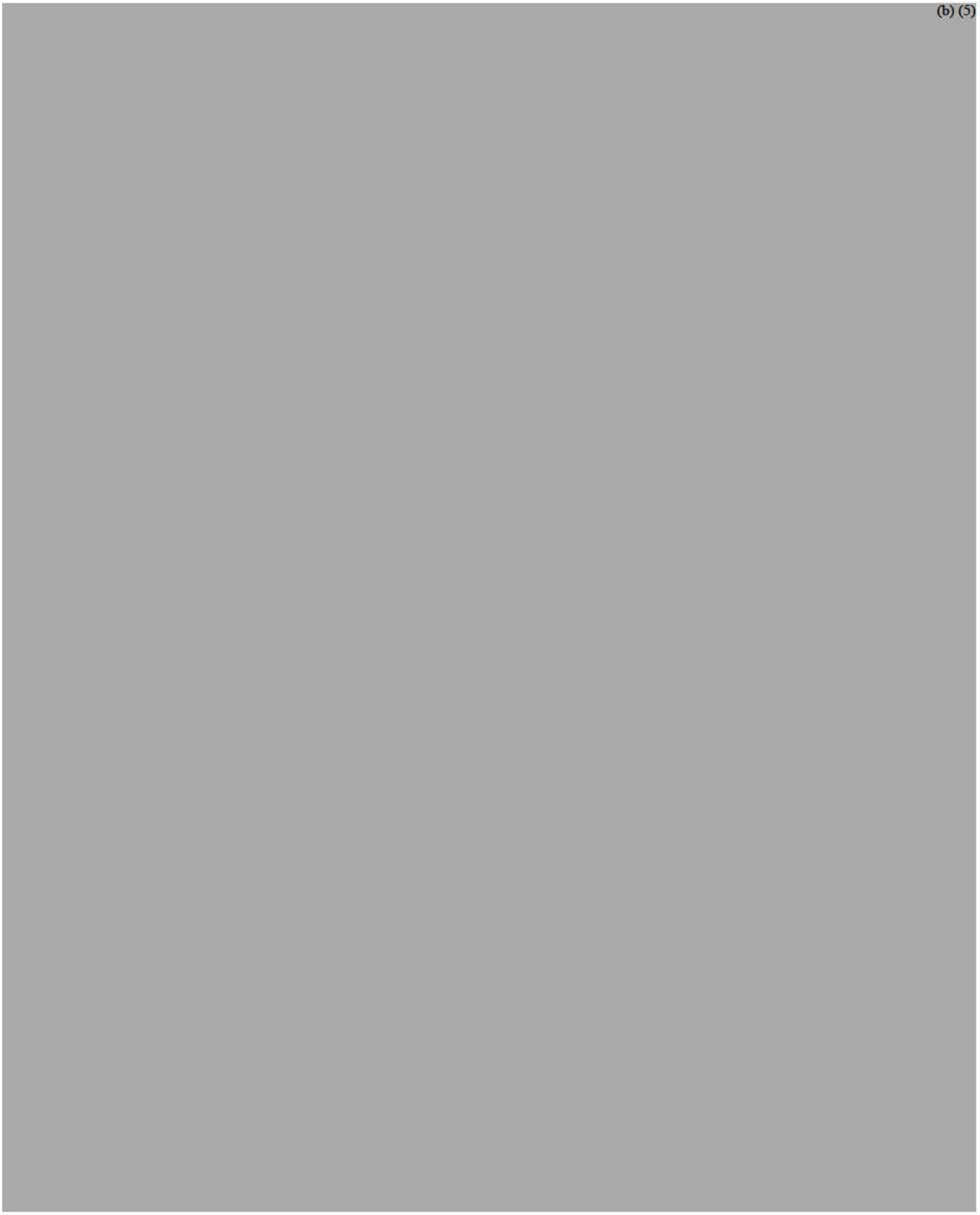

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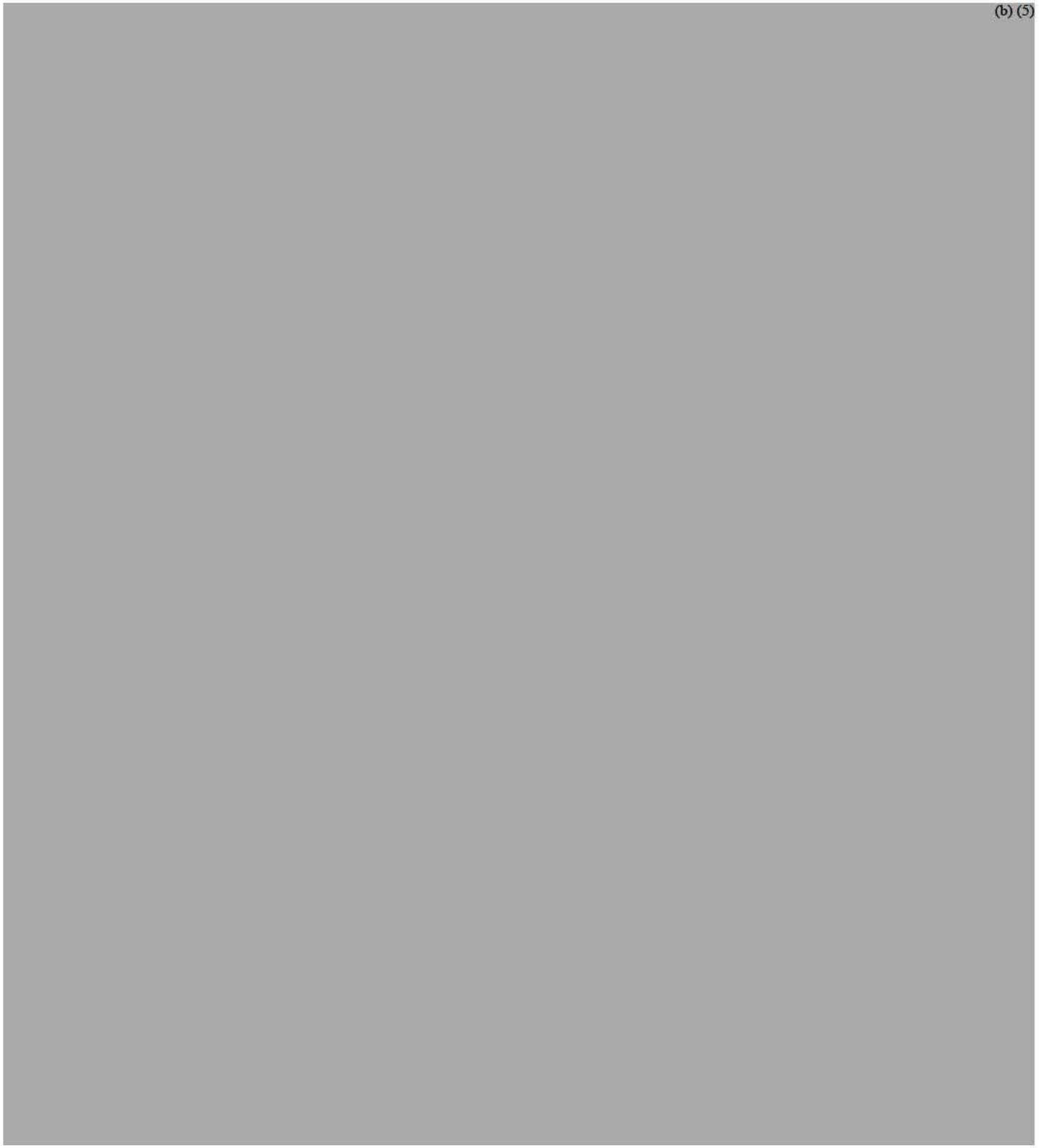

(b) (5)

[redacted]

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, July 26, 2021 6:01:05 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
(b) (4), (b) (6)						
R01AI157827-02	Haselton	2021-09-01	2021-07-14	Y	35	Ceron
R01AI157155-02	Diamond	2021-09-01	2021-07-14	Y	35	Steele
R01AI110700-07	Baric	2021-09-01	2021-07-20	Y	35	Khandjian
R01AI157253-02	Heise	2021-09-01	2021-07-19	Y	35	Chacon
F31AI147560-02	Gribble	2021-09-01	2021-07-06	Y	35	Champagne

From:	Lauer, Michael (NIH/OD) [E]
To:	Linde, Emily (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Bulls, Michelle G. (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]
Cc:	Lauer, Michael (NIH/OD) [E]
Subject:	FW: Regarding 2R01AI110964
Date:	Friday, July 23, 2021 5:31:29 PM
Attachments:	Regarding 2R01AI110964.msg To EcoHealth 7 23 21 R01AI110964.pdf 5U01AI151797-02[2].pdf

FYI and many thanks

Mike

From: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Date: Friday, July 23, 2021 at 5:27 PM
To: Peter Daszak (b) (6), Aleksei Chmura (b) (6)
Cc: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Re: Regarding 2R01AI110964

Dear Dr. Chmura and Dr. Daszak

Please see attached.

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Peter Daszak (b) (6)
Date: Sunday, April 25, 2021 at 5:22 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: Aleksei Chmura (b) (6)
Subject: RE: Regarding 2R01AI110964

Thank you Dr. Lauer.

I hope you will consider our responses to all 10 of these conditions in the spirit that they are intended. Our research demonstrates that COVID-19 is unlikely to be the last coronavirus to spill over in China. The research that this grant funds is likely to be a critical part of the fight to prevent future spillover events. It is also a critical opportunity for the USA to have eyes and ears on the ground in a country that has seen two coronaviruses emerge and spread globally in the past 2

decades.

I urge you also to consider the toll that the termination of this grant has had on EcoHealth Alliance's reputation and our staff's welfare. During the last 12 months we have been the subject of a growing series of horrific attacks in the press, and via online conspiracy theorists, and physically (including a white powder letter delivered to my home address). This has had a damaging toll on myself, my family, and the staff at EcoHealth Alliance. These unwarranted attacks have been amplified by the public discourse around the termination and current suspension of this award.

We await your decision on this suspension with great interest and remain at-the-ready to continue this work, as do our collaborators in China.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Sunday, April 25, 2021 4:23 PM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: Re: Regarding 2R01AI110964

Thank you, we were able to access to download all the files. We will review and let you know what additional information we need.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
(b) (6)
(b) (6)

From: Peter Daszak (b) (6)
Date: Friday, April 23, 2021 at 7:10 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: Aleksei Chmura (b) (6)
Subject: RE: Regarding 2R01AI110964

Thanks – I've uploaded all the files into the Box account now.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Friday, April 23, 2021 6:11 AM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: Re: Regarding 2R01AI110964

Thank you Dr. Daszak. We cannot use Dropbox due to security concerns. I've just created a Box folder. I put this letter into it and gave you Editor permission. You should be receiving an email from Box shortly. Please upload your files there.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
(b) (6)
(b) (6)

From: Peter Daszak (b) (6)
Date: Thursday, April 22, 2021 at 11:44 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: Aleksei Chmura (b) (6)
Subject: Regarding 2R01AI110964

Dear Dr. Lauer,

Please see attached our response to your request dated 4.13.21. The files we refer to in the letter can be accessed on the following Dropbox link. Please let me know if you need them sent in another format.

https://www.dropbox.com/sh/qbfw1dywds6host/AACUofeilkA4QMALEJLH4FXza?dl=0

We look forward to hearing of your decision on our efforts to address the 10 conditions on the suspended grant.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Tuesday, April 13, 2021 1:17 PM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: Re: Regarding R01AI110964

Many thanks again Dr. Daszak. We are continuing our review, but in the meantime please see attached. The third (last) attachment is what's new.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Date: Sunday, April 11, 2021 at 5:19 PM

To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Many thanks, Dr. Daszak, I received your letter. We will review it and get back to you.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
(b) (6)
(b) (6)

From: Peter Daszak (b) (6)
Date: Sunday, April 11, 2021 at 4:39 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: Aleksei Chmura (b) (6)
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

Please find attached a detailed response to your two previous letters.

I hope you will take our response in the way it was intended – a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

Cheers,

Peter

Peter Daszak
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520 Eighth Avenue, Suite 1200
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Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Dear Dr. Daszak

Attached please find two letters that I sent you previously.

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Peter Daszak (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: Aleksei Chmura (b) (6) ***[Peter Daszak:]*** REDACTED>
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence

(2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. ***[Peter Daszak:]*** **REDACTED** joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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Disclaimer

From: Peter Daszak
Sent: Thu, 22 Apr 2021 23:43:18 -0400
To: Lauer, Michael (NIH/OD) [E]
Cc: Aleksei Chmura
Subject: Regarding 2R01AI110964
Attachments: Response to letter of 4.13.21.pdf
Importance: High

Dear Dr. Lauer,

Please see attached our response to your request dated 4.13.21. The files we refer to in the letter can be accessed on the following Dropbox link. Please let me know if you need them sent in another format.

https://www.dropbox.com/sh/qbfw1dywds6host/AACUofeiIkA4QMALEJLH4FXza?dl=0

We look forward to hearing of your decision on our efforts to address the 10 conditions on the suspended grant.

Cheers,

Peter

Peter Daszak
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Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Tuesday, April 13, 2021 1:17 PM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6); Lauer, Michael (NIH/OD) [E]
(b) (6)
Subject: Re: Regarding R01AI110964

Many thanks again Dr. Daszak. We are continuing our review, but in the meantime please see attached. The third (last) attachment is what's new.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Date: Sunday, April 11, 2021 at 5:19 PM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6), "Lauer, Michael (NIH/OD) [E]"
(b) (6)
Subject: Re: Regarding 2R01AI110964-06

Many thanks, Dr. Daszak, I received your letter. We will review it and get back to you.

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One Center Drive, Building 1, Room 144
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Date: Sunday, April 11, 2021 at 4:39 PM
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I hope you will take our response in the way it was intended – a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

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Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Dear Dr. Daszak

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Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892

Phone: (b) (6)
Email: (b) (6)

From: Peter Daszak (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: Aleksei Chmura (b) (6) ***[Peter Daszak:]*** REDACTED>
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. ***[Peter Daszak:]*** **REDACTED** joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

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President

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New York, NY 10001

USA

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EcoHealth Alliance

Dr. Michael Lauer
Deputy Director for Extramural Research,
NIH, Bethesda, MD.

Re: R01AI110964 and 2R01AI110964
"Understanding the Risk of Bat Coronavirus Emergence"

April 23rd 2021

Dear Dr. Lauer,

I am responding your letter of 4/13/21 regarding our response to conditions placed on the suspended NIH grant 2R01AI110964 "*Understanding the Risk of Bat Coronavirus Emergence*". In particular, this letter addresses your request for documentation on our assessment of WIV's compliance with terms of our subcontracts from the initial (now expired) 5-year award:

"*...copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any and all other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award .... NIH must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5)...*"

As requested, we have supplied all EcoHealth Alliance-WIV subrecipient agreements, as well as documents pertaining to EHA's monitoring of WIV's compliance with the terms and conditions of award. The attached documents demonstrate that we have fulfilled all requirements in the CFR codes listed in your letter excerpted above. These documents include:

1. EcoHealth Alliance 2016-2019 Subrecipient Monitoring Forms for WIV. EcoHealth Alliance began this formal subrecipient monitoring policy in 2016 as per OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR 200) ("Uniform Guidance"), specifically §200.331.
2. 2006-2018 WIV Annual Reports. In addition, NIH has full reports on the programmatic results that we filed annually.
3. Wuhan Institute of Virology contracts and invoices for all 5 Years of Grant R01AI110964: 2014-2019
4. Federal Funding Accountability & Transparency Act Reports for WIV. From 2015 – 2019
5. Annual Independent Audit Reports from 2014-2019
6. Inter-Institutional Agreements from DHHS for WIV 2014 & 2019

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018
(b) (6)
EcoHealthAlliance.org

We hope these documents satisfy your request by demonstrating that EcoHealth Alliance maintained detailed records of our appropriate monitoring of WIV's performance against the conditions of our initial (now expired) R01 grant and our contracts with them.

We also would like draw your attention to our letter dated 4.11.2021 regarding plans for biosafety monitoring for the renewal R01, under which we had not yet set up a subcontract with WIV, specifically:

"8. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.

As we related in response to your letter of 4/19/2020 that asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of this award, therefore no such subrecipient agreements exist. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a leading lab biosafety contractor based in Southeast Asia (b) (4), (b) (6) (b) (4), (b) (6) who has extensive experience commissioning, accrediting and auditing BSL-2, -3, and -4 labs, and has worked for over a decade at the BSL-4 (b) (4). We will be using their services where appropriate for foreign lab subcontractees to assess lab biosafety procedures and conduct audits, including following the full reinstatement of 2R01AI110964. Finally, we have appointed a Senior Field Veterinarian who will oversee all EcoHealth Alliance fieldwork in the region and ensure continued compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, despite our unblemished record on biosafety, to pre-empt calls for further sanctions against our work given the continued attacks against EcoHealth Alliance in the press after the termination of our NIH grant."

We believe the attached documents lay out details of how we had previously monitored compliance according to the federal codes you cite, and the above response lays out an appropriate plan for biosafety monitoring. Together, we believe they appropriately and fully addresses your condition #8 for full reinstatement with access to funding for the renewal phase of the R01.

Yours sincerely,

Dr. Peter Daszak, President
(t) (b) (6) (e) (b) (6)

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018
(b) (6)
EcoHealthAlliance.org

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 July 2021

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: R01AI110964, U01AI151797, U01AI153420

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of April 11, 2021 and April 23, 2021 regarding R01AI110964. We are in the process of conducting detailed analyses of your answers to our questions and well as of the documents you sent, and we have the following additional requests:

1. Records

For us to continue our analyses, we will need to receive and review WIV's records validating expenditures specific to R01AI110964 as well as any and all monitoring, safety, and financial reports specific to R01AI110964 that WIV submitted to you. As a reminder, subawardees are required to have a financial management system that includes records that identify adequately the source and application of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income and interest and be supported by source documentation. 45 C.F.R. §§ 75.101 and 75.302.

As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). This right of access applies not only to awardee records, but also to subawardee records. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS Section 5).

We will also need to see subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports submitted to you, and subawardee financial and accounting records for two other NIH EcoHealth Alliance grants. Specifically, please send us all responsive documents for:

- U01AI151797 (Daszak): subawardees Chulalongkorn Hospital, Chulalongkorn University, Duke-National Singapore University, and University of North Carolina at Chapel Hill
- U01AI153420 (Epstein): subawardees International Center for Diarrhoeal Disease Research of Bangladesh, Institute of Epidemiology Disease Control and Research of Bangladesh.

We remind you that the Notice of Award for U01AI151797 already contains the following specific award conditions that must still be satisfied by 30 days from establishment.

> Subaward Agreement Requirements: The ECOHEALTH ALLIANCE, INC. must provide NIAID with copies of all (existing and newly established) subaward agreements established under this award, including descriptions of the biosafety monitoring plans, within 30 days of establishment.
>
> Federal Funding Accountability and Transparency Subaward Reporting System (FSRS) Requirements: This award is subject to the Transparency Act subaward reporting requirement of 2 CFR Part 170, which must be reported through the Federal Funding Accountability and Transparency Subaward Reporting System (FSRS). The ECOHEALTH ALLIANCE, INC. must provide NIAID with proof of documentation of timely entries of subaward information into the FSRS within 30 days of submitting to FSRS.

2. Reports

We are also writing to notify you that a review of our records for R01AI110964 indicates that EcoHealth Alliance, Inc. is out of compliance with requirements to submit the following reports that are outlined in the NIHGPS: the Federal Financial Report (FFR, see 8.4.1.2.3 Modified Financial Reporting Requirements) and the Interim Research Performance Progress Report (I-RPPR, see NIHGPS 8.4.1.4 Final Research Performance Progress Report).

R01AI110964 was issued under the Streamlined Noncompeting Award Process (SNAP). For awards under SNAP, an FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment.

Additionally, NIH requires that organizations submit an Interim-RPPR while their Type 2 application is under consideration. In the event that the Type 2 is funded, NIH treats the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.

The FFR and I-RPPR for R01AI110964 were due within 120 days after the end of the project period. In this case, the competitive segment ended on May 31, 2019, and reports were due September 30, 2019. To date, NIH has still not received these reports. Compliance with Section 8, Administrative Requirements within the NIH Grants Policy Statement (NIHGPS) is a standard term and condition of award that applies to all NIH recipients.

A recipient's failure to comply with the terms and conditions of award, may cause NIH to take one or more actions on the award, depending on the severity and duration of the non-compliance. Additionally, a history of non-compliance related to R01AI110964, including reporting non-compliance, may impact other projects where EcoHealth serves as the primary grant recipient. When a recipient has a history of failure to comply with the general or specific terms and conditions of a previous Federal award, NIH may impose specific award conditions on other awards of the recipient, including withholding authority to proceed to the next phase of a project until receipt of evidence of acceptable performance (see NIHGPS Section 8.5, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).

In closing, please be advised that EcoHealth Alliance, Inc. must satisfy the existing specific award condition for U01AI151797 by 30 days from establishment and must provide the remaining documents and reports requested herein for all three grants (R01AI110964, U01AI151797, U01AI153420) no later than August 27, 2021.

Please let me know if you have any questions concerning the information in this letter.

Sincerely,

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2021.07.23 17:24:01 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

Notice of Award
FAIN# U01AI151797
Federal Award Date
06/11/2021

Recipient Information

1. Recipient Name
ECOHEALTH ALLIANCE INC.
520 8TH AVE RM 1200

NEW YORK, NY 10018

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1311726494A1

4. Employer Identification Number (EIN)
311726494

5. Data Universal Numbering System (DUNS)
077090066

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
Peter Daszak, PHD
Executive Director
(b) (6)
(b) (6)

8. Authorized Official
Dr. Peter Daszak
(b) (6)
(b) (6)
(b) (6)

Federal Agency Information

9. Awarding Agency Contact Information
Shaun W Gratton
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
(b) (6)
(b) (6)

10. Program Official Contact Information
Jean Lois Patterson

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
(b) (6)
(b) (6)

Federal Award Information

11. Award Number
5U01AI151797-02

12. Unique Federal Award Identification Number (FAIN)
U01AI151797

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title
Understanding Risk of Zoonotic Virus Emergence in EID Hotspots of Southeast Asia

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 06/01/2021 – **End Date** 05/31/2022	
20. Total Amount of Federal Funds Obligated by this Action	$1,505,568
20 a. Direct Cost Amount	$1,348,346
20 b. Indirect Cost Amount	$157,222
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$1,505,568
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,505,568
26. Project Period Start Date 06/17/2020 – **End Date** 05/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,052,312

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Gregory P. Smith

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

RESEARCH PROJECT COOPERATIVE AGREEMENT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5U01AI151797-02

Principal Investigator(s):
Peter Daszak, PHD

Award e-mailed to: (b) (6)

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $1,505,568 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to EcoHealth Alliance in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number U01AI151797. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Gregory P. Smith
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$272,729
Fringe Benefits	$96,545
Personnel Costs (Subtotal)	$369,274
Consultant Services	$29,976
Materials & Supplies	$917
Travel	$72,168
Other	$11,991
Subawards/Consortium/Contractual Costs	$857,026
Publication Costs	$6,994
Federal Direct Costs	$1,348,346
Federal F&A Costs	$157,222
Approved Budget	$1,505,568
Total Amount of Federal Funds Authorized (Federal Share)	$1,505,568
TOTAL FEDERAL AWARD AMOUNT	$1,505,568
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,505,568

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$1,505,568	$1,505,568
3	$1,504,400	$1,504,400
4	$1,503,220	$1,503,220
5	$1,502,037	$1,502,037

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1311726494A1
Document Number:	UAI151797A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2021

IC	CAN	2021	2022	2023	2024
AI	8472315	$1,505,568	$1,504,400	$1,503,220	$1,502,037

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M32F B / **OC**: 41029 / **Released**: Smith, Gregory 06/10/2021
Award Processed: 06/11/2021 12:07:49 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01AI151797-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5U01AI151797-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) U01AI151797. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 5U01AI151797-02

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Total costs requested in the non-competing grant progress report exceed the amount previously committed. Funds are awarded at the committed level from the last Notice of Award.

****

Subaward Agreement Requirements: The ECOHEALTH ALLIANCE, INC. must provide NIAID with copies of all (existing and newly established) subaward agreements established under this award, including descriptions of the biosafety monitoring plans, within 30 days of establishment.

Federal Funding Accountability and Transparency Subaward Reporting System (FSRS) Requirements: This award is subject to the Transparency Act subaward reporting requirement of 2 CFR Part 170, which must be reported through the Federal Funding Accountability and Transparency Subaward Reporting System (FSRS). The ECOHEALTH ALLIANCE, INC. must provide NIAID with proof of documentation of timely entries of subaward information into the FSRS within 30 days of submitting to FSRS.

+++++++

This award does not include funds to support research subject to the *Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (DHHS P3CO Framework) Therefore:

- For Aim 1: Identify, characterize and rank spillover risk of high zoonotic potential viruses from wildlife, the building of chimeric SARS-like bat coronaviruses will be based on the SHC014 or the pangolin coronavirus molecular clones and the building of chimeric MERS-CoV will be based on the HKU5 strain. Prior to further altering the mutant viruses you must provide NIAID with a detailed description of the proposed alterations and supporting evidence for the anticipated phenotypic characteristics of each virus.
- Alternative approaches to those referenced above, including building chimeras based on SARS-CoV-1, SARS-CoV-2, and MERS-CoV, may be subject to the DHHS P3CO Framework and must be submitted to NIAID for review and approval prior to the work commencing.

If any of the experiments proposed for Aim 1 result in a virus with a phenotype of enhanced pathogenicity and/or transmissibility, enhanced growth by more than 10 fold when compared to wild type strains, or if the mice display significant increases in weight loss, viral titer, or mortality when compared to wild-type strains, the recipient must immediately stop the work and notify the NIAID Program Officer, Grants Management Specialist, and appropriate institutional biosafety committee. Policy changes regarding the classification of these experiments or components used in these experiments may be subject to immediate halting of experimentation. No NIH funding can be used to perform such experiments until these experiments have been approved by NIAID with a revised NOA.

****

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated on page(s) **373** of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

****

This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

****

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

Jeppesen Field Consulting Australia - AUSTRALIA
Conservation Medicine Ltd. - MALAYSIA
Duke-NUS Medical School - SINGAPORE
Chulalongkorn University - THAILAND

****

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

****

This Notice of Award (NoA) includes funds for activity with **Conservation Medicine Ltd. - MALAYSIA** in the amount of **$224,821** (**$208,167** direct costs + **$16,654** F&A costs).

****

This Notice of Award (NoA) includes funds for activity with **Duke-NUS Medical School - SINGAPORE** in the amount of **$107,915** (**$99,921** direct costs + **$7,994** F&A costs).

****

This Notice of Award (NoA) includes funds for activity with **Chulalongkorn University - THAILAND** in the amount of **$215,774** (**$199,791** direct costs + **$15,983** F&A costs).

****

This Notice of Award (NoA) includes funds for activity with **The University of North Carolina at Chapel Hill** in the amount of **$194,221** (**$124,901** direct costs + **$69,320** F&A costs).

****

This Notice of Award (NoA) includes funds for activity **The Henry M. Jackson Fdn. for the Adv'mt. of Mil. Med., Inc**. in the amount of **$114,294** (**$74,941** direct costs + **$39,353** F&A costs).

****

This award is issued as a Cooperative Agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the Terms and Conditions of Award as set forth in Section VI: Award Administrative Information of **RFA AI-19-028**, "**Emerging Infectious Diseases Research Centers**," posted date **3/5/2019**, which are hereby incorporated by reference as special terms and conditions of this award.

This RFA may be accessed at: http://grants.nih.gov/grants/guide/index.html

****

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

****

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted

experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

o A list of the new and/or additional Agent(s) that will be studied;
o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

SPREADSHEET SUMMARY
AWARD NUMBER: 5U01AI151797-02

INSTITUTION: EcoHealth Alliance

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$272,729	$272,938	$272,938	$272,938
Fringe Benefits	$96,545	$96,628	$96,628	$96,628
Personnel Costs (Subtotal)	$369,274	$369,566	$369,566	$369,566
Consultant Services	$29,976	$15,000	$15,000	$15,000
Materials & Supplies	$917	$7,918	$7,918	$7,918
Travel	$72,168	$72,225	$72,225	$72,225
Other	$11,991	$27,000	$27,000	$27,000
Subawards/Consortium/Contractual Costs	$857,026	$855,344	$854,164	$852,981
Publication Costs	$6,994			
TOTAL FEDERAL DC	$1,348,346	$1,347,053	$1,345,873	$1,344,690
TOTAL FEDERAL F&A	$157,222	$157,347	$157,347	$157,347
TOTAL COST	$1,505,568	$1,504,400	$1,503,220	$1,502,037

Facilities and	Year 2	Year 3	Year 4	Year 5

Administrative Costs				
F&A Cost Rate 1	32%	32%	32%	32%
F&A Cost Base 1	$491,320	$491,709	$491,709	$491,709
F&A Costs 1	$157,222	$157,347	$157,347	$157,347

From: Embry, Alan (NIH/NIAID) [E]
To: Selgrade, Sara (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Cc: Mulach, Barbara (NIH/NIAID) [E]; Haskins, Melinda (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]
Subject: RE: URGENT: congressional language for review
Date: Thursday, July 22, 2021 12:39:51 PM
Attachments: Master Document - Congressional Responses re Origin (7.6) NIAID ae.docx

Thanks. Responses and minor typo edit in attached.
Alan

From: Selgrade, Sara (NIH/NIAID) [E] (b) (6)
Sent: Thursday, July 22, 2021 12:31 PM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Cc: Mulach, Barbara (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Haskins, Melinda (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6)
Subject: RE: URGENT: congressional language for review

Thanks very much, all.

I have tried to incorporate all the edits in the attached (b) (5) There are also a couple of comments (I think mostly for Alan).

I would appreciate if you could take a quick look and let me know if you have any concerns.

Thanks,
Sara

From: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Sent: Thursday, July 22, 2021 12:04 PM
To: Selgrade, Sara (NIH/NIAID) [E] (b) (6)
Cc: Mulach, Barbara (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Haskins, Melinda (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: Re: URGENT: congressional language for review

Hey Sara,

A few additional edits/comments from me and Barbara.

Thanks
Andrew

From: Teresa Hauguel (b) (6)

Date: Thursday, July 22, 2021 at 11:53 AM
To: Sara Selgrade (b) (6)
Cc: "Mulach, Barbara (NIH/NIAID) [E]" (b) (6), "Embry, Alan (NIH/NIAID) [E]" (b) (6), "Ford, Andrew (NIH/NIAID) [E]" (b) (6), "Haskins, Melinda (NIH/NIAID) [E]" (b) (6), "Stemmy, Erik (NIH/NIAID) [E]" (b) (6)
Subject: RE: URGENT: congressional language for review

Sara,

Attached are a few edits/comments from me. I will defer to Erik on the details of the EcoHealth and UNC projects.

Best,
Teresa

Teresa M. Hauguel, Ph.D.
Acting Chief, Respiratory Diseases Branch
COR, Collaborative Influenza Vaccine Innovation Centers (CIVICs)
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Rockville, MD 20852
Phone: (b) (6)
Email: (b) (6)

From: Haskins, Melinda (NIH/NIAID) [E] (b) (6)
Sent: Thursday, July 22, 2021 10:30 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Selgrade, Sara (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6); Mulach, Barbara (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: FW: URGENT: congressional language for review
Importance: High

From: Selgrade, Sara (NIH/NIAID) [E] (b) (6)
Sent: Thursday, July 22, 2021 10:19 AM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6)
Cc: Embry, Alan (NIH/NIAID) [E] (b) (6); Haskins, Melinda (NIH/NIAID) [E] (b) (6)
Subject: URGENT: congressional language for review

Importance: High

Hello Andrew and Teresa,

We have been asked to review the attached document on quick turnaround. It contains standard language that will be used to respond to congressional letters on various topics, primarily related to EcoHealth Alliance and GOF research.

Alan and I have made a few edits and comments, and we would appreciate your expert review. If you feel others in DMID should review, please share with them and submit compiled comments.

Please let us know if you have any changes by NOON today.

Thanks very much for your help on this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

From: Ford, Andrew (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Park, Eun-Chung (NIH/NIAID) [E]; Patterson, Jean (NIH/NIAID) [E]
Cc: Challberg, Mark (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; NIAID BUGS
Subject: FW: Action by COB Tuesday, July 27th: OIG RFI (A-05-21-00025)
Date: Monday, July 19, 2021 10:39:30 PM
Attachments: Notification letter...6.11.21.pdf
REVISED NIH Oversight of Grantee-Subgrantee Entrance Conference Agenda...06.29.2021_toDivisions.docx

Dear Erik, Eun-Chung, and Jean,

Please see Erin's email below. In brief, NIH is currently participating in an OIG engagement; the majority of the questions relate to NIAID funding provided to EcoHealth Alliance.

REQUEST – **Please review the second attachment and send any edits/comments to BUGS by COB, Tuesday, July 27, 2021**; there are a few comment boxes with questions directed to DMID. Please note, NIH OER is the lead for this engagement and drafted the majority of the responses to the request for information. NIAID OCGR-Leg included some additional comments in the second attachment.

Should you have any questions or need additional time to complete the request, please let BUGS know as soon as possible.

Thanks,
andrew

From: "Arms, Erin (NIH/NIAID) [E]" (b) (6)
Date: Monday, July 19, 2021 at 4:20 PM
To: NIAID DEA DART (b) (6), NIAID BUGS (b) (6)
Cc: "Harper, Jill (NIH/NIAID) [E]" (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" (b) (6) "Linde, Emily (NIH/NIAID) [E]" (b) (6) Emily Erbelding (b) (6), "Embry, Alan (NIH/NIAID) [E]" (b) (6), "Billet, Courtney (NIH/NIAID) [E]" (b) (6), NIAID OCGR Leg (b) (6)
Subject: Action by COB Tuesday, July 27th: OIG RFI (A-05-21-00025)

Hello,

Background
NIH currently is participating in an OIG engagement "NIH and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025; notification letter first attachment). NIH OER is the lead for this engagement.

NIH has received a request for information (RFI) for this engagement (second attachment). The majority of this question set is related to NIAID funding provided to EcoHealth Alliance, and includes several document requests. OER has drafted the majority of the responses to this RFI, and has

included specific comments directing particular questions to other NIH entities, including NIAID.

OCGR-Leg has included some additional comments in the second attachment, as well as some suggested edits to a few of the responses in tracked changes.

Action

By COB Tuesday, July 27th, please review the attached responses and provide any requested information and edits as appropriate. If you think you will require more time to complete this request, please let us know as soon as possible.

Please let me know if you have any questions.

Thanks,
Erin

Erin Arms, Ph.D.
Public Health Analyst
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
31 Center Drive
Bldg. 31, Room 7A17H, MSC 2520
Bethesda, MD 20892-2080
(b) (6)
(b) (6)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

June 11, 2021

TO: Meredith Stein
Director, Division of Risk Management and Audit Liaison
Office of Management Assessment
National Institutes of Health

FROM: Carla J. Lewis
CARLA LEWIS Digitally signed by CARLA LEWIS Date: 2021.06.11 11:15:34 -04'00'
Assistant Inspector General for Audit Services
Public Health and Human Services Programs

SUBJECT: Notice of Audit Start: *Audit of National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees,* (A-05-21-00025)

Assignment: The objectives of this audit are to determine whether: (1) the National Institutes of Health (NIH) monitored grants to EcoHealth Alliance in accordance with Federal regulations and (2) EcoHealth Alliance used and managed its NIH grant funds in accordance with Federal requirements.

OIG/OAS Division and Region(s): Public Health and Human Services Audit Division (PHHSAD) and Office of Audit Services (OAS), Region V.

Background and General Description of Work: NIH is the primary Federal agency that conducts and supports medical research. NIH funds grants, cooperative agreements, and contracts that support the advancement of fundamental knowledge about the nature and behavior of living systems. Approximately 80 percent of NIH funding goes to support research grants, including grants and subawards to support research conducted outside the United States. OIG has previously identified NIH's oversight of grants to foreign applicants as a potential risk to the Department meeting program goals and the appropriate use of Federal funds. NIH must manage and administer Federal awards to ensure that Federal funding is expended and associated programs are implemented in full accordance with statutory and public policy requirements. To do so, NIH must monitor grantee performance and grantee use of NIH funds.

In fiscal years 2014–2020, NIH awarded approximately $5.9 million in grants to EcoHealth Alliance. Grantees, including EcoHealth Alliance, are responsible for complying with all requirements of the Federal award, including maintaining effective internal controls over the Federal award (45 CFR §§ 75.300 and 75.305). Grantees that function as pass-through entities

must monitor the activities of subrecipients, including foreign subrecipients, to ensure that subawards are used for authorized purposes in compliance with relevant laws and the terms and conditions of the subaward (45 CFR § 75.352). We will review NIH's monitoring of EcoHealth Alliance grants, and the grantee's use and management of NIH grant funds, in accordance with Federal requirements.

Where Work Will Be Done: We will perform our work at NIH, EcoHealth Alliance, and OAS Region V offices. Fieldwork may be conducted remotely as necessary.

Entrance Conference: We will request an entrance conference to discuss this audit.

Method for Securely Transmitting Audit Information to OAS Over the Internet: When transmitting any audit information to OAS over the Internet, please properly safeguard the information. We request that you use the HHS/OIG Delivery Server, not email or attachments to email. Information transmitted through the HHS/OIG Delivery Server complies with Federal Information Processing Standard (FIPS) 140-2, *Security Requirements for Cryptographic Modules*. At the entrance conference, we will discuss authorizing your staff to use the HHS/OIG Delivery Server and give you instructions in its use.

We are required to report as a security breach any audit information sent to us that does not meet FIPS 140-2 requirements.

OIG Contact(s): Jeffrey D. Stitz, Director-PHHSAD, (b) (6)
Mike Barton, Assistant Regional Inspector General-Region V, (b) (6)

cc:
Amy J. Frontz
Deputy Inspector General for Audit Services

OIG Components

GAO

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, July 19, 2021 6:02:29 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
						(b) (4), (b) (6)
R01AI157155-02	Diamond	2021-09-01	2021-07-14	Y	35	Steele
R01AI157827-02	Haselton	2021-09-01	2021-07-14	Y	35	Ceron
R01AI157253-02	Heise	2021-09-01	Not Recvd	N	35	Chacon
R01AI110700-07	Baric	2021-09-01	Not Recvd	N	35	Khandjian
F31AI147560-02	Gribble	2021-09-01	2021-07-06	Y	35	Champagne

From: Bateman, Karen (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: PO Checklist Pending
Date: Tuesday, July 13, 2021 4:20:50 PM

I am sure! NIAID deadlines supersede those in PMM. You are not the first to question this.

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, July 13, 2021 3:17 PM
To: Bateman, Karen (NIH/NIAID) [E] (b) (6)
Subject: Re: PO Checklist Pending

Thanks! Haven't been able to make the bumps talks lately either :)

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
Email: (b) (6)
Pronouns: He/Him/His

On Jul 13, 2021, at 2:24 PM, Bateman, Karen (NIH/NIAID) [E] (b) (6) wrote:

Hi Erik,

Thanks for the updates. I cringed sending this to you as I know how busy you have been.

The NIAID grants timeline is what to go by. These PMM dates never have matched. They are set in IMPAC by someone or something. Emily Linde has covered this in her Bumps talk.

Karen

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, July 13, 2021 2:08 PM
To: DMID GrantOps (b) (6)
Subject: RE: PO Checklist Pending

Thanks Karen! Please see attached for my status updates. I've been trying to keep on top of these but have been fully occupied with the prep for ASF's testimony next week. Out of curiosity, do you know why the Grants timeline due dates don't match the due dates in PMM?

Erik

From: DMID GrantOps (b) (6)
Sent: Tuesday, July 13, 2021 12:42 PM
To: Beisel, Christopher (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/NIAID) [E] (b) (6); Davis, Mindy (NIH/NIAID) [E] (b) (6); Deye, Greg (NIH/NIAID) [E] (b) (6); Gautam, Rajeev (NIH/NIAID) [E] (b) (6); Huntley, Clayton (NIH/NIAID) [E] (b) (6); Ilias, Maliha (NIH/NIAID) [E] (b) (6); Mcgugan, Glen (NIH/NIAID) [E] (b) (6); Mendez, Susana (NIH/NIAID) [E] (b) (6); Morabito, Kaitlyn (NIH/DMID) [E] (b) (6); Park, Eun-Chung (NIH/NIAID) [E] (b) (6); Perdue, Samuel (NIH/NIAID) [E] (b) (6); Ritchie, Alec (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: DMID GrantOps (b) (6)
Subject: FW: PO Checklist Pending

Dear all,

The following checklists were due on the 1st of the month, per the NIAID grants timeline. I have sorted the original list

by PO for your convenience and have indicated the IMPAC status as of this morning. We understand that many of these are "in progress". Please let us know if you will complete the checklist today or provide an update regarding its status and estimate to complete.

Thank you,
Karen
DMID GrantOps

DMID							DMID PO Notes	Appl Received	Chklst Stat (PM)
8/1/2021	5/26/2021	5P01AI098681-08	M34B	35	COEN	Beisel		2021/05/26	-
8/1/2021	6/11/2021	5R01AI106934-08	M34B	35	KNIPE	Beisel		2021/06/11	-
7/30/2021	6/8/2021	5SC1AI112785-08	M34B	35	Tang	Beisel		2021/06/08	In Progress
8/1/2021	5/18/2021	5R21AI149013-02	M51B B	35	FORST	Bozick		2021/05/18	In Progress
8/1/2021	7/9/2021	5F30AI136410-06	M55A B	35	King	Davis		2021/07/09	-
8/1/2021	7/5/2021	5U01AI129783-04	M91B	35	ALMEIDA	Deye		2021/07/05	-
8/1/2021	6/21/2021	5R44AI147744-03	M55G B	35	Herrera	Dyall		2021/06/21	-
8/1/2021	6/17/2021	5R01AI095394-07	M34A B	35	Jacobs	Gautam		2021/06/17	-
								(b) (4), (b) (6)	In Progress
8/1/2021	6/9/2021	5R01AI101175-08	M35	35	STEERE	Ilias		2021/06/09	-
8/1/2021	6/15/2021	5R01AI130105-04	M35 B	35	Telford	Ilias		2021/06/15	-
								(b) (4), (b) (6)	In Progress
								(b) (4), (b) (6)	In Progress
8/1/2021	6/2/2021	5P01AI106695-07	M32C B	35	Harris	Morabito		2021/06/02	In Progress
8/1/2021	7/2/2021	5DP1AI158186-02	M32A	35	Veesler	Park		2021/07/02	-
8/1/2021	6/16/2021	5R01AI136035-05	M46C B	35	Gaff	Perdue		2021/06/16	In Progress
8/1/2021	7/6/2021	5R21AI151929-02	M30B BR	35	White	Ritchie		2021/07/06	-
8/1/2021	5/24/2021	5P01AI060699-15	M51C B	35	Perlman	Stemmy		2021/05/24	-
								(b) (4), (b) (6)	In Progress
8/1/2021	6/15/2021	5R01AI132178-05	M51C B	35	Baric	Stemmy		2021/06/15	-
8/1/2021	6/15/2021	5R01AI135270-04	M51C B	35	Whittaker	Stemmy		2021/06/15	-
7/1/2021	6/14/2021	5R01AI158060-02	M51C B	35	BenMohamed	Stemmy		2021/06/14	-
8/1/2021	5/24/2021	5R01AI158068-02	M51C B	35	HOGAN	Stemmy		2021/05/24	-
8/1/2021	6/15/2021	5R01AI158154-02	M51C B	35	CHENG	Stemmy		2021/06/15	-
8/1/2021	6/15/2021	5R01AI158177-02	M51C B	35	MITTAL	Stemmy		2021/06/15	-
8/1/2021	7/7/2021	5R01AI158214-02	M51C B	35	Powell	Stemmy		2021/07/07	-
8/1/2021	6/11/2021	5R01AI158463-02	M51C B	35	Kirchdoerfer	Stemmy		2021/06/11	-
8/1/2021	6/15/2021	5R01AI158552-02	M51C B	35	Ware	Stemmy		2021/06/15	In Progress

From: Khurana, Dhana (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, July 13, 2021 10:33 AM
To: Bateman, Karen (NIH/NIAID) [E] (b) (6)
Cc: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: PO Checklist Pending

Hi Karen,

Below is the list of PO checklist pending.

Thank you for the follow up.

Regards,
Dhana

DMID						
8/1/21	6/18/21	5	R44AI141264-04	M30B	35	Pogorzelski	Ritchie

8/1/21	7/6/21	5	R21AI151929-02	M30B BR	35	White	Ritchie

8/1/21	7/2/21	5	DP1AI158186-02	M32A	35	Veesler	Park
8/1/21	6/2/21	5	P01AI106695-07	M32C B	35	Harris	Morabito
							(b) (4), (b) (6)
8/1/21	6/17/21	5	R01AI095394-07	M34A B	35	Jacobs	Gautam
8/1/21	5/26/21	5	P01AI098681-08	M34B	35	COEN	Beisel
8/1/21	6/8/21	5	SC1AI112785-08	M34B	35	Tang	Beisel
8/1/21	6/11/21	5	R01AI106934-08	M34B	35	KNIPE	Beisel
8/1/21	6/9/21	5	R01AI101175-08	M35	35	STEERE	Ilias
8/1/21	6/15/21	5	R01AI130105-04	M35 B	35	Telford	Ilias
8/1/21	6/14/21	5	DP1AI152073-03	M36	35	Herman	Ernst
							(b) (4), (b) (6)
							(b) (4), (b) (6)
8/1/21	6/18/21	5	R01AI129529-04	M40 B	35	Boothroyd	McGugan
8/1/21	6/16/21	5	R01AI136035-05	M46C B	35	Gaff	Perdue
7/1/21	5/18/21	5	R21AI149013-02	M51B B	35	FORST	Bozick
							(b) (4), (b) (6)
8/1/21	5/24/21	5	P01AI060699-15	M51C B	35	Perlman	Stemmy
8/1/21	6/15/21	5	R01AI132178-05	M51C B	35	Baric	Stemmy
8/1/21	6/15/21	5	R01AI135270-04	M51C B	35	Whittaker	Stemmy
8/1/21	6/14/21	5	R01AI158060-02	M51C B	35	BenMohamed	Stemmy
8/1/21	5/24/21	5	R01AI158068-02	M51C B	35	HOGAN	Stemmy

8/1/21	6/15/21	5	R01AI158154-02	M51C B	35	CHENG	Stemmy
8/1/21	6/15/21	5	R01AI158177-02	M51C B	35	MITTAL	Stemmy
8/1/21	7/7/21	5	R01AI158214-02	M51C B	35	Powell	Stemmy
8/1/21	6/11/21	5	R01AI158463-02	M51C B	35	Kirchdoerfer	Stemmy
8/1/21	6/15/21	5	R01AI158552-02	M51C B	35	Ware	Stemmy
8/1/21	6/11/21	5	R01AI134818-05	M53B	35	Guo	Koshy
7/30/21	7/9/21	5	F30AI136410-06	M55A B	35	King	Davis
8/1/21	6/21/21	5	R44AI147744-03	M55G B	35	Herrera	Dyall
8/1/21	4/5/21	5	T32AI141346-03	M66A	35	Lodoen	Coomes
8/1/21	7/5/21	5	U01AI129783-04	M91B	35	ALMEIDA	Deye

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, July 12, 2021 6:01:47 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
						(b) (4), (b) (6)
R01AI158214-02	Powell	2021-08-01	2021-07-07	Y	35	Ranellone
P01AI060699-15	Perlman	2021-08-01	2021-05-24	Y	35	Hodor
R01AI158552-02	Ware	2021-08-01	2021-06-15	Y	35	Pazmany
R01AI158068-02	HOGAN	2021-08-01	2021-05-24	Y	35	Allen
						(b) (4), (b) (6)
R01AI135270-04	Whittaker	2021-08-01	2021-06-15	Y	35	Ranellone
R01AI132178-05	Baric	2021-08-01	2021-06-15	Y	35	Gormley
R01AI158177-02	MITTAL	2021-08-01	2021-06-15	Y	35	Saeed
R01AI158463-02	Kirchdoerfer	2021-08-01	2021-06-11	Y	35	Guidetti
R01AI158060-02	BenMohamed	2021-08-01	2021-06-14	Y	35	Pazmany
R01AI157827-02	Haselton	2021-09-01	Not Recvd	N	35	Ceron
F31AI147560-02	Gribble	2021-09-01	2021-07-06	Y	35	Champagne
R01AI157155-02	Diamond	2021-09-01	Not Recvd	N	35	Steele
R01AI157253-02	Heise	2021-09-01	Not Recvd	N	35	Chacon
R01AI110700-07	Baric	2021-09-01	Not Recvd	N	35	Khandjian

From: Selgrade, Sara (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]
Cc: Auchincloss, Hugh (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Haskins, Melinda (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]
Subject: URGENT for ASF by NOON today: Revised Burr letter
Date: Sunday, July 11, 2021 11:38:13 AM
Attachments: Burr Marshall Paul 5.25.pdf
110964 Daszak GoF Determination Letter 7-7-2016.pdf
110964 P3CO Determination Letter 7-5-2018.pdf
Burr Marshall Paul_NIAID Draft_revised_071121_AM.docx

Hello all,

After discussing with ASF last evening, we have made some changes to the letter. We would appreciate your review of the edits (marked in tracked changes). Please note these include minor edits to the final section that you reviewed last evening and edits to the section discussing the grant on pages 4-5.

Please let me know if you have any must-change edits by **noon today**, as we will discuss with ASF after your review.

Thanks again to all for your continued assistance on short notice.

Thank you,
Sara

From: Selgrade, Sara (NIH/NIAID) [E]
Sent: Saturday, July 10, 2021 6:26 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6)
Cc: Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Folkers, Greg (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); Haskins, Melinda (NIH/NIAID) [E] (b) (6); Hauguel, Teresa (NIH/NIAID) [E] (b) (6)
Subject: For ASF - please review by 7:30PM: Revised Burr letter
Importance: High

Hello all,

Attached please find the incoming and revised Burr response letter for your review. The highlighted section at the end of the letter has changes requested by Dr. Collins (marked in tracked changes). The remainder of the letter has already been approved by Drs. Collins and Fauci and does not require review.

Please send any necessary changes ASAP (no later than 7:30pm) as we will then send to ASF for review this evening.

I am also attaching both relevant GoF determination letters for your reference.

We greatly appreciate your help on short notice. Please let me know if you have any questions.

Thanks,
Sara

From: Haskins, Melinda (NIH/NIAID) [E] (b) (6)
Sent: Saturday, July 10, 2021 4:15 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6)
Cc: Selgrade, Sara (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6)
Subject: Update

Colleagues –

I have spoken to Adrienne Hallett (b) (5) ASF knows that Sara and I will make the requested edits to the draft, clear the edits with you, and run the draft past him.

Please expect the updated draft Burr response later this afternoon/early evening for review.

I appreciate your ongoing help.

Melinda

United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510-6300

May 25, 2021

Delivered via E-Mail

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane, MSC 9806
Bethesda, MD 20892-9806

Dear Dr. Fauci:

Thank you for your testimony last Tuesday, May 11, regarding the status of the federal government's efforts to combat the COVID-19 pandemic. During the hearing, you offered to provide this Committee with "any information [it] would like" regarding the National Institute of Allergy and Infectious Diseases (NIAID) and gain-of-function (GOF) research of concern.

We write to follow-up on your commitment with the following questions to help us better understand NIAID policies and past actions regarding GOF research of concern and related research that could result in unintended GOF, including associated information related to NIAID awards and grant applications. Accordingly, please respond to the following questions by May 28, 2021:

1. Dr. Peter Daszak, President of EcoHealth Alliance, reported in a December 2019 podcast for *Today in Virology*[1] that the Alliance and Dr. Shi Zhengli of the Wuhan Institute of Virology (WIV) investigated and cataloged bat coronaviruses across China as part of an NIH grant.

   Dr. Daszak stated that his team discovered over 100 SARS-related coronaviruses. Some of these viruses could infect human cells and caused SARS-like disease in

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humanized mouse models. Their research also discovered serologic evidence of human exposures in communities with exposure to certain bat populations. During the interview, Dr. Daszak described these SARS-related coronaviruses a "clear and present danger."

Dr. Daszak previously stated in a presentation that research with novel viruses in humanized mice and other animal models has the highest risk of spillover compared to other types of research on novel viruses.[2] Even though Dr. Daszak's work at the WIV was not determined to fall within the scope of the Department of Health and Human Services' (HHS) *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (P3CO),[3] we are raising questions to more fully understand the nature of this research and why this federally funded work was being conducted in laboratories outside the United States.

a. Previous research has demonstrated using synthetic biology techniques the potential for SARS-CoV to naturally re-emerge from coronaviruses currently circulating in animals.[4] A group of 18 experts in virology and immunology also recently published an article in *Science* stating that SARS-CoV-2 might have first spilled over into humans in a laboratory accident and that this possibility has not been sufficiently investigated.[5] Do you agree? If you agree, do you believe that it is likely that the wild-type SARS-CoV-2, which was first detected in Wuhan, had been previously collected from an animal, or is it possible that the virus evolved while in the laboratory environment before emerging in humans?
b. If it is possible that the virus evolved in a laboratory environment, would it be possible for scientists to determine whether the virus evolved naturally or was manipulated? If yes, what kind of evidence would be needed to make that determination?
c. Although EcoHealth Alliance's work in the above-mentioned grant program was not subject to the P3CO policy, do you believe this type of work is high risk?

---

[2] From slide 10 of a presentation entitled "Assessing Coronavirus Threats," which is available through the website of the *National Academies of Sciences, Engineering, and Medicine*.. Dr. Daszak listed the WIV as a collaborator at the end of the presentation. https://www.taiwannews.com.tw/en/news/4104828

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[5] https://science.sciencemag.org/content/372/6543/694.1

2. Please provide the entire file for the EcoHealth Alliance grant, "Understanding the Risk of Bat Coronavirus Emergence." (Project Nos. 1R01AI110964-01, 5R01AI110964-02, 5R01AI110964-03, 5R01AI110964-04, 5R01AI110964-05, and 2R01AI110964-06.)

3. Please describe and provide copies of the processes and protocols that NIAID follows to ensure compliance with the P3CO policy, including protocols that NIAID staff follow to identify proposed research that would fall within the scope of the P3CO policy and refer such research to HHS for consideration by the P3CO review group.

4. What criteria does NIAID use to determine if proposed GOF research would fall within the scope of the P3CO framework? Are there specific virus families that NIAID considers to fall within the scope of a potentially pandemic pathogen?

5. How many projects have NIAID reviewers identified and referred to HHS for review under the P3CO Framework since the policy was enacted in 2017, and which pathogens were involved in the proposed research?

6. In addition to adhering to biosafety best practices, such as those described in the *Biosafety in Microbiological and Biomedical Laboratories* guidance, what steps does NIAID take to ensure NIAID-funded researchers conducting GOF research of concern are taking appropriate steps to manage biosafety and biosecurity risks associated with their research? What types of additional measures has the P3CO review group previously recommended for NIAID-funded projects?
7. Did NIAID perform a risk-benefit analysis with quantifiable metrics before funding the above-mentioned EcoHealth Alliance project, which then sub-granted NIH dollars to the WIV? If yes, please provide your risk-benefit report to the Committee.

8. The publicly available summary of EcoHealth Alliance's NIAID-funded research includes a description of inserting "sequence receptor binding domains (spike proteins)"[6] into the backbone of other viruses. Did NIAID officials and other individuals involved in reviewing the EcoHealth Alliance project (to include reviews of annual progress reports) consider whether the specific projects

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summarized in this description could result in GOF? If so, would this have constituted GOF research of concern?

9. Did NIAID officials and other officials reviewing the EcoHealth Alliance project consider its research high risk prior to making the award or while the project was ongoing?

10. We do not know how COVID-19 started and how SARS-CoV-2 emerged. We may never know with certainty. The two hypotheses are (1) natural emergence, and (2) laboratory accidental release. Regardless of the origins of SARS-CoV-2, is it *possible* that research within laboratories that do not have the same regulatory standards as U.S. laboratory facilities with the capabilities to modify could result in a community outbreak if an enhanced or naturally occurring virus escaped from a laboratory like the WIV due to a biological safety breach?

We look forward to working with you on these issues, which are critical to the long-term health of our nation. Thank you in advance for your time and attention to this matter.

Sincerely,

Richard Burr
Ranking Member

Rand Paul, M.D.

Roger Marshall, M.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 7, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is not subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 05, 2018

Mr. Aleksei Chmura
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-05

Dear Mr. Chmura:

On December 19, 2017, the U.S. Department of Health and Human Services (DHHS) issued the *Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) (https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf). The HHS P3CO Framework is responsive to and in accordance with the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (Recommended Policy Guidance) (https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf) issued by the White House Office of Science and Technology Policy on January 9, 2017. Additionally, and as noted in the Recommended Policy Guidance, adoption of the HHS P3CO Framework satisfies the requirement for lifting the Research Funding Pause on certain gain-of-function (GoF) research.

The HHS P3CO Framework guides DHHS funding decisions on research that is reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (PPPs). A PPP is a pathogen that satisfies both of the following:

- It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and
- It is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

In accordance with the HHS P3CO Framework, research involving an enhanced PPP is subject to additional HHS department-level review. NIAID re-reviewed the grant application and other information provided by you, and made the following assessment:

> The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO Framework. The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and

Grants Management Specialist immediately and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

Please remember that the institution must comply in full with all terms and conditions placed on this grant.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Adam Graham
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Emily Linde
Dr. Emily Erbelding
Dr. Irene Glowinski
Dr. Andrew Ford

From: Selgrade, Sara (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]
Cc: Auchincloss, Hugh (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Haskins, Melinda (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]
Subject: For ASF - please review by 7:30PM: Revised Burr letter
Date: Saturday, July 10, 2021 6:25:34 PM
Attachments: Burr Marshall Paul 5.25.pdf
Burr Marshall Paul_NIAID Draft_OD comments_NIAID final_edits for review.docx
110964 Daszak GoF Determination Letter 7-7-2016.pdf
110964 P3CO Determination Letter 7-5-2018.pdf

Hello all,

Attached please find the incoming and revised Burr response letter for your review. The highlighted section at the end of the letter has changes requested by Dr. Collins (marked in tracked changes). The remainder of the letter has already been approved by Drs. Collins and Fauci and does not require review.

Please send any necessary changes ASAP (no later than 7:30pm) as we will then send to ASF for review this evening.

I am also attaching both relevant GoF determination letters for your reference.

We greatly appreciate your help on short notice. Please let me know if you have any questions.

Thanks,
Sara

From: Haskins, Melinda (NIH/NIAID) [E] (b) (6)
Sent: Saturday, July 10, 2021 4:15 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6)
Cc: Selgrade, Sara (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6)
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United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510-6300

May 25, 2021

Delivered via E-Mail

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane, MSC 9806
Bethesda, MD 20892-9806

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We look forward to working with you on these issues, which are critical to the long-term health of our nation. Thank you in advance for your time and attention to this matter.

Sincerely,

Richard Burr
Ranking Member

Rand Paul, M.D.

Roger Marshall, M.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 7, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

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Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 05, 2018

Mr. Aleksei Chmura
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-05

Dear Mr. Chmura:

On December 19, 2017, the U.S. Department of Health and Human Services (DHHS) issued the *Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) (https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf). The HHS P3CO Framework is responsive to and in accordance with the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (Recommended Policy Guidance) (https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf) issued by the White House Office of Science and Technology Policy on January 9, 2017. Additionally, and as noted in the Recommended Policy Guidance, adoption of the HHS P3CO Framework satisfies the requirement for lifting the Research Funding Pause on certain gain-of-function (GoF) research.

The HHS P3CO Framework guides DHHS funding decisions on research that is reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (PPPs). A PPP is a pathogen that satisfies both of the following:

- It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and
- It is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

In accordance with the HHS P3CO Framework, research involving an enhanced PPP is subject to additional HHS department-level review. NIAID re-reviewed the grant application and other information provided by you, and made the following assessment:

> The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO Framework. The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and

Grants Management Specialist immediately and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

Please remember that the institution must comply in full with all terms and conditions placed on this grant.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Adam Graham
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
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From:	Haskins, Melinda (NIH/NIAID) [E]
To:	Stemmy, Erik (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]
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Subject:	Update
Date:	Saturday, July 10, 2021 4:14:59 PM
Attachments:	110964 Daszak GoF Determination Letter 7-7-2016.pdf

Colleagues –

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I appreciate your ongoing help.

Melinda

DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 7, 2016

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Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is not subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

From: Haskins, Melinda (NIH/NIAID) [E]
To: Fauci, Anthony (NIH/NIAID) [E]
Cc: Erbelding, Emily (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Selgrade, Sara (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: Information
Date: Saturday, July 10, 2021 3:40:08 PM
Attachments: 110964 Daszak GoF Letter 5-28-2016-signed.pdf
Response to GoF letter, 5R01AI110964 - 03 DASZAK, PETER.pdf
110964 Daszak GoF Determination Letter 7-7-2016.pdf
110964 P3CO Determination Letter 7-5-2018.pdf

Dr. Fauci –

The attached letters were included in the grant file for EH. The attachment with the date 7-7-2016 addresses the GoF determination.

I will follow up with Adrienne.

Melinda

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Saturday, July 10, 2021 3:32 PM
To: Haskins, Melinda (NIH/NIAID) [E] (b) (6)
Cc: Embry, Alan (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Subject: Correspondence

Hi Melinda,
Attached are the letters we discussed for the EH review. Let me know if you need anything else.

Erik

Erik J. Stemmy, Ph.D.
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
Phone: (b) (6)
Pronouns: He/Him/His

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

May 28, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 West 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-03

Dear Mr. Chmura:

Based upon information in the most recent progress report, NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the U.S. Government funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The following specific aims appear to involve research covered under the pause:

Aim 3: Testing predictions of CoV inter-species transmission

As per the funding pause announcement, new USG funding will not be released for GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. Therefore, the next non-competing segment of the award that starts June 1, 2016 cannot be released until a determination is reached based on the receipt and review of the information requested below. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, or SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.

NIAID requests that you provide the following information within 15 days of the date of this letter:

- **Determination as to whether the above research does or does not include GoF work subject to the funding pause**. Please provide a detailed explanation for this determination, including, but not limited to, descriptions of the MERS and MERS-like chimeric CoVs that you propose to create, and detailed descriptions of the experiments you plan to conduct. Your determination should also include whether each chimeric virus is reasonably anticipated to exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type MERS-CoV.

- **In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.** NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.
- **If it is determined that the above research <u>DOES</u> include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:**
    - For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or
    - Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If you have any questions about this matter please do not hesitate to contact the NIAID Program Officer.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

EcoHealth Alliance

Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01AI110964-03). We have provided the details you requested, below, including alternative strategies if we remove work that could be deemed gain of function. We look forward to your response and will modify our workplan accordingly. In the meantime, please rest assured that none of the proposed work for Specific Aim #3 that you have requested information about will begin.

Determination as to whether the above research does or does not include GoF work subject to the funding pause. Please provide a detailed explanation for this determination, including, but not limited to, descriptions of the MERS and MERS-like chimeric CoVs that you propose to create, and detailed descriptions of the experiments you plan to conduct. Your determination should also include whether each chimeric virus is reasonably anticipated to exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type MERS-CoV.

Firstly, we would like to reiterate that this work is *proposed* for year 3, and none has been conducted to date. Furthermore, we will not proceed with any of this unless we are given the go-ahead by NIAID. The goal of our proposed work to construct MERS and MERS-like chimeric CoVs is to understand the potential origins of MERS-CoV in bats by studying bat MERS-like CoVs in detail. The chimeric viruses will be used to ascertain receptor usage and infectivity of bat MERS-related CoVs *in vitro* and in a mouse model. To achieve this purpose, our aim is to firstly construct a MERS-CoV infectious clone based on the genomic sequence of EMC2012 (GenBank no. NC_019843) and then chimeric CoVs with the replacement of the spike envelope genes from bat derived MERS-like CoVs. We have very recently discovered a small number (9 different strains) of bat MERS-like CoVs in 99 samples from bats in Guangxi, Guangdong, and Szechuan provinces. Phylogenetically, these bat viruses are not very close to MERS-CoV (only 63-66% homology to the S-protein of MERS-CoV).

We aim to test the chimeric viruses for receptor usage of DPP4 (the MERS-CoV receptor) in cells and then in DPP4 transgenic mice, to see if these bat viruses have any capacity to use the same receptor. That said, given the phylogenetic distance from MERS-CoV, we believe it is *highly unlikely* that these bat spike proteins attach to DPP4, and if so, that they would have any pathogenic potential. Finally, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or other DPP4 receptor over wildtype parental backbone MERS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.
NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in

EcoHealth Alliance
460 West 34th Street, 17th Floor
New York, NY 10001-2320
(b) (6)
EcoHealthAlliance.org

mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.

These two chimeric bat-like CoVs were constructed on September 24, 2015. They use the backbone of a group 2b SARS-like bat CoV WIV1 and the spike proteins of two newly discovered bat SL-CoVs (Rs7327 and RsSHC014). The construction of these chimeric viruses aims to understand the receptor usage and infectivity of bat SL-CoVs that may be progenitors of SARS-CoV. We have not yet tested the pathogenicity of these viruses in animals.

We believe that this work would not be considered GoF because the pause specifically targeted experiments that altered the pathogenicity or transmissibility of SARS-CoV, MERS-CoV and any influenza virus. Our molecular clone is WIV1, which is a group 2b SARS-like bat coronavirus that has never been demonstrated to infect humans or cause human disease. It is about 10% different from SARS-CoV. Thus, we feel that introducing other group 2b SARS-like bat coronavirus spike glycoproteins into WIV1 is not subject to the pause. Moreover, we are introducing progressively more distant S glycoproteins into WIV1 (The RBD of Rs7327 differs from WIV1 in several amino acid residues while RsSHC014 is even more distantly related phylogenetically), so it seems progressively less likely that any of these viruses would be more pathogenic or transmissible than the SARS-CoV. This is further supported by the fact that Prof. Ralph Baric's group (Menacherya *et al*., 2015, Nature Medicine, 21 (12):1508-1512; Menacherya *et al*., 2016, PNAS, 113 (11): 3048-3053) took WIV1 spike and inserted it onto a SARS-CoV backbone and showed reduced pathogenicity in mice with human ACE-2 relative to SARS-CoV (mortality rates were much lower, therefore this is *loss-of-function*). This strongly suggests that the chimeric bat spike/bat backbone viruses should not have enhanced pathogenicity in animals.

Finally, as proposed above for the MERS-like viruses, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or civet receptor over wildtype parental backbone SARS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

If it is determined that the above research DOES include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:

- For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or
- Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If these proposed activities within Specific Aim #3 are considered gain of function, we would propose changing them as follows:

1) Instead of the proposed work on MERS-like chimeric CoVs, we would
    a. model the 3-D structure of bat MERS-like CoV spike to assess its potential to bond to DPP4; and
    b. build pseudoviruses with MERS-like CoV spike to conduct experiments for DPP4 binding.

2) Instead of the proposed work on SARS-like chimeric bat CoVs, we would build pseudoviruses with the spike proteins from these viruses and assess receptor binding *in vitro*.

We look forward to your response to our letter and will not conduct any of this proposed work until we hear back from you.

Yours sincerely,

Dr. Peter Daszak

PI
President and Chief Scientist
EcoHealth Alliance

Tel: (b) (6)
e-mail: (b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 7, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is not subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 05, 2018

Mr. Aleksei Chmura
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-05

Dear Mr. Chmura:

On December 19, 2017, the U.S. Department of Health and Human Services (DHHS) issued the *Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) (https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf). The HHS P3CO Framework is responsive to and in accordance with the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (Recommended Policy Guidance) (https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf) issued by the White House Office of Science and Technology Policy on January 9, 2017. Additionally, and as noted in the Recommended Policy Guidance, adoption of the HHS P3CO Framework satisfies the requirement for lifting the Research Funding Pause on certain gain-of-function (GoF) research.

The HHS P3CO Framework guides DHHS funding decisions on research that is reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (PPPs). A PPP is a pathogen that satisfies both of the following:

- It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and
- It is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

In accordance with the HHS P3CO Framework, research involving an enhanced PPP is subject to additional HHS department-level review. NIAID re-reviewed the grant application and other information provided by you, and made the following assessment:

> The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO Framework. The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and

Grants Management Specialist immediately and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

Please remember that the institution must comply in full with all terms and conditions placed on this grant.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Adam Graham
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Emily Linde
Dr. Emily Erbelding
Dr. Irene Glowinski
Dr. Andrew Ford

From:	Haskins, Melinda (NIH/NIAID) [E]
To:	Stemmy, Erik (NIH/NIAID) [E]
Cc:	Embry, Alan (NIH/NIAID) [E]
Subject:	Fwd: Letters
Date:	Saturday, July 10, 2021 3:18:55 PM
Attachments:	GoF.pdf P3CO.pdf

Sent from my iPhone

Begin forwarded message:

From: "Embry, Alan (NIH/NIAID) [E]" (b) (6)
Date: July 10, 2021 at 3:14:50 PM EDT
To: "Haskins, Melinda (NIH/NIAID) [E]" (b) (6)
Subject: Letters

I think referencing the 1st attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 7, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

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Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 05, 2018

Mr. Aleksei Chmura
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-05

Dear Mr. Chmura:

On December 19, 2017, the U.S. Department of Health and Human Services (DHHS) issued the *Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) (https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf). The HHS P3CO Framework is responsive to and in accordance with the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (Recommended Policy Guidance) (https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf) issued by the White House Office of Science and Technology Policy on January 9, 2017. Additionally, and as noted in the Recommended Policy Guidance, adoption of the HHS P3CO Framework satisfies the requirement for lifting the Research Funding Pause on certain gain-of-function (GoF) research.

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Grants Management Specialist immediately and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

Please remember that the institution must comply in full with all terms and conditions placed on this grant.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Adam Graham
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Emily Linde
Dr. Emily Erbelding
Dr. Irene Glowinski
Dr. Andrew Ford

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, July 5, 2021 6:01:06 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
(b) (4), (b) (6)						
R01AI158177-02	MITTAL	2021-08-01	2021-06-15	Y	35	Saeed
R01AI158214-02	Powell	2021-08-01	Not Recvd	N	35	Ranellone
R01AI158552-02	Ware	2021-08-01	2021-06-15	Y	35	Pazmany
R01AI158068-02	HOGAN	2021-08-01	2021-05-24	Y	35	Allen
(b) (4), (b) (6)						
R01AI135270-04	Whittaker	2021-08-01	2021-06-15	Y	35	Ranellone
R01AI132178-05	Baric	2021-08-01	2021-06-15	Y	35	Gormley
P01AI060699-15	Perlman	2021-08-01	2021-05-24	Y	35	Hodor
R01AI158463-02	Kirchdoerfer	2021-08-01	2021-06-11	Y	35	Guidetti
R01AI158060-02	BenMohamed	2021-08-01	2021-06-14	Y	35	Pazmany
F31AI147560-02	Gribble	2021-09-01	Not Recvd	N	35	Champagne
R01AI157155-02	Diamond	2021-09-01	Not Recvd	N	35	Steele
R01AI157253-02	Heise	2021-09-01	Not Recvd	N	35	Chacon
R01AI110700-07	Baric	2021-09-01	Not Recvd	N	35	Khandjian
R01AI157827-02	Haselton	2021-09-01	Not Recvd	N	35	Ceron

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, June 28, 2021 6:00:47 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
(b) (4), (b) (6)						
R01AI158463-02	Kirchdoerfer	2021-08-01	2021-06-11	Y	35	Guidetti
R01AI158060-02	BenMohamed	2021-08-01	2021-06-14	Y	35	Pazmany
P01AI060699-15	Perlman	2021-08-01	2021-05-24	Y	35	Hodor
R01AI132178-05	Baric	2021-08-01	2021-06-15	Y	35	Gormley
R01AI135270-04	Whittaker	2021-08-01	2021-06-15	Y	35	Ranellone
R01AI158214-02	Powell	2021-08-01	Not Recvd	N	35	Ranellone
R01AI158552-02	Ware	2021-08-01	2021-06-15	Y	35	Pazmany
(b) (4), (b) (6)						
R01AI158177-02	MITTAL	2021-08-01	2021-06-15	Y	35	Saeed
R01AI158068-02	HOGAN	2021-08-01	2021-05-24	Y	35	Allen

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, June 21, 2021 6:00:47 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
						(b) (4), (b) (6)
R21AI145400-02	MENACHERY	2021-07-01	2021-05-13	Y	35	Gerhart
						(b) (4), (b) (6)
R01AI135270-04	Whittaker	2021-08-01	2021-06-15	Y	35	Ranellone
R01AI158060-02	BenMohamed	2021-08-01	2021-06-14	Y	35	Pazmany
R01AI158463-02	Kirchdoerfer	2021-08-01	2021-06-11	Y	35	Guidetti
R01AI132178-05	Baric	2021-08-01	2021-06-15	Y	35	Gormley
R01AI158552-02	Ware	2021-08-01	2021-06-15	Y	35	Pazmany
R01AI158177-02	MITTAL	2021-08-01	2021-06-15	Y	35	Saeed
P01AI060699-15	Perlman	2021-08-01	2021-05-24	Y	35	Hodor
R01AI158214-02	Powell	2021-08-01	Not Recvd	N	35	Ranellone
R01AI158068-02	HOGAN	2021-08-01	2021-05-24	Y	35	Allen

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, June 14, 2021 6:00:58 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R21AI145400-02	MENACHERY	2021-07-01	2021-05-13	Y	35	Gerhart
(b) (4), (b) (6)						
P01AI060699-15	Perlman	2021-08-01	2021-05-24	Y	35	Hodor
R01AI158177-02	MITTAL	2021-08-01	Not Recvd	N	35	Saeed
R01AI158060-02	BenMohamed	2021-08-01	Not Recvd	N	35	Pazmany
R01AI135270-04	Whittaker	2021-08-01	Not Recvd	N	35	Ranellone
(b) (4), (b) (6)						
R01AI158068-02	HOGAN	2021-08-01	2021-05-24	Y	35	Allen
R01AI158552-02	Ware	2021-08-01	Not Recvd	N	35	Pazmany
R01AI132178-05	Baric	2021-08-01	Not Recvd	N	35	Gormley
R01AI158214-02	Powell	2021-08-01	Not Recvd	N	35	Ranellone
R01AI158463-02	Kirchdoerfer	2021-08-01	2021-06-11	Y	35	Guidetti

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]; Gratton, Shaun (NIH/NIAID) [E]; NIAID GM I2 Notifications
Subject: eRA Commons: RPPR for Grant (b) (4), (b) (6) Received by Agency
Date: Wednesday, June 9, 2021 6:11:55 PM

RPPR for grant (b) (4), (b) (6) associated with Program Director/Principal Investigator (b) (4), (b) (6) has been received electronically through the eRA Commons. You may view the progress report through one of the IMPAC II modules by going to the Grant Folder and selecting the e-Application.

Program Class Code:	M51C B
Program Officer:	Stemmy, Erik J.
Grants Management Specialist:	Gratton, Shaun W

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact. Please access Commons at http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, June 7, 2021 6:01:22 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R21AI145400-02	MENACHERY	2021-07-01	2021-05-13	Y	35	Gerhart
[redacted]						(b) (4), (b) (6)
R01AI132178-05	Baric	2021-08-01	Not Recvd	N	35	Gormley
P01AI060699-15	Perlman	2021-08-01	2021-05-24	Y	35	Hodor
R01AI158068-02	HOGAN	2021-08-01	2021-05-24	Y	35	Allen
R01AI158552-02	Ware	2021-08-01	Not Recvd	N	35	Pazmany
R01AI158177-02	MITTAL	2021-08-01	Not Recvd	N	35	Saeed
R01AI158060-02	BenMohamed	2021-08-01	Not Recvd	N	35	Pazmany
R01AI135270-04	Whittaker	2021-08-01	Not Recvd	N	35	Ranellone
[redacted]						(b) (4), (b) (6)
R01AI158214-02	Powell	2021-08-01	Not Recvd	N	35	Ranellone
R01AI158463-02	Kirchdoerfer	2021-08-01	Not Recvd	N	35	Guidetti

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 31, 2021 6:00:48 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R21AI145400-02	MENACHERY	2021-07-01	2021-05-13	Y	35	Gerhart
[redacted]						(b) (4), (b) (6)

From: Miers, Sarah (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Cc: NIAID DMID Policy; DMID FOIA Group
Subject: FW: 399943 Comer (origins of SARS-CoV-2)
Date: Friday, May 28, 2021 2:02:47 PM
Attachments: 399943 Comer #2 corr.pdf

Hi Erik and Andrew, no action at this time but wanted to bring this to your attention. (b) (5)

Sarah

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Friday, May 28, 2021 at 1:50 PM
To: NIAID DEA DART (b) (6), NIAID BUGS (b) (6)
Cc: NIAID OCGR Leg (b) (6), NIAID OCGR Correspondence (b) (6), "Handley, Gray (NIH/NIAID) [E]" (b) (6), "Billet, Courtney (NIH/NIAID) [E]" (b) (6), "Harper, Jill (NIH/NIAID) [E]" (b) (6), "Auchincloss, Hugh (NIH/NIAID) [E]" (b) (6), "Embry, Alan (NIH/NIAID) [E]" (b) (6), "Eisinger, Robert (NIH/NIAID) [E]" (b) (6), "Lerner, Andrea (NIH/NIAID) [E]" (b) (6)>, "Conrad, Patricia (NIH/NIAID) [E]" (b) (6)
Subject: FYI: 399943 Comer (origins of SARS-CoV-2)

FYI ONLY

An action assignment may be forthcoming once further guidance is received.

Building 1 has sent us the attached letter from Rep. James Comer and Rep. Jim Jordon to Dr. Collins and Dr. Fauci regarding the origins of SARS-CoV-2.

Congress of the United States

Washington, DC 20515

May 28, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Rockville, M.D. 20892

Dr. Anthony Fauci
Director
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane, MSC 9806
Bethesda, M.D. 20892

Dear Directors Collins and Fauci:

House Republicans are investigating the origins of COVID-19. We are particularly interested in a National Institutes of Health (NIH) grant awarded to EcoHealth Alliance (EcoHealth), which subsequently awarded funds to the Wuhan Institute of Virology (WIV).[1] Under this grant, EcoHealth and the WIV conducted studies on emerging coronaviruses—like COVID-19, their potential for human-to-human transmission, and the risk of a new pandemic.[2] There is mounting evidence the COVID-19 pandemic started in the WIV, and the Chinese Communist Party (CCP) covered it up.[3] If U.S. taxpayer money was used to develop COVID-19, conduct gain of function research, or assist in any sort of cover-up, EcoHealth must be held accountable.

EcoHealth has awarded almost $600,000 dollars to the WIV and another $200,000 to the Wuhan University School of Public Health. On July 8, 2020, NIH Deputy Director for Extramural Research Dr. Michael Lauer sent a letter to EcoHealth expressing concern over its relationship with the WIV and suspended EcoHealth's grant pending answers to several routine

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[1] Grant from U.S. Dep't of Health & Human Servs., Nat'l Inst. Of Allergy and Infectious Diseases, to EcoHealth Alliance Inc., R01AI110964 (June 1, 2014), https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529.

[2] Josh Rogin, *State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses,* THE WASH. POST (Apr. 14, 2020), https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

[3] Michael R. Gordon, Warren P. Strobel, and Drew Hinshaw, *Intelligence on Sick Staff at Wuhan Lab Fuels Debate on Covid-19 Origin,* WALL ST. J. (May 23, 2021), https://www.wsj.com/articles/intelligence-on-sick-staff-at-wuhan-lab-fuels-debate-on-covid-19-origin-11621796228.

questions.[4] The questions posed by Dr. Lauer raise serious concerns and suggest COVID-19 was spreading worldwide by October 2019. Specifically, Dr. Lauer asked EcoHealth to:

1. Explain the disappearance of Huang Yanling, a scientist who worked in the WIV but whose online presence has since been deleted;

2. Disclose and explain out-of-ordinary restrictions on laboratory facilities, such as diminished cell-phone traffic in October 2019 and roadblocks surrounding the WIV from October 14-19, 2019;

3. Explain the 2012 deaths of three Chinese mine workers from a viral illness, in the WIV collection, with symptoms remarkably similar to COVID-19; and

4. Allow a U.S. government-led inspection of lab facilities and lab records at the WIV regarding COVID-19, including collection of animals.[5]

These questions suggest that EcoHealth knew of the CCP's attempts to cover-up the origins of the COVID-19 pandemic and failed to act or inform the U.S. government. When asked if EcoHealth and WIV could have lied to the government, Dr. Fauci, you said, "I cannot guarantee that . . . because you never know."[6] The actions of both EcoHealth and the CCP must be thoroughly investigated.

This investigation is more urgent now considering the recent report that, according to U.S. intelligence sources, three researchers from the WIV became ill and sought hospital care in November 2019.[7] Dr. Lauer's letter suggests that the first cases of COVID-19 occurred even earlier—in October 2019. However, the CCP did not report any COVID-19 cases until December 2019. Based on this new timeline, it is likely COVID-19 was circulating worldwide three months before anyone outside of China was informed of its existence.

Despite U.S. intelligence concerns about the ability of the WIV to properly contain the deadly diseases—including the virus that causes COVID-19—they study, EcoHealth still awarded U.S. taxpayer grant funds to the WIV.[8] Intelligence reports stated, "during interactions with scientists at the WIV laboratory, [U.S. officials] noted the new lab has a serious shortage of

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[4] Letter from Dr. Michael Lauer, Deputy Director for Extramural Research, U.S. Nat'l Inst of Health, to Drs. Aleksei Chmura & Peter Daszak, EcoHealth Alliance Inc. (July 8, 2020).
[5] *Id.*
[6] *National Institutes of Health's FY22 budget and the State of Medical Research: Hearing Before Subcomm. On Labor, Health and Human Services, Education and Related agencies, S. comm. On Appropriations,* 117th Cong. (May 26, 2021)(statement by Dr. Anthony Fauci).
[7] Gordon, *supra* note 3.
[8] Grace Panetta, *US officials were reportedly concerned that safety breaches at a Wuhan lab studying coronaviruses in bats could cause a pandemic*, BUSINESS INSIDER (Apr. 14, 2020), https://www.businessinsider.com/us-officials-raised-alarms-about-safety-issues-in-wuhan-lab-report-2020-4; Sarah Owermohle, *Trump cuts U.S. research on bat-human virus transmission over China ties*, POLITICO (Apr. 27, 2020), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.

appropriately trained technicians and investigators needed to safely operate this high-containment laboratory."[9] This is alarming.

To prevent future pandemics, Congress is obligated to conduct robust oversight of grant recipients, both current and historic. It is incumbent upon grant recipients to ensure their work is performed within the scope of the grant, advances our national interest, and protects our national security. It is vital to understand if U.S. taxpayer funds were at all affiliated with a pandemic that has taken the lives of nearly 600,000 Americans so we can prevent similar future catastrophes.

To help us better understand the relationship between the U.S. government and EcoHealth and EcoHealth's ties to the WIV, please provide the following information as soon as possible, but no later than June 11, 2021:

1. All documents and communications between NIH and EcoHealth regarding grant R01AI110964.

2. All documents and communications between NIH and WIV regarding grant R01AI110964.

3. All documents and communications pertaining to or resulting from any U.S. government-led inspection of the WIV arranged by EcoHealth.

4. All documents and communications regarding Potential Pandemic Pathogen Care and Oversight Committee review of R01AI110964.

5. All documents and communications regarding gain of function research funded by EcoHealth or any other U.S. entity.

In addition to these documents, please provide a staff-level briefing as soon as possible but no later than June 4, 2021. To schedule the briefing or ask any follow-up or related questions, please contact Committee on Oversight and Reform staff at (202) 225-5074.

The Committee on Oversight and Reform is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you in advance for your cooperation with this inquiry.

---

[9] *Id.*

Sincerely,

James Comer
Ranking Member
Committee on Oversight and Reform

Jim Jordan
Ranking Member
Committee on the Judiciary

cc: The Honorable Carolyn B. Maloney, Chairwoman
Committee on Oversight and Reform

The Honorable Jerrold Nadler, Chairman
Committee on the Judiciary

Enclosure: Letter from Dr. Michael Lauer to EcoHealth Alliance on July 8, 2020.

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 24, 2021 6:00:48 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
						(b) (4), (b) (6)
R21AI145400-02	MENACHERY	2021-07-01	2021-05-13	Y	35	Gerhart
						(b) (4), (b) (6)

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 17, 2021 6:01:01 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
(b) (4), (b) (6)						
R21AI145400-02	MENACHERY	2021-07-01	2021-05-13	Y	35	Gerhart
(b) (4), (b) (6)						

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 10, 2021 6:01:46 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI153087-02	Waghmare	2021-06-01	2021-04-15	Y	35	Khandjian
R01AI153602-02	MENACHERY	2021-06-01	2021-04-15	Y	35	Wilson
R01AI148166-02	Frieman	2021-06-01	2021-04-15	Y	35	Gormley
R21AI145372-02	Gralinski	2021-06-01	2021-04-15	Y	35	Gormley
[redacted]						(b) (4), (b) (6)
R21AI145400-02	MENACHERY	2021-07-01	Not Recvd	N	35	Gerhart
[redacted]						(b) (4), (b) (6)

From: Miers, Sarah (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: FW: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV
Date: Friday, May 7, 2021 10:33:53 AM
Attachments: Pallone WIV DRAFT 5-7.docx

Hi Erik, please see the (hopefully last) edits on page 8, question 10. Are these okay?

Thanks
Sarah

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Friday, May 7, 2021 at 10:28 AM
To: "Ford, Andrew (NIH/NIAID) [E]" (b) (6)
Cc: NIAID OCGR Correspondence (b) (6), NIAID BUGS (b) (6), NIAID DEA DART (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6), NIAID OCGR Leg (b) (6)
Subject: RE: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Thank you, Andrew.

Please see our suggested edits on page 8 in response to Question 10. Do these look OK to you?

Please ensure NIAID OCGR Leg is on your response back to me per usual.

Thanks!
Kara

From: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Sent: Friday, May 7, 2021 8:49 AM
To: Harris, Kara (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Correspondence (b) (6); NIAID BUGS (b) (6); NIAID DEA DART (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg (b) (6)
Subject: Re: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Hey Kara,

Please see a few edits in the attached.

Thanks,

Andrew

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Thursday, May 6, 2021 at 6:26 PM
To: "Ford, Andrew (NIH/NIAID) [E]" (b) (6)
Cc: NIAID OCGR Correspondence (b) (6), NIAID BUGS (b) (6), NIAID DEA DART (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6), NIAID OCGR Leg (b) (6)
Subject: RE: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Hi Andrew –

Please see our highlighted responses in the attached draft.

Please let me know if these are OK. We would appreciate your input by 10:00 a.m. tomorrow.

Thank you,
Kara

From: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Sent: Thursday, May 6, 2021 3:43 PM
To: Harris, Kara (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Correspondence (b) (6); NIAID BUGS (b) (6); NIAID DEA DART (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg (b) (6)
Subject: Re: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Hey Kara,

Incorporated into the attached version are responses to the questions/comments.

Let me know if you have any additional questions.

Thanks,
Andrew

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Thursday, May 6, 2021 at 8:56 AM
To: "Ford, Andrew (NIH/NIAID) [E]" (b) (6)

Cc: NIAID OCGR Correspondence (b) (6), NIAID BUGS (b) (6), NIAID DEA DART (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6), NIAID OCGR Leg (b) (6)
Subject: RE: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Hi Andrew –

Thank you for the additional comments. We have revised the language in response to your and Dr. Stemmy's input.

We would appreciate your review and input on the comment bubbles highlighted in yellow by COB today.

Thank you,
Kara

From: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, May 5, 2021 9:07 AM
To: Harris, Kara (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Correspondence (b) (6); NIAID BUGS (b) (6)
Subject: Re: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Hey Kara,

Incorporated into the attached version are additional comments.

Should you have any questions please let me know (I will be offline for about 1 to 1.5 hours).

Thanks,
Andrew

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Wednesday, May 5, 2021 at 8:47 AM
To: Emily Erbelding (b) (6), NIAID BUGS (b) (6)
Cc: NIAID OCGR Correspondence (b) (6)
Subject: FW: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Good morning, DMID –

This is a reminder that your input is due by 10:00 a.m.

Thank you!
Kara

From: Harris, Kara (NIH/NIAID) [E]
Sent: Tuesday, May 4, 2021 7:32 AM
To: Erbelding, Emily (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Cc: Linde, Emily (NIH/NIAID) [E] (b) (6); NIAID OCGR Correspondence (b) (6); NIAID OCGR Leg (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6); NIAID BUGS (b) (6); NIAID DEA DART (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6)
Subject: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Good morning:

Attached is a letter to Dr. Collins from the Minority leadership of the House Energy and Commerce Committee regarding WIV. You may recall that we recently discussed this letter and suggested that OER take the lead with limited NIAID input. OER has responded with the attached draft response requesting broad NIAID input.

OCGR Leg had drafted input for the response that you reviewed last week. The response has now been updated to incorporate your feedback.

The following documents are attached:

1. The incoming.
2. The current draft response. Please see comment bubbles highlighted in yellow, as well as background information regarding our response to Question 2a under State Department Cables.

Please review the updated attached draft that NIAID Leg has annotated, including the comment bubbles highlighted in yellow. We would appreciate your specific edits and comments no later than 10:00 a.m. tomorrow, Wednesday, May 5.

Let us know if you have any questions.

Thanks,
Kara

From: Ford, Andrew (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Ford, Andrew (NIH/NIAID) [E]; Lyon, Rickie (NIH/NIAID) [C]
Subject: INPUT DUE 4PM Today (5/6): Updated Input for Response to House Energy and Commerce Committee on WIV
Date: Thursday, May 6, 2021 9:20:11 AM
Attachments: Pallone WIV DRAFT 5-5_to DMID.docx
2021.03.16 - NIH Letter on WIV2.pdf

Hey Erik,

Back for another round of review are the responses to inquiries from Congressperson Pallone. **Please review the highlighted comments and associated edits in track changes, make any additional edits or note via comment that the language is fine, and send the resulting document to me by 4:00pm, today, Thursday, May 6, 2021.** I took a look at the edits and they seem fine to me, but you certainly have a greater perspective; I will handle the response to question 12.

Thanks,
Andrew

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Thursday, May 6, 2021 at 8:56 AM
To: "Ford, Andrew (NIH/NIAID) [E]" (b) (6)
Cc: NIAID OCGR Correspondence (b) (6), NIAID BUGS (b) (6), NIAID DEA DART (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6), NIAID OCGR Leg (b) (6)
Subject: RE: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Hi Andrew –

Thank you for the additional comments. We have revised the language in response to your and Dr. Stemmy's input.

We would appreciate your review and input on the comment bubbles highlighted in yellow by COB today.

Thank you,
Kara

From: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, May 5, 2021 9:07 AM
To: Harris, Kara (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Correspondence (b) (6); NIAID BUGS (b) (6)
Subject: Re: For Review: Updated Input for Response to House Energy and Commerce Committee on

WIV

Hey Kara,

Incorporated into the attached version are additional comments.

Should you have any questions please let me know (I will be offline for about 1 to 1.5 hours).

Thanks,
Andrew

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Wednesday, May 5, 2021 at 8:47 AM
To: Emily Erbelding (b) (6), NIAID BUGS (b) (6)
Cc: NIAID OCGR Correspondence (b) (6)
Subject: FW: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Good morning, DMID –

This is a reminder that your input is due by 10:00 a.m.

Thank you!
Kara

From: Harris, Kara (NIH/NIAID) [E]
Sent: Tuesday, May 4, 2021 7:32 AM
To: Erbelding, Emily (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Cc: Linde, Emily (NIH/NIAID) [E] (b) (6); NIAID OCGR Correspondence (b) (6); NIAID OCGR Leg (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6); NIAID BUGS (b) (6); NIAID DEA DART (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6)
Subject: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Good morning:

Attached is a letter to Dr. Collins from the Minority leadership of the House Energy and Commerce Committee regarding WIV. You may recall that we recently discussed this letter and suggested that OER take the lead with limited NIAID input. OER has responded with the attached draft response requesting broad NIAID input.

OCGR Leg had drafted input for the response that you reviewed last week. The response has now been updated to incorporate your feedback.

The following documents are attached:

1. The incoming.
2. The current draft response. Please see comment bubbles highlighted in yellow, as well as background information regarding our response to Question 2a under State Department Cables.

Please review the updated attached draft that NIAID Leg has annotated, including the comment bubbles highlighted in yellow. We would appreciate your specific edits and comments no later than 10:00 a.m. tomorrow, Wednesday, May 5.

Let us know if you have any questions.

Thanks,
Kara

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

March 18, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

We write to request information, assistance, and needed-leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.

The COVID-19 pandemic has been the worst public health crisis in the U.S. in about a hundred years. Over a year has passed since the deadly virus reached our shores and yet, the origin of the virus has yet to be determined. An independent, expert investigation of the origin of COVID-19 is of paramount importance to public health and biosecurity. As noted by Stanford Medical School Professor David Relman:

> A more complete understanding of the origins of COVID-19 clearly serves the interests of every person in every country on this planet. It will limit further recriminations and diminish the likelihood of conflict; it will lead to more effective responses to this pandemic, as well as efforts to anticipate and prevent the next one. It will also advance our discussions about risky science. And it will do something else: Delineating COVID-19's origin story will help elucidate the nature of our very precarious coexistence within the biosphere.[1]

Recently, the World Health Organization (WHO) attempted to investigate the origin of COVID-19. The WHO said that this investigative mission would be guided by the science, be

[1] David A. Relman, *Opinion: To stop the next pandemic, we need to unravel the origins of COVID-19*, PNAS (Nov. 2020), *available at* https://www.pnas.org/content/117/47/29246.

"open-minded," and "not exclude[e] any hypothesis."[2] Unfortunately, China did not provide complete access or independence for the critical WHO mission. On February 13, 2021, National Security Advisor Jake Sullivan issued the following statement:

> We have deep concerns about the way in which the early findings of the COVID-19 investigation were communicated and questions about the process used to reach them. It is imperative that this report be independent, with expert findings free from intervention or alteration by the Chinese government. To better understand this pandemic and prepare for the next one, China must make available its data from the earliest days of the outbreak.[3]

Because of rising tensions between the U.S. and China, the WHO scrapped plans for an interim report.[4] An international group of science experts, including specialists in virology, microbiology, and zoology, asked for a new review.[5]

The NIH, as a premier scientific institution, must lead in order to foster a transparent, independent, and science-based investigation into the origin of the COVID-19 pandemic. Such an effort must meet the WHO's stated goals of an open-minded investigation that does not exclude any plausible hypothesis.[6] In addition, the NIH is well-positioned to gather and provide information through oversight of its grants and other federal awards. Thus, the NIH is in a unique position to investigate the possibility that the pandemic stemmed from a laboratory accident or leak, especially regarding the Wuhan Institute of Virology (WIV).

NIH raised concerns over a possible link between WIV and the COVID-19 outbreak during its review of federal awards to EcoHealth Alliance, a global environmental health nonprofit organization dedicated to protecting wildlife and public health from the emergence of disease. Of the $13.7 million in federal awards that NIH authorized for EcoHealth Alliance, 17

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[2] Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), *available at* https://www.nature.com/articles/d41586-020-03165-9.
[3] The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/.
[4] Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), *available at* https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines
[5] Jaime Metzl, et al, *Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19* (March 4, 2021), *available at* https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).pdf. The co-organizer of the letter and a WHO advisor on human genome editing, Jaime Metzl, PhD, said there is an eighty-five percent chance the pandemic started with an accidental leak from the WIV or Wuhan CDC laboratory, *available at* https://jamiemetzl.com/origins-of-sars-cov-2/. ("I have no definitive way of proving this thesis but the evidence is, in my view, extremely convincing. If forced to place odds on the confidence of my hypothesis, I would say there's an 85% chance the pandemic started with an accidental leak from the Wuhan Institute of Virology or Wuhan CDC and a 15% chance it began in some other way (in fairness, here is an article making the case for a zoonotic jump "in the wild"). If China keeps preventing a full and unrestricted international forensic investigation into the origins of the pandemic, I believe it is fair to deny Beijing the benefit of the doubt.")
[6] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

projects sponsored by the National Institute of Allergy and Infectious Disease (NIAID) have provided over $7.9 million in federal awards for research of viral emergence from bats in Southeast Asia.[7] EcoHealth Alliance passed some of its funding to the WIV, and in 2020, NIH made efforts to obtain information from EcoHealth Alliance about WIV related to concerns about the origins of COVID-19. In April 2020, NIH wrote to EcoHealth Alliance and Columbia University about an NIH-funded project entitled, "Understanding the Risk of Bat Coronavirus Emergency:"

> It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ('WIV'). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs. It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.[8]

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.[9] Among other revelations, it reported the following:

- The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses. This raises questions about the credibility of WIV senior researcher Shi Zhengli's public claim that there was "zero infection" among the WIV's staff and students of SARS-CoV-2 or SARS-related viruses.[10]

- Starting in at least 2016, WIV researchers conducted experiments involving RaTG13, the bat coronavirus identified by the WIV in January 2020 as the closest sample to SARS-CoV-2 (96.2 percent similar).[11] There was no indication that this research was suspended at any time prior to the COVID-19 outbreak.

- The WIV has a published record of conducting "gain-of-function" research to engineer chimeric viruses.[12] But the WIV has not been transparent or consistent about its record of

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[7] NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), *available at* https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts.
[8] Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), *available at* https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/.
[9] U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), *available at* https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html.
[10] *Id.*
[11] *Id.*
[12] *Id.*

studying viruses similar to the COVID-19 virus, including "RaTG13," which was sampled from a cave in Yunnan Province in 2013 after several miners died of SARS-like illness.[13]

- WHO investigators must have access to the records of the WIV's work on bat and other coronaviruses before the COVID-19 outbreak. As part of a thorough inquiry, they must have a full accounting of why the WIV altered and then removed online records of its work with RaTG13 and other viruses.[14]

- Despite the WIV presenting itself as a civilian institution, the U.S. has determined that the WIV has collaborated on projects with China's military.[15] The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.[16]

- The U.S. and other donors who funded or collaborated on civilian research at the WIV have a right and obligation to determine whether any of our research funding was diverted to secret Chinese military projects at the WIV.[17]

Notably, the State Department's former lead investigator who oversaw the Task Force into the COVID-19 virus origin stated recently that he not only believes the virus escaped from the WIV, but that it may have been the result of research that the Chinese military, or People's Liberation Army, was doing on a bioweapon.[18]

Accordingly, it is imperative to determine not only where SARS-CoV-2 originated, but also how and if NIH's funding and research to projects at the WIV could have contributed to SARS CoV-2. To assist our requests and inquiry, please provide the following by April 19, 2021:

1. An assessment from a classified U.S. Defense Intelligence Agency (DIA) report included the possibility that the origins of SARS CoV-2 could have emerged accidentally from a laboratory in Wuhan, China due to unsafe laboratory practices.[19] The DIA report cited U.S. government and Chinese researchers who found "about 33 percent of the original 41 identified cases did not have direct exposure" to the market.[20] That, along with what is known of the WIV's work in past few years, raised reasonable suspicion that the

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[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

[18] Jennifer Griffin, Former top State Dept. investigator says COVID-19 outbreak may have resulted from bioweapons research accident, Fox News (March 13, 2021), *available at* https://www.foxnews.com/world/top-state-official-coronavirus-bioweapon-accident

[19] Fred Guterl, Naveed Jamali and Tom O'Connor, *The Controversial Experiments ad Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), *available at* https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503.
[20] *Id.*

pandemic may have been caused by a lab error, not a wet market.[21] Further, a WHO inspector on the recent mission noted that "we know not all of those first 174 early COVID-19 cases visited the market, including the man diagnosed in December 2019 with the earliest onset date."[22] What information does the NIH have on the earliest COVID-19 cases?

2. According to an editorial on February 23, 2021, in *The Wall Street Journal* by former Secretary of State Mike Pompeo and Miles Yu, "[China's] army of scientists claim to have discovered almost 2,000 new viruses in a little over a decade."[23] How many of these discovered viruses does the NIH have information on and were any of these viruses discovered at the WIV?

3. According to *The Wall Street Journal* editorial mentioned in the previous question, some have alleged that the WIV's virus-carrying animals were sold as pets and may even show up at local wet markets.[24] Is the NIH aware of these allegations? If so, please provide any information the NIH has related to these allegations.

4. Please provide all information that NIH has about laboratory accidents and/or biosafety practices at the WIV since January 1, 2015.

5. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about communications and events at the WIV from August 2019 to the present.

6. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about their communications with China-based NIH, Chinese National Science Foundation, CDC, and China CDC about events at the WIV from August 2019 to the present.

State Department Cables

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[21] *Id.*

[22] Dominic Dwyer, I was the Australian doctor on the WHO's COVID-19 mission to China. Here's what we found about the origins of the coronavirus, THE CONVERSATION (Feb. 21, 2021), *available at*https://www.theguardian.com/commentisfree/2021/feb/22/i-was-on-the-whos-covid-mission-to-china-heres-what-we-found. *See also* Jeremy Page and Drew Hinshaw, *China Refuses to Give WHO Raw Data on Early Covid-19 Cases*, THE WALL STREET JOURNAL (Feb. 12, 2021), *available at* https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580#:~:text=BEIJING%E2%80%94Chinese%20authorities%20refused%20to,over%20the%20lack%20of%20detail. ("Chinese authorities refused to provide World Health Organization investigators with raw, personalized data on early Covid-19 cases that could help them determine how and when the coronavirus first began to spread in China, according to WHO investigators who described heated exchanges over the lack of detail. The Chinese authorities turned down requests to provide such data on 174 cases of Covid-19 that they have identified from the early phase of the outbreak in the Chinese city of Wuhan in December 2019. Investigators are part of a WHO team that this week completed a monthlong mission in China aimed at determining the origins of the pandemic.")

[23] *Id.*

[24] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab,* THE WALL STREET JOURNAL (Feb. 23, 2021), available at https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

7. What information does NIH have about the WIV's responses to the 2018 U.S. Department of State cables (attached to this letter) regarding safety concerns?

8. The April 2018 cable from the U.S. Department of State stated that the WIV planned to invite University of Texas Medical Branch Galveston (UTMBG) researchers to do research in Wuhan's labs. Please provide any information NIH received that indicates whether the WIV invited UTMBG researchers, and whether UTMBG researchers conducted any research in Wuhan's labs.

    a. If there was such research, please provide information and any documents related to this research.

9. Why was it pertinent to the NIH investigation that the "nonprofit [EcoHealth Alliance] must provide the "WIV's responses to the 2018 Department of State cables regarding safety concerns"?[25]

    a. Did EcoHealth Alliance provide this information? If so, how did NIH use the information to further its investigation?

<u>EcoHealth Alliance, Columbia University Health Sciences</u>

10. Was the 2019 NIH federal award to EcoHealth Alliance reviewed and approved by the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) committee?[26]

    a. If so, please provide the documentation with the committee's decision.

    b. Please also provide the names of the individuals who were members of the committee at the time.

11. Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.

12. In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with "program goals and agency priorities."[27] Please specify the work that was done by the EcoHealth Alliance that did

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[25] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[26] National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), *available at* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html.
[27] *Id.*

not align with the agency's program goals and priorities, and when that work was conducted.

a. Was an evaluation of EcoHealth Alliance's work and whether it aligned with the agency's program goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?

13. In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology…has been conducting research at its facilities in China that pose serious bio-safety concerns."[28] What are the sources for those reports to NIH and what were the specific allegations reported?

14. Why did the NIH request that EcoHealth Alliance provide a sample of the pandemic coronavirus that the WIV used to determine its genetic sequence for SARS CoV-2?[29]

a. Why is this information important to NIH's investigation?

b. Has NIH obtained the sample and if so, what evaluations have been done, and for what purpose?

c. If NIH has not yet obtained the sample, what are the planned studies and evaluations NIH will conduct with the sample when it is obtained?

15. What is the nature of NIH's concerns about purported restrictions at the WIV including "diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019[,]" about the WIV lab or virus origin?[30]

a. What is the basis of information to NIH about the purported restrictions at the WIV?

b. What are the other purported restrictions at the WIV in October 2019?

16. After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions.[31]

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[28] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.
[29] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[30] *Id.*
[31] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

a. Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement.

b. What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?

c. One condition for the federal award reinstatement was for EcoHealth Alliance to arrange for an outside inspection of the WIV and its records, "with specific attention to addressing the question of whether WIV staff had SARS-CoV-2their possession prior to December 2019."[32] Why is it pertinent to the NIH's investigation if staff at WIV had SARS-CoV-2 in their possession prior to December 2019? What is the potential significance if the staff did have the virus in their possession prior to December 2019?

d. What information does NIH have that was used for the basis of requesting that the EcoHealth Alliance "must 'explain the apparent disappearance' of a scientist who worked in the Wuhan lab," and on social media was rumored to be "patient zero" of the pandemic?[33]

i. What is the potential significance about the whereabouts of this scientist and the photo being removed from the website?

17. Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University.

a. In an April 2020 email, Dr. Lauer advised Naomi Schrag of Columbia University that it would be helpful for NIH "to know about all China-based participants in this work since the Type 1 grant started in 2014 - who they were and how much money they received."[34] Why did NIH request that Columbia University provide information about all of the China-based participants?

i. What is the pertinence of the timeframe starting in 2014 for the requested information?

ii. Did Columbia University provide the NIH with the requested information about all of the China-based participants from all grantees since 2014? If so, please provide the information1. If not, why not?

Federal Funding Records

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[32] *Id.*
[33] *Id.*
[34] Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), *available at* https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say.

18. Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support.[35]

19. What is the total amount of NIH federal funding per year from 2017 through 2021 that has directly or indirectly supported the WIV scientists or research through grant recipients, including to EcoHealth Alliance; Wildlife Trust, Inc.; Columbia University Health Sciences; Trustees of Columbia University; University of North Carolina Chapel Hill; Vanderbilt University; University of Virginia; and Oregon Health and Science University?[36]

20. According to a report in *The Washington Post* on April 14, 2020, the WIV issued a news release in English about the final visit from U.S. Embassy scientist diplomats in Beijing, which occurred on March 27, 2018.[37] Does the NIH have a copy of this news release? If so, please provide a copy.

21. For NIH award recipients that have provided support to the WIV since January 1, 2012, please provide annual reports, trip reports related to the WIV, documentation of any survey or field trips by the WIV, and interim data summaries from the WIV.

22. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 where foreign sites for all Type 1 and Type 2 awards have been documented as involving the WIV.

23. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 for NIH domestic grantee awards with a foreign component involving the WIV.

24. Please provide the name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility.

25. Please provide the name(s) of the NIH Scientific Review Officers responsible for reviewing and approving any NIH financial awards to EcoHealth Alliance and any other funding recipients that supported the WIV.

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[35] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[36] National Institutes of Health, Research Portfolio online Reporting Tools, NIH RePorter *available at* https://report.nih.gov/ (last accessed March 6, 2020).

[37] Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), *available at* https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.[38] Please provide any information the NIH has on the number of bat samples and animals at the WIV.

    a. Did any NIH scientists who are fluent in Mandarin review the Chinese scientific literature on the WIV research related to coronaviruses that is dated before February 1, 2020?

27. Does the NIH have the unpublished sequences of bat coronaviruses that were maintained in the WIV database before December 30, 2019, or before the database was removed from the internet?[39] Does NIH have the full sequences of the eight viruses sampled in the Yunnan province on an EcoHealth Alliance bat-virus sampling trip in 2015?

    a. Please provide NIH's analysis if the sequences have been analyzed.

    b. If NIH does not have the sequences, can NIH get this information from the EcoHealth Alliance or from other NIH-funded sources?

28. Please provide the original version of "Origin and cross-species transmission of bat coronaviruses in China" that was submitted to *Nature* by EcoHealth Alliance on October 6, 2019, published August 25, 2020, and funded in part by NIAID (award number R01AI110964).[40] If NIH does not have the October 6, 2019 report, can NIH obtain it from EcoHealth Alliance for this response? If so, please provide the report.

29. Have NIH, EcoHealth Alliance, or other NIH award recipient(s) been denied permission or access to results of any WIV research, which indirectly received financial support from NIH awards? If so, please provide the date(s), individuals involved, and circumstances of each denial.

We request that the NIH provide the requested documents and information in a coordinated response from all stakeholders and the appropriate divisions within NIH, including but not limited to subject matter experts from NIH's Division of Security and Emergency Response, the Office of Management Assessment, the Center for Scientific Review, the National Institute of Allergy and Infectious Diseases, and the Office of Extramural Research. After the requested information has been provided, we ask that the NIH provide a briefing to the Minority Committee staff to discuss the information that the NIH has related to the origins of SARS-CoV-2, including any potential links to the WIV. Finally, we request that you appoint an NIH working group representing an appropriate diversity of scientific disciplines to collect data and

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[38] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), *available at* https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

[39] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

[40] Latinne, A., Hu, B., Olival, K.J. et al,. *Origin and cross-species transmission of bat coronaviruses in China*, Nature (Aug. 25, 2020), *available at* https://www.nature.com/articles/s41467-020-17687-3#Ack1.

information related to COVID-19 origins (including the WIV), and that the NIH working group coordinate and consult with foreign scientific agencies involved in similar work.

Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Attachment

Cc: The Honorable Frank Pallone, Chairman
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

From: Ford, Andrew (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Ford, Andrew (NIH/NIAID) [E]; Lyon, Rickie (NIH/NIAID) [C]
Subject: RESPONSE DUE 10:00am 5/5 - For Review: Updated Input for Response to House Energy and Commerce Committee on WIV
Date: Tuesday, May 4, 2021 3:08:09 PM
Attachments: 2021.03.16 - NIH Letter on WIV2.pdf
Pallone WIV DRAFT 5-4 to Divs.docx

Hey Eric,

Per Kara's email below, attached for another round of review are the responses to Congressperson Pallone regarding correspondence about the WIV. Could you please review the attached version, particular those flagged by comments directed to you, and send your feedback to me by 10:00am tomorrow, Wednesday, May 5, 2021. [redacted] (b) (5)

Please note, [redacted] (b) (5)

Happy to discuss.

Thanks,
Andrew

From: "Harris, Kara (NIH/NIAID) [E]" [redacted] (b) (6)
Date: Tuesday, May 4, 2021 at 7:32 AM
To: Emily Erbelding [redacted] (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" [redacted] (b) (6)
Cc: "Linde, Emily (NIH/NIAID) [E]" [redacted] (b) (6), NIAID OCGR Correspondence [redacted] (b) (6), NIAID OCGR Leg [redacted] (b) (6), "Lane, Cliff (NIH/NIAID) [E]" [redacted] (b) (6), NIAID BUGS [redacted] (b) (6), NIAID DEA DART [redacted] (b) (6), "Billet, Courtney (NIH/NIAID) [E]" [redacted] (b) (6), "Harper, Jill (NIH/NIAID) [E]" [redacted] (b) (6)
Subject: For Review: Updated Input for Response to House Energy and Commerce Committee on WIV

Good morning:

Attached is a letter to Dr. Collins from the Minority leadership of the House Energy and Commerce Committee regarding WIV. You may recall that we recently discussed this letter and suggested that OER take the lead with limited NIAID input. OER has responded with the attached draft response requesting broad NIAID input.

OCGR Leg had drafted input for the response that you reviewed last week. The response has now been updated to incorporate your feedback.

The following documents are attached:

1. The incoming.
2. The current draft response. Please see comment bubbles highlighted in yellow, as well as background information regarding our response to Question 2a under State Department Cables.

Please review the updated attached draft that NIAID Leg has annotated, including the comment bubbles highlighted in yellow. We would appreciate your specific edits and comments no later than 10:00 a.m. tomorrow, Wednesday, May 5.

Let us know if you have any questions.

Thanks,
Kara

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

March 18, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

We write to request information, assistance, and needed-leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.

The COVID-19 pandemic has been the worst public health crisis in the U.S. in about a hundred years. Over a year has passed since the deadly virus reached our shores and yet, the origin of the virus has yet to be determined. An independent, expert investigation of the origin of COVID-19 is of paramount importance to public health and biosecurity. As noted by Stanford Medical School Professor David Relman:

> A more complete understanding of the origins of COVID-19 clearly serves the interests of every person in every country on this planet. It will limit further recriminations and diminish the likelihood of conflict; it will lead to more effective responses to this pandemic, as well as efforts to anticipate and prevent the next one. It will also advance our discussions about risky science. And it will do something else: Delineating COVID-19's origin story will help elucidate the nature of our very precarious coexistence within the biosphere.[1]

Recently, the World Health Organization (WHO) attempted to investigate the origin of COVID-19. The WHO said that this investigative mission would be guided by the science, be

[1] David A. Relman, *Opinion: To stop the next pandemic, we need to unravel the origins of COVID-19*, PNAS (Nov. 2020), *available at* https://www.pnas.org/content/117/47/29246.

"open-minded," and "not exclude[e] any hypothesis."[2] Unfortunately, China did not provide complete access or independence for the critical WHO mission. On February 13, 2021, National Security Advisor Jake Sullivan issued the following statement:

> We have deep concerns about the way in which the early findings of the COVID-19 investigation were communicated and questions about the process used to reach them. It is imperative that this report be independent, with expert findings free from intervention or alteration by the Chinese government. To better understand this pandemic and prepare for the next one, China must make available its data from the earliest days of the outbreak.[3]

Because of rising tensions between the U.S. and China, the WHO scrapped plans for an interim report.[4] An international group of science experts, including specialists in virology, microbiology, and zoology, asked for a new review.[5]

The NIH, as a premier scientific institution, must lead in order to foster a transparent, independent, and science-based investigation into the origin of the COVID-19 pandemic. Such an effort must meet the WHO's stated goals of an open-minded investigation that does not exclude any plausible hypothesis.[6] In addition, the NIH is well-positioned to gather and provide information through oversight of its grants and other federal awards. Thus, the NIH is in a unique position to investigate the possibility that the pandemic stemmed from a laboratory accident or leak, especially regarding the Wuhan Institute of Virology (WIV).

NIH raised concerns over a possible link between WIV and the COVID-19 outbreak during its review of federal awards to EcoHealth Alliance, a global environmental health nonprofit organization dedicated to protecting wildlife and public health from the emergence of disease. Of the $13.7 million in federal awards that NIH authorized for EcoHealth Alliance, 17

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[2] Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), *available at* https://www.nature.com/articles/d41586-020-03165-9.
[3] The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/.
[4] Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), *available at* https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines
[5] Jaime Metzl, et al, *Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19* (March 4, 2021), *available at* https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).pdf. The co-organizer of the letter and a WHO advisor on human genome editing, Jaime Metzl, PhD, said there is an eighty-five percent chance the pandemic started with an accidental leak from the WIV or Wuhan CDC laboratory, *available at* https://jamiemetzl.com/origins-of-sars-cov-2/. ("I have no definitive way of proving this thesis but the evidence is, in my view, extremely convincing. If forced to place odds on the confidence of my hypothesis, I would say there's an 85% chance the pandemic started with an accidental leak from the Wuhan Institute of Virology or Wuhan CDC and a 15% chance it began in some other way (in fairness, here is an article making the case for a zoonotic jump "in the wild"). If China keeps preventing a full and unrestricted international forensic investigation into the origins of the pandemic, I believe it is fair to deny Beijing the benefit of the doubt.")
[6] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

projects sponsored by the National Institute of Allergy and Infectious Disease (NIAID) have provided over $7.9 million in federal awards for research of viral emergence from bats in Southeast Asia.[7] EcoHealth Alliance passed some of its funding to the WIV, and in 2020, NIH made efforts to obtain information from EcoHealth Alliance about WIV related to concerns about the origins of COVID-19. In April 2020, NIH wrote to EcoHealth Alliance and Columbia University about an NIH-funded project entitled, "Understanding the Risk of Bat Coronavirus Emergency:"

> It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ('WIV'). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs. It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.[8]

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.[9] Among other revelations, it reported the following:

- The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses. This raises questions about the credibility of WIV senior researcher Shi Zhengli's public claim that there was "zero infection" among the WIV's staff and students of SARS-CoV-2 or SARS-related viruses.[10]

- Starting in at least 2016, WIV researchers conducted experiments involving RaTG13, the bat coronavirus identified by the WIV in January 2020 as the closest sample to SARS-CoV-2 (96.2 percent similar).[11] There was no indication that this research was suspended at any time prior to the COVID-19 outbreak.

- The WIV has a published record of conducting "gain-of-function" research to engineer chimeric viruses.[12] But the WIV has not been transparent or consistent about its record of

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[7] NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), *available at* https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts.
[8] Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), *available at* https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/.
[9] U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), *available at* https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html.
[10] *Id.*
[11] *Id.*
[12] *Id.*

studying viruses similar to the COVID-19 virus, including "RaTG13," which was sampled from a cave in Yunnan Province in 2013 after several miners died of SARS-like illness.[13]

- WHO investigators must have access to the records of the WIV's work on bat and other coronaviruses before the COVID-19 outbreak. As part of a thorough inquiry, they must have a full accounting of why the WIV altered and then removed online records of its work with RaTG13 and other viruses.[14]

- Despite the WIV presenting itself as a civilian institution, the U.S. has determined that the WIV has collaborated on projects with China's military.[15] The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.[16]

- The U.S. and other donors who funded or collaborated on civilian research at the WIV have a right and obligation to determine whether any of our research funding was diverted to secret Chinese military projects at the WIV.[17]

Notably, the State Department's former lead investigator who oversaw the Task Force into the COVID-19 virus origin stated recently that he not only believes the virus escaped from the WIV, but that it may have been the result of research that the Chinese military, or People's Liberation Army, was doing on a bioweapon.[18]

Accordingly, it is imperative to determine not only where SARS-CoV-2 originated, but also how and if NIH's funding and research to projects at the WIV could have contributed to SARS CoV-2. To assist our requests and inquiry, please provide the following by April 19, 2021:

1. An assessment from a classified U.S. Defense Intelligence Agency (DIA) report included the possibility that the origins of SARS CoV-2 could have emerged accidentally from a laboratory in Wuhan, China due to unsafe laboratory practices.[19] The DIA report cited U.S. government and Chinese researchers who found "about 33 percent of the original 41 identified cases did not have direct exposure" to the market.[20] That, along with what is known of the WIV's work in past few years, raised reasonable suspicion that the

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[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

[18] Jennifer Griffin, Former top State Dept. investigator says COVID-19 outbreak may have resulted from bioweapons research accident, Fox News (March 13, 2021), *available at* https://www.foxnews.com/world/top-state-official-coronavirus-bioweapon-accident

[19] Fred Guterl, Naveed Jamali and Tom O'Connor, *The Controversial Experiments ad Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), *available at* https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503.
[20] *Id.*

pandemic may have been caused by a lab error, not a wet market.[21] Further, a WHO inspector on the recent mission noted that "we know not all of those first 174 early COVID-19 cases visited the market, including the man diagnosed in December 2019 with the earliest onset date."[22] What information does the NIH have on the earliest COVID-19 cases?

2. According to an editorial on February 23, 2021, in *The Wall Street Journal* by former Secretary of State Mike Pompeo and Miles Yu, "[China's] army of scientists claim to have discovered almost 2,000 new viruses in a little over a decade."[23] How many of these discovered viruses does the NIH have information on and were any of these viruses discovered at the WIV?

3. According to *The Wall Street Journal* editorial mentioned in the previous question, some have alleged that the WIV's virus-carrying animals were sold as pets and may even show up at local wet markets.[24] Is the NIH aware of these allegations? If so, please provide any information the NIH has related to these allegations.

4. Please provide all information that NIH has about laboratory accidents and/or biosafety practices at the WIV since January 1, 2015.

5. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about communications and events at the WIV from August 2019 to the present.

6. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about their communications with China-based NIH, Chinese National Science Foundation, CDC, and China CDC about events at the WIV from August 2019 to the present.

State Department Cables

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[21] *Id.*

[22] Dominic Dwyer, I was the Australian doctor on the WHO's COVID-19 mission to China. Here's what we found about the origins of the coronavirus, THE CONVERSATION (Feb. 21, 2021), *available at*https://www.theguardian.com/commentisfree/2021/feb/22/i-was-on-the-whos-covid-mission-to-china-heres-what-we-found. *See also* Jeremy Page and Drew Hinshaw, *China Refuses to Give WHO Raw Data on Early Covid-19 Cases*, THE WALL STREET JOURNAL (Feb. 12, 2021), *available at* https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580#:~:text=BEIJING%E2%80%94Chinese%20authorities%20refused%20to,over%20the%20lack%20of%20detail. ("Chinese authorities refused to provide World Health Organization investigators with raw, personalized data on early Covid-19 cases that could help them determine how and when the coronavirus first began to spread in China, according to WHO investigators who described heated exchanges over the lack of detail. The Chinese authorities turned down requests to provide such data on 174 cases of Covid-19 that they have identified from the early phase of the outbreak in the Chinese city of Wuhan in December 2019. Investigators are part of a WHO team that this week completed a monthlong mission in China aimed at determining the origins of the pandemic.")

[23] *Id.*

[24] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab,* THE WALL STREET JOURNAL (Feb. 23, 2021), available at https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

7. What information does NIH have about the WIV's responses to the 2018 U.S. Department of State cables (attached to this letter) regarding safety concerns?

8. The April 2018 cable from the U.S. Department of State stated that the WIV planned to invite University of Texas Medical Branch Galveston (UTMBG) researchers to do research in Wuhan's labs. Please provide any information NIH received that indicates whether the WIV invited UTMBG researchers, and whether UTMBG researchers conducted any research in Wuhan's labs.

    a. If there was such research, please provide information and any documents related to this research.

9. Why was it pertinent to the NIH investigation that the "nonprofit [EcoHealth Alliance] must provide the "WIV's responses to the 2018 Department of State cables regarding safety concerns"?[25]

    a. Did EcoHealth Alliance provide this information? If so, how did NIH use the information to further its investigation?

<u>EcoHealth Alliance, Columbia University Health Sciences</u>

10. Was the 2019 NIH federal award to EcoHealth Alliance reviewed and approved by the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) committee?[26]

    a. If so, please provide the documentation with the committee's decision.

    b. Please also provide the names of the individuals who were members of the committee at the time.

11. Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.

12. In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with "program goals and agency priorities."[27] Please specify the work that was done by the EcoHealth Alliance that did

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[25] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[26] National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), *available at* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html.
[27] *Id.*

not align with the agency's program goals and priorities, and when that work was conducted.

a. Was an evaluation of EcoHealth Alliance's work and whether it aligned with the agency's program goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?

13. In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology…has been conducting research at its facilities in China that pose serious bio-safety concerns."[28] What are the sources for those reports to NIH and what were the specific allegations reported?

14. Why did the NIH request that EcoHealth Alliance provide a sample of the pandemic coronavirus that the WIV used to determine its genetic sequence for SARS CoV-2?[29]

a. Why is this information important to NIH's investigation?

b. Has NIH obtained the sample and if so, what evaluations have been done, and for what purpose?

c. If NIH has not yet obtained the sample, what are the planned studies and evaluations NIH will conduct with the sample when it is obtained?

15. What is the nature of NIH's concerns about purported restrictions at the WIV including "diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019[,]" about the WIV lab or virus origin?[30]

a. What is the basis of information to NIH about the purported restrictions at the WIV?

b. What are the other purported restrictions at the WIV in October 2019?

16. After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions.[31]

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[28] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.
[29] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[30] *Id.*
[31] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

a. Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement.

b. What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?

c. One condition for the federal award reinstatement was for EcoHealth Alliance to arrange for an outside inspection of the WIV and its records, "with specific attention to addressing the question of whether WIV staff had SARS-CoV-2their possession prior to December 2019."[32] Why is it pertinent to the NIH's investigation if staff at WIV had SARS-CoV-2 in their possession prior to December 2019? What is the potential significance if the staff did have the virus in their possession prior to December 2019?

d. What information does NIH have that was used for the basis of requesting that the EcoHealth Alliance "must 'explain the apparent disappearance' of a scientist who worked in the Wuhan lab," and on social media was rumored to be "patient zero" of the pandemic?[33]

i. What is the potential significance about the whereabouts of this scientist and the photo being removed from the website?

17. Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University.

a. In an April 2020 email, Dr. Lauer advised Naomi Schrag of Columbia University that it would be helpful for NIH "to know about all China-based participants in this work since the Type 1 grant started in 2014 - who they were and how much money they received."[34] Why did NIH request that Columbia University provide information about all of the China-based participants?

i. What is the pertinence of the timeframe starting in 2014 for the requested information?

ii. Did Columbia University provide the NIH with the requested information about all of the China-based participants from all grantees since 2014? If so, please provide the information1. If not, why not?

Federal Funding Records

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[32] *Id.*
[33] *Id.*
[34] Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), *available at* https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say.

18. Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support.[35]

19. What is the total amount of NIH federal funding per year from 2017 through 2021 that has directly or indirectly supported the WIV scientists or research through grant recipients, including to EcoHealth Alliance; Wildlife Trust, Inc.; Columbia University Health Sciences; Trustees of Columbia University; University of North Carolina Chapel Hill; Vanderbilt University; University of Virginia; and Oregon Health and Science University?[36]

20. According to a report in *The Washington Post* on April 14, 2020, the WIV issued a news release in English about the final visit from U.S. Embassy scientist diplomats in Beijing, which occurred on March 27, 2018.[37] Does the NIH have a copy of this news release? If so, please provide a copy.

21. For NIH award recipients that have provided support to the WIV since January 1, 2012, please provide annual reports, trip reports related to the WIV, documentation of any survey or field trips by the WIV, and interim data summaries from the WIV.

22. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 where foreign sites for all Type 1 and Type 2 awards have been documented as involving the WIV.

23. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 for NIH domestic grantee awards with a foreign component involving the WIV.

24. Please provide the name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility.

25. Please provide the name(s) of the NIH Scientific Review Officers responsible for reviewing and approving any NIH financial awards to EcoHealth Alliance and any other funding recipients that supported the WIV.

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[35] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[36] National Institutes of Health, Research Portfolio online Reporting Tools, NIH RePorter *available at* https://report.nih.gov/ (last accessed March 6, 2020).

[37] Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), *available at* https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.[38] Please provide any information the NIH has on the number of bat samples and animals at the WIV.

    a. Did any NIH scientists who are fluent in Mandarin review the Chinese scientific literature on the WIV research related to coronaviruses that is dated before February 1, 2020?

27. Does the NIH have the unpublished sequences of bat coronaviruses that were maintained in the WIV database before December 30, 2019, or before the database was removed from the internet?[39] Does NIH have the full sequences of the eight viruses sampled in the Yunnan province on an EcoHealth Alliance bat-virus sampling trip in 2015?

    a. Please provide NIH's analysis if the sequences have been analyzed.

    b. If NIH does not have the sequences, can NIH get this information from the EcoHealth Alliance or from other NIH-funded sources?

28. Please provide the original version of "Origin and cross-species transmission of bat coronaviruses in China" that was submitted to *Nature* by EcoHealth Alliance on October 6, 2019, published August 25, 2020, and funded in part by NIAID (award number R01AI110964).[40] If NIH does not have the October 6, 2019 report, can NIH obtain it from EcoHealth Alliance for this response? If so, please provide the report.

29. Have NIH, EcoHealth Alliance, or other NIH award recipient(s) been denied permission or access to results of any WIV research, which indirectly received financial support from NIH awards? If so, please provide the date(s), individuals involved, and circumstances of each denial.

We request that the NIH provide the requested documents and information in a coordinated response from all stakeholders and the appropriate divisions within NIH, including but not limited to subject matter experts from NIH's Division of Security and Emergency Response, the Office of Management Assessment, the Center for Scientific Review, the National Institute of Allergy and Infectious Diseases, and the Office of Extramural Research. After the requested information has been provided, we ask that the NIH provide a briefing to the Minority Committee staff to discuss the information that the NIH has related to the origins of SARS-CoV-2, including any potential links to the WIV. Finally, we request that you appoint an NIH working group representing an appropriate diversity of scientific disciplines to collect data and

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[38] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), *available at* https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

[39] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

[40] Latinne, A., Hu, B., Olival, K.J. et al,. *Origin and cross-species transmission of bat coronaviruses in China*, Nature (Aug. 25, 2020), *available at* https://www.nature.com/articles/s41467-020-17687-3#Ack1.

information related to COVID-19 origins (including the WIV), and that the NIH working group coordinate and consult with foreign scientific agencies involved in similar work.

Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Attachment

Cc: The Honorable Frank Pallone, Chairman
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 3, 2021 6:01:46 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI153087-02	Waghmare	2021-06-01	2021-04-15	Y	35	Khandjian
R01AI153602-02	MENACHERY	2021-06-01	2021-04-15	Y	35	Wilson
R01AI148166-02	Frieman	2021-06-01	2021-04-15	Y	35	Gormley
R21AI145372-02	Gralinski	2021-06-01	2021-04-15	Y	35	Gormley
R01AI157975-02	Du	2021-07-01	Not Recvd	N	35	Ranellone
R21AI145400-02	MENACHERY	2021-07-01	Not Recvd	N	35	Gerhart

(b) (4), (b) (6)

From: Peter Daszak
To: Fenton, Matthew (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]
Cc: Aleksei Chmura
Subject: Confidential RE: Regarding 2R01AI110964-06
Date: Thursday, April 29, 2021 1:48:22 PM
Attachments: Response to letter of 4.13.21.pdf
To Daszak 4 13 21.pdf

Just to keep you all aware. Michael Lauer got back to us within a few hours with a further request re. detailed information on how we monitored WIV compliance in the first 5 years of our funding ("To Daszak.." letter attached). I believe he's fishing for material to support his earlier insinuation that EHA has done a poor job of monitoring biosafety, and that this was in breach of some Federal CFR codes. We did not, and we were not – we complied with all CFR's in the way we managed our award, and are audited annually on these issues by an outside company that considers us in a 'low risk' category. It is however, very worrying that he seems to be trying to provide cover so that he can publicly state that we weren't in compliance. He cited these CFRs again in the attached letter, and my "scientist-to-scientist" response is attached. I also sent over 40 docs over to him.

I'll let you know what their response is. Any nudging you could give to Dr. Lauer would be welcome. I realize that the politics are not great right now, but this is science, not politics, and we have a job to do in trying to identify the next COVID-like disease, which is surely out there and probably already spilling over somewhere in S. China.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Peter Daszak (b) (6)

Sent: Sunday, April 11, 2021 5:11 PM
To: (b) (6); 'Erbelding, Emily (NIH/NIAID) [E]' (b) (6); 'Cristina (NIH/NIAID) Cassetti' (b) (6); (b) (6); 'Post, Diane (NIH/NIAID) [E]' (b) (6); 'Erik (NIH/NIAID) Stemmy' (b) (6)
Cc: 'Aleksei Chmura (b) (6)
Subject: FW: Regarding 2R01AI110964-06
Importance: High

Dear all,

I'm just forwarding my response (attached letter and email chain below) to Michael Lauer re. the 10 conditions imposed on the grant to EcoHealth Alliance.

I've tried to stick to a logical argument, but I'm also mindful of the dozens of FoIA requests targeting EHA and myself and that previous letters have been leaked to the press, so have made sure all details are laid out. I do not aim to make this letter public, of course and am sending this to you confidentially.

As per my email to Dr. Lauer below, the intent of this letter is to demonstrate in good faith what we believe are reasonable efforts to address these conditions and to state the limits of what is possible. The goal is full and rapid reinstatement of our funding – not only because of the damage this has already done to our organization and my personal safety, but more importantly because coronaviruses are likely continuing to spill over into people in the region and our research may help reduce that risk.

Thanks for all your help and support and I will let you know what I hear back from the Director's Office in due course.

Cheers,

Peter

Peter Daszak
President

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USA

Tel.: (b) (6)

Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Peter Daszak (b) (6)
Sent: Sunday, April 11, 2021 4:36 PM
To: 'Lauer, Michael (NIH/OD) [E]' (b) (6)
Cc: Aleksei Chmura (b) (6); 'Lauer, Michael (NIH/OD) [E]' (b) (6)
Subject: Regarding 2R01AI110964-06
Importance: High

Dear Dr. Lauer,

Please find attached a detailed response to your two previous letters.

I hope you will take our response in the way it was intended – a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

Cheers,

Peter

Peter Daszak
President

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Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak (b) (6)

Cc: Aleksei Chmura (b) (6); Lauer, Michael (NIH/OD) [E]
(b) (6)
Subject: Re: Regarding 2R01AI110964-06

Dear Dr. Daszak

Attached please find two letters that I sent you previously.

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Peter Daszak (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: Aleksei Chmura (b) (6) ***[Peter Daszak:]*** REDACTED>
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. ***[Peter Daszak:]*** **REDACTED** joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

Peter Daszak
President

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460 West 34th Street
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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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EcoHealth Alliance

Dr. Michael Lauer
Deputy Director for Extramural Research,
NIH, Bethesda, MD.

Re: R01AI110964 and 2R01AI110964
"Understanding the Risk of Bat Coronavirus Emergence"

April 23rd 2021

Dear Dr. Lauer,

I am responding your letter of 4/13/21 regarding our response to conditions placed on the suspended NIH grant 2R01AI110964 "*Understanding the Risk of Bat Coronavirus Emergence*". In particular, this letter addresses your request for documentation on our assessment of WIV's compliance with terms of our subcontracts from the initial (now expired) 5-year award:

"*…copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any and all other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award …. NIH must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5)…"*

As requested, we have supplied all EcoHealth Alliance-WIV subrecipient agreements, as well as documents pertaining to EHA's monitoring of WIV's compliance with the terms and conditions of award. The attached documents demonstrate that we have fulfilled all requirements in the CFR codes listed in your letter excerpted above. These documents include:

1. EcoHealth Alliance 2016-2019 Subrecipient Monitoring Forms for WIV. EcoHealth Alliance began this formal subrecipient monitoring policy in 2016 as per OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR 200) ("Uniform Guidance"), specifically §200.331.
2. 2006-2018 WIV Annual Reports. In addition, NIH has full reports on the programmatic results that we filed annually.
3. Wuhan Institute of Virology contracts and invoices for all 5 Years of Grant R01AI110964: 2014-2019
4. Federal Funding Accountability & Transparency Act Reports for WIV. From 2015 – 2019
5. Annual Independent Audit Reports from 2014-2019
6. Inter-Institutional Agreements from DHHS for WIV 2014 & 2019

EcoHealth Alliance
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New York, NY 10018
212.380.4460
EcoHealthAlliance.org

We hope these documents satisfy your request by demonstrating that EcoHealth Alliance maintained detailed records of our appropriate monitoring of WIV's performance against the conditions of our initial (now expired) R01 grant and our contracts with them.

We also would like draw your attention to our letter dated 4.11.2021 regarding plans for biosafety monitoring for the renewal R01, under which we had not yet set up a subcontract with WIV, specifically:

"8. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.

As we related in response to your letter of 4/19/2020 that asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of this award, therefore no such subrecipient agreements exist. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a leading lab biosafety contractor based in Southeast Asia (Dr. Paul Selleck) who has extensive experience commissioning, accrediting and auditing BSL-2, -3, and -4 labs, and has worked for over a decade at the BSL-4 Australian Animal Health Lab. We will be using their services where appropriate for foreign lab subcontractees to assess lab biosafety procedures and conduct audits, including following the full reinstatement of 2R01AI110964. Finally, we have appointed a Senior Field Veterinarian who will oversee all EcoHealth Alliance fieldwork in the region and ensure continued compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, despite our unblemished record on biosafety, to pre-empt calls for further sanctions against our work given the continued attacks against EcoHealth Alliance in the press after the termination of our NIH grant."

We believe the attached documents lay out details of how we had previously monitored compliance according to the federal codes you cite, and the above response lays out an appropriate plan for biosafety monitoring. Together, we believe they appropriately and fully addresses your condition #8 for full reinstatement with access to funding for the renewal phase of the R01.

Yours sincerely,

(b) (6)

Dr. Peter Daszak, President
(t) (b) (6); (e) (b) (6)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

13 April 2021

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964 and your letter of April 11, 2021

Dear Drs. Chmura and Daszak:

Thank you for your letter of April 11, 2021. We are reviewing your responses in detail.

In the meantime, though, and in interest of expediting our review, we would note that our previous letters were concerned with NIH Grant R01AI110964 (which started on started on June 1, 2014 as documented in RePORTER) and not solely with 2R01AI110964-06. Therefore, as we asked on October 23, 2020, please send us copies of *all* EcoHealth Alliance – WIV subrecipient agreements as well as any and all other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety. While we understand that you may not have activated a subaward for year 6, we would expect there to be substantial documentation of your oversight of WIV subaward activities during years 1 through 5.

Also, as we asked, please send us copies of *all* biosafety reports; we would expect that as part of your oversight you would have copies of all such reports through at least year 5.

As a reminder, as a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit as requested.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2021.04.13 13:12:57 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

From:	Chen, Ping (NIH/NIAID) [E]
To:	Ford, Andrew (NIH/NIAID) [E]; Boyd, Nancy (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]
Cc:	Bryant, Paula (NIH/NIAID) [E]; Hewitt, Judith (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Lyon, Rickie (NIH/NIAID) [C]
Subject:	Re: INPUT DUE noon 4/28 - For Review: Response to House Energy and Commerce Committee on WIV
Date:	Monday, April 26, 2021 4:47:08 PM
Attachments:	Pallone WIV NIAID DRAFT 4-26EE AOF_PC.docx

Andrew,

I provided information on two questions for your reference. I will have you draft the appropriate response.

Ping

From: "Ford, Andrew (NIH/NIAID) [E]" (b) (6)
Date: Monday, April 26, 2021 at 12:42 PM
To: "Boyd, Nancy (NIH/NIAID) [E]" (b) (6), "Chen, Ping (NIH/NIAID) [E]" (b) (6), "Stemmy, Erik (NIH/NIAID) [E]" (b) (6)
Cc: "Bryant, Paula (NIH/NIAID) [E]" (b) (6), "Hewitt, Judith (NIH/NIAID) [E]" (b) (6), "Hauguel, Teresa (NIH/NIAID) [E]" (b) (6), "Post, Diane (NIH/NIAID) [E]" (b) (6), "Ford, Andrew (NIH/NIAID) [E]" (b) (6), "Lyon, Rickie (NIH/NIAID) [C]" (b) (6)
Subject: INPUT DUE noon 4/28 - For Review: Response to House Energy and Commerce Committee on WIV

Dear Nancy, Ping, and Erik,

Please see the email below regarding the attached request (PDF attachment) from the Minority leadership of the House Energy and Commerce Committee concerning WIV and CoV research.

NIH OER has begun drafting responses to the questions; these draft responses and initial thoughts from me and Emily can be found in the second attachment.

Please review the draft responses, incorporate any edits/comments using track changes and send the resulting document to me by **12:00pm (noon), Wednesday, April 28, 2021**. Please note, for some responses OER had indicated that advice/guidance from OLPA would be helpful; thus far we have not received any corresponding advice/guidance. Additionally, some of the questions regard information that NIH may have received from extramural entities; if we have the requested information, please do send it with your response, if we do not, there is no need to seek the information.

I will also be taking another look at the draft responses.

Should you wish to discuss, please let me know.

Thanks,
Andrew

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Monday, April 26, 2021 at 9:09 AM
To: Emily Erbelding (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" (b) (6)
Cc: NIAID OCGR Correspondence (b) (6), NIAID OCGR Leg (b) (6), NIAID BUGS (b) (6), NIAID DEA DART (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6), "Billet, Courtney (NIH/NIAID) [E]" (b) (6), "Harper, Jill (NIH/NIAID) [E]" (b) (6), "Lane, Cliff (NIH/NIAID) [E]" (b) (6)
Subject: For Review: Response to House Energy and Commerce Committee on WIV

Colleagues:

Attached is a letter to Dr. Collins from the Minority leadership of the House Energy and Commerce Committee regarding WIV. You may recall that we recently discussed this letter and suggested that OER take the lead with limited NIAID input. OER has responded with the attached draft response requesting broad NIAID input.

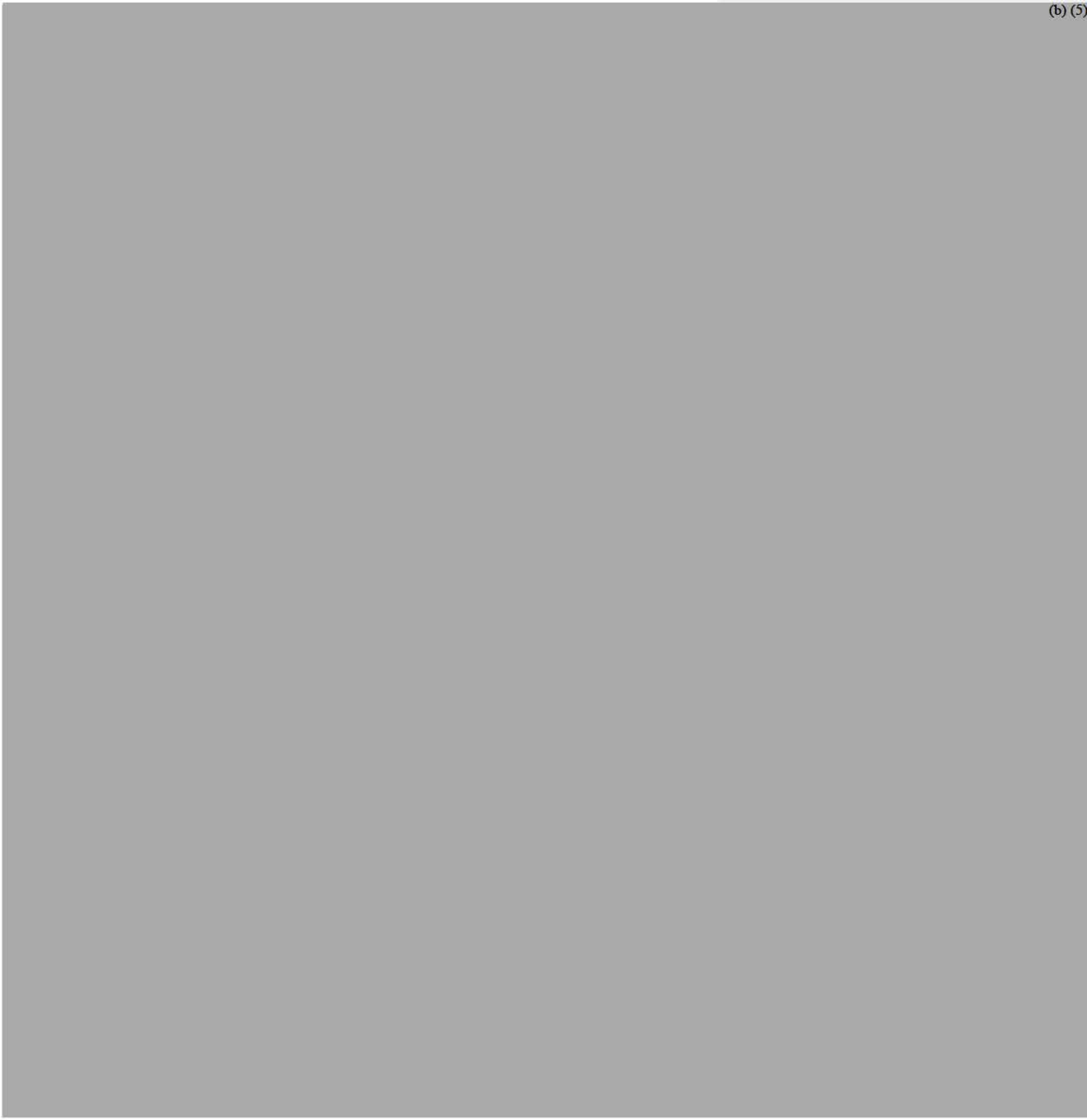
The following documents are attached:

1. The incoming.
2. The current draft response.

Please review the attached draft that NIAID Leg has annotated. We would appreciate your specific edits and comments no later than COB, Wednesday, April 28th. Note that Dr. Collins will testify before the Committee this week at its hearing on PACS.

Let us know if you have any questions.

Thanks,
Kara



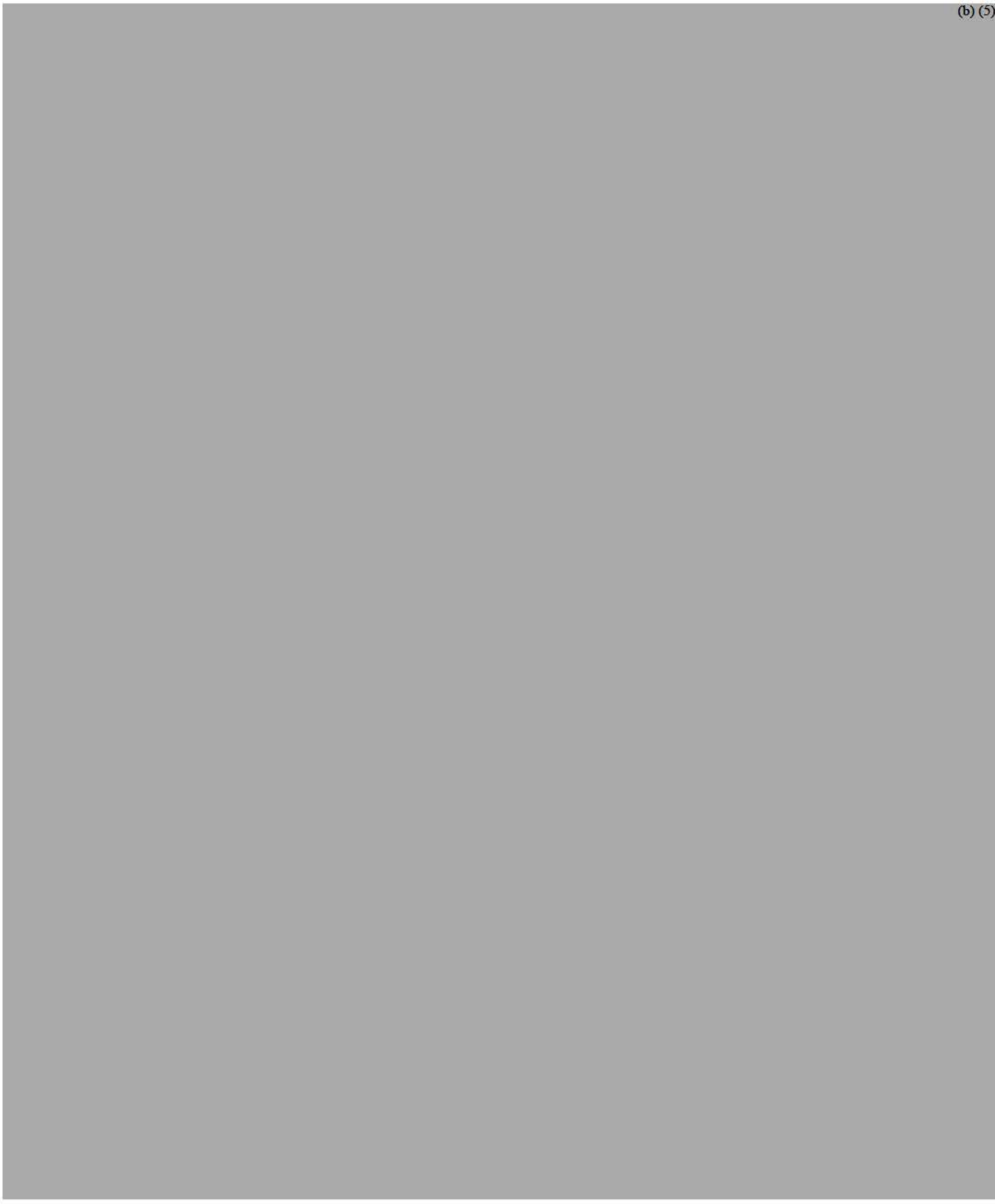
(b) (5)

[redacted]

(b) (5)

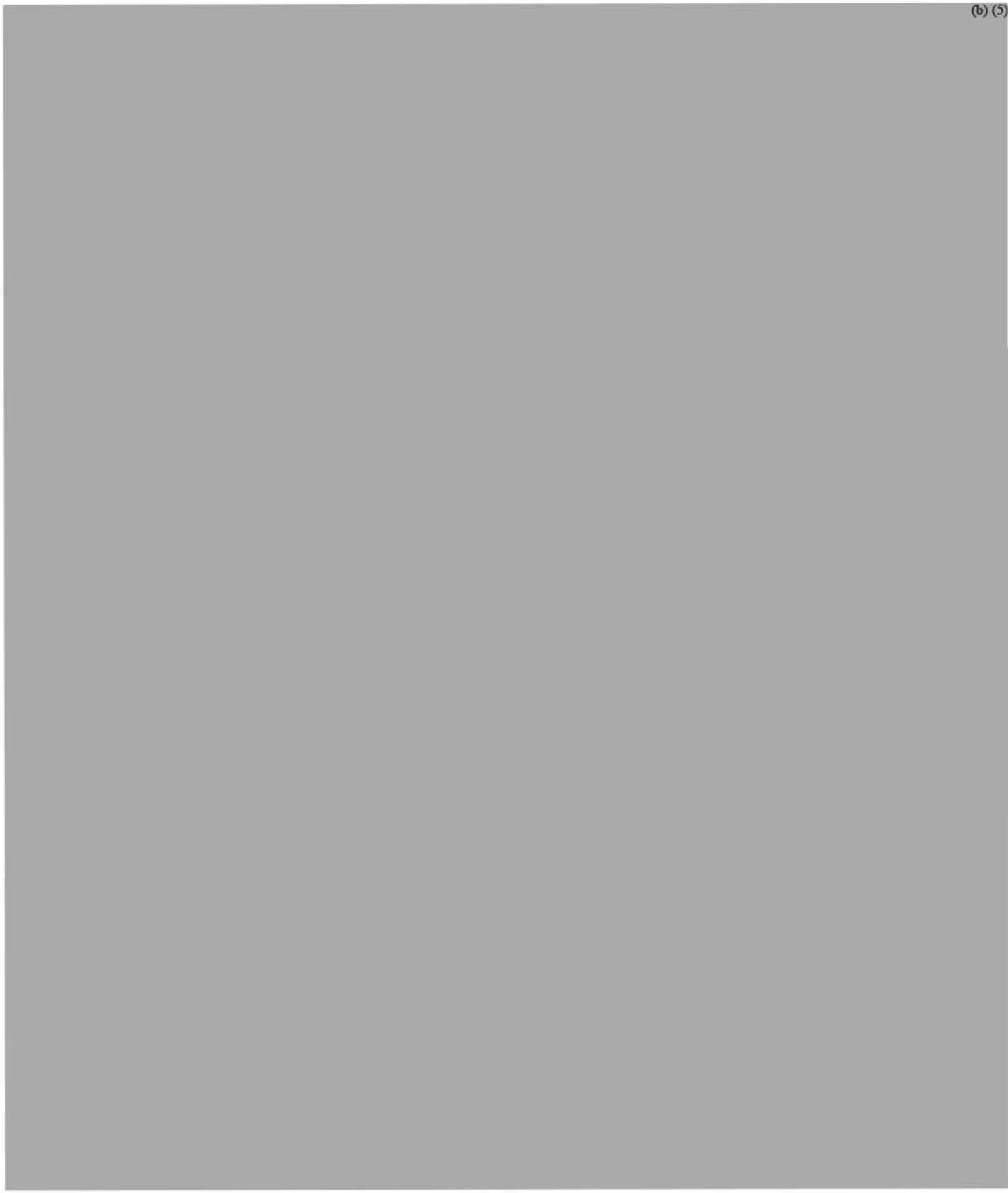
(b) (5)

[redacted]



(b) (5)

[redacted]



From:	Peter Daszak
To:	Fenton, Matthew (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]
Cc:	Aleksei Chmura
Subject:	FW: Regarding 2R01AI110964-06
Date:	Sunday, April 11, 2021 5:14:05 PM
Attachments:	Response to NIH April 2021 re. reactivation and suspension of 2R01AI110964.pdf

Dear all,

I'm just forwarding my response (attached letter and email chain below) to Michael Lauer re. the 10 conditions imposed on the grant to EcoHealth Alliance.

I've tried to stick to a logical argument, but I'm also mindful of the dozens of FoIA requests targeting EHA and myself and that previous letters have been leaked to the press, so have made sure all details are laid out. I do not aim to make this letter public, of course and am sending this to you confidentially.

As per my email to Dr. Lauer below, the intent of this letter is to demonstrate in good faith what we believe are reasonable efforts to address these conditions and to state the limits of what is possible. The goal is full and rapid reinstatement of our funding – not only because of the damage this has already done to our organization and my personal safety, but more importantly because coronaviruses are likely continuing to spill over into people in the region and our research may help reduce that risk.

Thanks for all your help and support and I will let you know what I hear back from the Director's Office in due course.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
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Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance

Dr. Michael Lauer
Deputy Director for Extramural Research,
NIH, Bethesda, MD.

Response to the Reinstatement and immediate suspension of 2R01AI110964 "Understanding the Risk of Bat Coronavirus Emergence"

April 11th 2021

Dear Dr. Lauer,

I am responding your letters of 7/8/2020 and 10/3/2020 regarding the reinstatement and immediate suspension of NIH grant 2R01AI110964 "*Understanding the Risk of Bat Coronavirus Emergence*", that was terminated "for convenience" on 4/24/2020. In particular, this letter addresses the conditions you state would need to be fulfilled in order for us to have access to the funds to continue this work.

As you know, we had not set up any subcontracts to the Wuhan Institute of Virology under this renewal R01. Immediately following NIH's letter on 4/19/2020 that the WIV was being 'investigated', we suspended all plans for contractual work with WIV. This termination of a funded relationship with the institute makes it extraordinarily difficult and more likely impossible to provide the information requested about an autonomous foreign organization – as would also be the case for a domestic one - that our organization neither works with currently, nor has control over.

Additionally, our collaborative work with the Wuhan Institute of Virology prior to your grant termination letter of 4/24/2020 and that planned in the suspended grant, is wholly unrelated to many of the conditions listed below. These conditions also pertain to certain events and situations that in no way involve EcoHealth Alliance or are not under our control. Thus, most of the conditions below are either unrelated to EcoHealth Alliance's planned research in our highly rated, approved and funded grant application, and/or to the biosafety of our continued research funded by the suspended grant when it is reinstated in full.

Furthermore, in our recent correspondence with NIH regarding the latest in a series of FoIA requests, we were informed (1/26/2021 – see email correspondence at the end of this letter) by an NIH staff member Garcia-Malene Gorka that "any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations into that organization." Because this was the explanation in your initial letter of 4/19/2020 for the decisions from your office regarding restrictions on, termination of, then reinstatement and suspension of our grant, we believe that these decisions should now be reassessed.

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Despite our concerns about the relevance, fairness, or ability to fulfil the conditions as set forth in detail below, I have made extensive efforts to satisfy NIH's broad concerns, and have provided details of how these are relevant to each condition below. This includes serving as an expert on the WHO-China joint Mission on the Animal Origins of COVID-19, which involved 1 month on the ground in China (including 2 weeks locked in quarantine), at great personal burden and risk to me, to our organization, and to my family. I undertook this mission at a time when I have had increasing levels of personal attack and harassment, including a white-powder letter to my home address a few weeks after the details of our grant termination went public, and death threats that begun at the same time and continue to this day. It is clear in the wording of these attacks that many are a direct result of dangerous conspiracy theories inadvertently amplified by NIH's grant termination, and repeated in the conditions listed below. This type of harassment has accelerated to the point that personal security guards are now stationed at my home address, where I have also had to install invasive equipment and set up procedures to protect my family against expected violent attacks. Additionally, I now meet regularly with FBI agents and others at my home to monitor these threats. As I am sure you appreciate, this has a significant toll on my work, my personal life and my family.

Below, I detail our response to each of the conditions placed on our suspended grant, in an effort to provide as much information as possible and to explain the limitations on what we can do to respond. I look forward to your reply and hope that these will allow NIH to lift the suspension on funding so that we can continue our work to help protect our nation, indeed the global population, against future coronavirus pandemics. Should you wish, I feel certain we may discuss these points without legal counsel in a scientist-to-scientist conversation, as you have suggested verbally to others at NIH, and they have conveyed to me.

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
We believe this condition is effectively impossible for us to fulfil, for the following reasons. Firstly, there is no scientific nor administrative rationale for us to attempt to obtain a SARS-CoV-2 aliquot given that it is not part of our funded collaboration with WIV. Secondly, EcoHealth Alliance scientists do not have any capacity to work on such an aliquot (EHA does not conduct virological laboratory work on SARS-CoV-2) in the USA. This further reduces the validity of a scientific basis for this request to WIV. Thirdly, EcoHealth Alliance scientists were not part of the work that WIV conducted to determine the viral sequence of SARS-CoV-2, and this was not part of our (then active) R01 funded collaboration. This is publicly stated by the lack of EHA authors listed on the paper and the lack of acknowledgement of our grant as a funding source for this work. This publicly discounts any claim of sample ownership or control. Fourthly, the collaborative research laid out in our now-suspended grant does not include the shipping of human viral isolates out of China. Finally, during the last 16 months, there has been a series of vitriolic attacks from the US Government accusing China of bioengineering and releasing SARS-CoV-2 or of otherwise allowing COVID to become pandemic. Given these attacks, and WIV's status as a government entity, it seems to us incredulous that any request, particularly without scientific rationale, from a US non-profit to a Chinese Government laboratory for an active sample of a pathogenic human virus would likely be successful. We note that 1) to our knowledge China has not supplied such an aliquot to any formal request from a government; and 2) that if circumstances were reversed and a Chinese non-

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governmental institution requested a similar pathogenic viral aliquot from a US government BSL-4 laboratory, this would also be unlikely to be fulfilled.

While we understand that it may be of scientific interest to some US-based researchers to analyze this viral sequence, this scientific interest could easily be satisfied without the need for an aliquot. The full genome of this viral sequence was uploaded to a freely accessible database on January 10 2020, and has been used widely by scientists in the USA (included those funded by NIH) and around the world in their work. Furthermore, isolates of the virus from patients in Thailand and Australia during early 2020 are essentially the same, and have been shared extensively.

2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.

International experts on the WHO COVID-19 origins mission, including myself, asked direct questions on this issue to staff at WIV, including the Director of the institute, the P4 Lab Director, Dr. Shi and others. The response from all was consistent, as stated in the WHO mission report published 3/30/2020: "This person according the WIV staff was an alumnus who graduated in 2015 and was now working in a different province and did not accept to talk with media. The person had been contacted and tested and ascertained to be healthy."

Given that the WHO team was not given access to this individual, and that China's personal privacy laws are preclude our ability to insist on a meeting, it is difficult to see how a request from a US non-profit would have been approved. It seems at the least to be significantly outside the remit of a US-based non-profit organization to inquire further about the whereabouts of a citizen of a foreign country who has never to our knowledge been involved in our work, and over whom we have no control, influence, nor legal responsibility.

Finally, while many conspiracy theorists have suggested that the lack of a web presence of this person suggests some nefarious activity, there are dozens of unremarkable and routine reasons why a person may be removed from a web listing of employees or students. Not least of these is when a staff member leaves an institution, or a student graduates.

3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.

We believe that WIV senior staff comments reported in the WHO COVID origins mission report directly address this request in that they publicly state that no significant safety issues were found in their laboratory prior to, or following, the emergence of COVID. Any questions regarding the safety of the WIV also need to be put into the context of the widely published history of this lab as being built to international safety engineering standards, adhering to international safety practice standards indicated in the BMBL, and with lead WIV staff trained in safety in the United States by a known authority running the BSL-4 lab at the University of Texas Medical Branch in Galveston (as reported in the U.S. Dept of State cables). Furthermore, no verifiable evidence of safety issues have been reported prior to, or following the U.S. Dept of State cables.

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Regarding the U.S. Dept. of State cables, these do not in fact provide evidence of safety concerns at the laboratory. Neither do they convincingly imply safety issues. In fact, they may be simply interpreted as a request for funding from a diplomatic mission set up to further joint US-China research. It is important to note that initially only very limited phrases from these cables were selectively leaked by a Washington Post reporter in an opinion piece that did not verify nor quote direct sources. This opinion piece is demonstrably incomplete in its reporting, however it has been widely cited as providing evidence of safety issues at WIV (https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/). I have some detailed knowledge of the background to these cables because the diplomatic visit to WIV that they report was a direct result of our NIH-funded work. As part of EcoHealth Alliance's work in China over the past 15 years, including that funded by NIAID, I visited the US Embassy in Beijing regularly and was involved in discussions with US Embassy staff to set up a field visit to the WIV in order to generate goodwill between the US and China at a time when President Trump was planning a state visit. I did this out of a sense of duty to our government, and to the NIH so that our project could help foster goodwill between our countries, as well as provide an indication of the importance of NIH's work. Following the US Embassy staff mission, I was told by people privy to the cable's contents that the articles were positive and supportive of the work we were doing under NIAID funding, and that the trip was a success.

Now that the full text of these cables (embedded at the end of this letter) has been released with minor redactions (https://news.slashdot.org/story/20/07/20/0611205/full-text-of-us-state-department-cables-finally-released-showing-safety-in-chinese-lab), it seems that this more positive interpretation is justified. As you can see in the excerpts below, the request for more laboratory technician support could be reasonably interpreted as simply a request for the funding for more laboratory technician support, rather than a statement that the lab was unsafe, particularly given that the visit was set up as part of an effort to further develop US-China collaborative research opportunities. Furthermore, the cables are extremely positive about the importance of the collaborative work we were conducting with WIV under NIAID funding:

"**REDACTED** noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China."

"The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study **REDACTED** (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS

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Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like corona viruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention."

4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.

The WIV staff categorically stated to the WHO mission that their lab is audited annually and no unusual events have been identified. The reports of diminished cell-phone traffic and roadblocks have not been verified or published by reliable sources. Furthermore, should hard evidence of diminished cell-phone traffic and roadblocks exist, it is not necessarily indicative of any issues related to concerns about the laboratory studies underway or safety or security incidents within the laboratory. These issues could be explained by any one of a series of issues that occur regularly in the US without nefarious connotations. For example, they could be due to roadwork or other infrastructure repair or maintenance, technical problems with cell-phone transmission, or rerouting of traffic as regularly occurs in Washington DC and other cities due to transport of visiting dignitaries or other events. Finally, there is no credible reason to think that any request a US non-profit might make to the Chinese government for an explanation of traffic or cell-phone issues would result in any response.

5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.

Since your letter of 7/8/2020, it has been widely reported that WIV scientists have published an addendum to their original paper in *Nature* that described SARS-CoV-2 and compared it phylogenetically to RaTG13. In this follow-up publication, they explain the rationale for conducting work in this mine, and any potential connection to the miner's illnesses and deaths. Importantly, they state that serological results in their lab at the time of the incident did not show that these miners were positive for SARSr-CoVs as some media articles have suggested. They then re-tested the miner samples in 2020 using a range of assays, and found no evidence of SARS-related CoV, nor of SARS-CoV-2 specific antibodies or nucleic acid. During the meeting of the WHO mission team with WIV staff, they were asked a series of questions about the miner's illnesses. The responses were that, while symptoms identified were similar to COVID in that they had pneumonia (a common occupational hazard for miners), their symptoms were also similar to other bacterial or fungal pneumonias. This, and the lack of evidence for SARSr-CoV infection, led them to conclude that SARS or COVID infection was not the cause of these miner's illnesses.

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6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV fieldwork (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.

The WHO mission was negotiated at the very highest levels as the legitimate way to proceed in an investigation of COVID-19 origins, particularly with such critical geopolitical ramifications from this pandemic. Given the intensity of political attacks and conspiracy theories around this lab, it is unreasonable to expect that the Chinese government or WIV would respond to a request from a US non-profit for an outside inspection team. The 11 international expert members of the WHO team included authorities on epidemiology, animal-origin viral infections and One Health. Members of this team have extensive experience conducting lab audits (e.g. Dr. Peter Ben Embarek), running laboratories dealing with human clinical samples (e.g. Drs. Dominic Dwyer, Thea Fischer), and commissioning, managing and accrediting laboratories in foreign countries (myself, Dr. Fabian Leendertz). The WHO-China Joint Study report details the field site visits to multiple labs in Wuhan, including the WIV and summarizes our findings. This includes information on the management of the WIV, safety at the labs, audits and training and testing of staff. I acted in good faith to try to conform to the WHO terms of reference while ensuring that as much information on the laboratory was provided in the report. This information specifically addresses one of your questions above, with categorical statements from WIV senior staff that they did not have SARS-CoV-2 in their possession prior to December 2019.

After returning to the USA, and in the weeks prior to the publication of the report, I worked hard to make sure this critical information was shared as rapidly as possible with the US Government and agencies, including by:

- Briefing Drs. Anthony Fauci and Clifford Lane of NIAID on the findings of the mission;
- Presenting a full talk about the work to the NIAID COVID PI group that meets weekly
- Briefing FBI and other US Government intelligence agency staff
- Briefing members of the US NASEM Forum on Microbial Threats
- Briefing staff on the White House National Security Council
- Briefing staff on the House Committee for Science, Space, and Technology

7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

This has been done and all subawards fully reported as soon as we could once you notified us of this requirement in your letter of 7/8/2020.

8. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.

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As we related in response to your letter of 4/19/2020 that asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of this award, therefore no such subrecipient agreements exist. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a leading lab biosafety contractor based in Southeast Asia (Dr. Paul Selleck) who has extensive experience commissioning, accrediting and auditing BSL-2, -3, and -4 labs, and has worked for over a decade at the BSL-4 Australian Animal Health Lab. We will be using their services where appropriate for foreign lab subcontractees to assess lab biosafety procedures and conduct audits, including following the full reinstatement of 2R01AI110964. Finally, we have appointed a Senior Field Veterinarian who will oversee all EcoHealth Alliance fieldwork in the region and ensure continued compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, despite our unblemished record on biosafety, to pre-empt calls for further sanctions against our work given the continued attacks against EcoHealth Alliance in the press after the termination of our NIH grant.

9. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.

Over a 15-year period of collaboration with WIV, we have found no evidence to suggest that there was any element of noncompliance with any of the conditions of the grants or contracts covering our collaboration. Our interactions with all staff at the institute have been professional, respectful, open, and with a focus on the science at a very high level. This has contributed to a relationship built on trust and one that is entirely comparable to our scientific collaborations with laboratories in the US, Europe, Australia, Thailand and over 20 other countries. We continue to believe that this laboratory is highly competent and is an extremely low risk for undisclosed accidental release of virus, and there is no verifiable indication as to why we should not continue to believe so. We would of course consider a change in this assessment if significant and verifiable evidence of lab biosafety issues or breach of other Federal statutes are brought forth, but to date we are aware of none.

10. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

Given the intense geopolitical pressure around the accusations that WIV intentionally or accidentally released SARS-CoV-2 (something which the WHO mission deemed 'extremely unlikely'), obtaining such information is not a plausible option at present.

11. Additional information, re. Lack of ongoing investigation into Wuhan Institute of Virology by NIH:

From: Garcia-Malene, Gorka (NIH/OD) [E] (b) (6)
Sent: Tuesday, January 26, 2021 12:20:51 PM
To: [REDACTED]
Cc: [REDACTED] Bartok, Lauren (NIH/NIAID) [E]; NIH FOIA
Subject: [EXT] FW: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

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Good afternoon, **[REDACTED]** –

I'd like to insert myself into the unfolding FOIA conversation in hopes of providing some helpful context. Our records show that this competing renewal has in fact been funded. In addition, any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations into that organization. If we can agree on the above, all that would remain is to receive your proposed redactions to the records sought under the FOIA request.

Please let me know if there are any questions. I look forward to facilitating the Pre-Disclosure Notification process as efficiently as possible.

Best regards.

Gorka Garcia-Malene | FOIA Officer for the National Institutes of Health

From: [REDACTED]
Sent: Monday, January 25, 2021 5:21 PM
To: Bartok, Lauren (NIH/NIAID) [E] (b) (6)
Cc: [REDACTED]
Subject: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

Dear Ms. Bartok:

As you may recall, this firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance"), with respect to certain FOIA requests, including the instant request, FOIA Case No. 55702. The instant request seeks the same documents sought last year in FOIA Case No. 53996, regarding the research project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01AI110964. A copy of our prior letter regarding FOIA 53996 is available via the link provided below using the password **[REDACTED]**. On the grounds set forth in the letter, FOIA 53996 was denied in its entirety.

Likewise, FOIA 55702 should be denied and the grant documents should be withheld. First, grant 2R01AI110964-06 remains an unfunded competing renewal grant that is the subject of a pending first-level appeal and, thus, the materials are not subject to disclosure under NIH Grants Policy Statement §2.3.11.2.2. Moreover, in the context of the appeal, NIH has made multiple requests for further information regarding The Wuhan Institute of Virology ("WIV"), which requests indicate that a law enforcement investigation concerning WIV remains ongoing. Second, as demonstrated by the recent attack on the US Capital fueled by disinformation and conspiracy theories, the need to protect the privacy of EcoHealth Alliance's employees and affiliates is more important than ever. Last, while EcoHealth Alliance did not initially identify that the grant proposal contained confidential-commercial and propriety information, this is not dispositive. Moreover, since the

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filing of the renewal application, there has been a global COVID-19 pandemic, which has sparked international and highly competitive research in the area of bat coronaviruses.

At the very least, the responsive documents will require significant redactions. While the grant documents were previously reviewed and redacted in connection with FOIA 53996, we require a further opportunity to review the documents to confirm, *inter alia*, that all personnel information has been removed given the heightened risk of harm in this unprecedented political environment. Accordingly, EcoHealth Alliance respectfully requests a forty-five (45) day extension of time to respond to FOIA 55702, to allow sufficient time for EcoHealth Alliance to conduct a further review of the responsive documents and provide an updated letter response that incorporates recent developments and specific justifications for additional redactions.

Please confirm that NIH will deny FOIA 55702 in its entirety or that NIH is agreeable to EcoHealth Alliance's request for an extension of time to provide a particularized response to FOIA 55702. Please also confirm NIH's receipt of this email.

Thank you.

Best,
[REDACTED]

FOIA Case No. 53996 - EcoHealth Alliance's Letter Response to FOIA Request, dated June 5, 2020 (With Exhibits)
[REDACTED]

[REDACTED]

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12. Publicly released details of U.S. Department of State Cables regarding visit to Wuhan Institute of Virology, as cited in condition #3 above. These are available from a number of sources, including the Washington Post and (https://news.slashdot.org/story/20/07/20/0611205/full-text-of-us-state-department-cables-finally-released-showing-safety-in-chinese-lab).

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MRN:	18 BEIJING 138
Date/DTG:	Jan 19, 2018 / 190739Z JAN 18
From:	AMEMBASSY BEIJING
Action:	WASHDC, SECSTATE *ROUTINE*
E.O.:	13526
TAGS:	SHLH, ETRD, ECON, PGOV, CN
Captions:	SENSITIVE
Reference:	17 WUHAN 48
Subject:	China Opens First Bio Safety Level 4 Laboratory

1. (SBU) **Summary and Comment:** The Chinese Academy of Sciences (CAS) has recently established what is reportedly China's first Biosafety Level 4 (BSL-4) laboratory in Wuhan. This state-of-the-art facility is designed for prevention and control research on diseases that require the highest level of biosafety and biosecurity containment. Ultimately, scientists hope the lab will contribute to the development of new antiviral drugs and vaccines, but its current productivity is limited by a shortage of the highly trained technicians and investigators required to safely operate a BSL-4 laboratory and a lack of clarity in related Chinese government policies and guidelines. (b)(5)

(b)(5)

(b)(5) **End Summary and Comment.**

China Investing in Infectious Disease Control

2. (U) Between November 2002 and July 2003, China faced an outbreak of Severe Acute Respiratory Syndrome (SARS), which, according to the World Health Organization, resulting in 8,098 cases and leading to 774 deaths reported in 37 countries. A majority of cases occurred in China, where the fatality rate was 9.6%. This incident convinced China to prioritize international cooperation for infectious disease control. An aspect of this prioritization was China's work with the Jean Merieux BSL-4 Laboratory in Lyon, France, to build China's first high containment laboratory at Wuhan's Institute of Virology (WIV), an institute under the auspices of the Chinese Academy of Sciences (CAS). Construction took 11 years and $44 million USD, and construction on the facility was completed on January 31, 2015. Following

two years of effort, which is not unusual for such facilities, the WIV lab was accredited in February 2017 by the China National Accreditation Service for Conformity Assessment. It occupies four floors and consists of over 32,000 square feet. WIV leadership now considers the lab operational and ready for research on class-four pathogens (P4), among which are the most virulent viruses that pose a high risk of aerosolized person-to-person transmission.

Unclear Guidelines on Virus Access and a Lack of Trained Talent Impede Research

3. (SBU) In addition to accreditation, the lab must also receive permission from the National Health and Family Planning Commission (NHFPC) to initiate research on specific highly contagious pathogens. According to some WIV scientists, it is unclear how NHFPC determines what viruses can or cannot be studied in the new laboratory. To date, WIV has obtained permission for research on three viruses: Ebola virus, Nipah virus, and Xinjiang hemorrhagic fever virus (a strain of Crimean Congo hemorrhagic fever found in China's Xinjiang Province). Despite this permission, however, the Chinese government has not allowed the WIV to import Ebola viruses for study in the BSL-4 lab. Therefore, WIV scientists are frustrated and have pointed out that they won't be able to conduct research project with Ebola viruses at the new BSL-4 lab despite of the permission.

(b)(6)

(b)(6) Thus, while the BSL-4 lab is ostensibly fully accredited, its utilization is limited by lack of access to specific organisms and by opaque government review and approval processes. As long as this situation continues, Beijing's commitment to prioritizing infectious disease control - on the regional and international level, especially in relation to highly pathogenic viruses, remains in doubt.

(b)(6) noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this, (b)(6) they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China. As China is building more BSL-4 labs, including one in Harbin Veterinary Research Institute subordinated to the Chinese Academy of Agricultural Sciences (CAAS) for veterinary research use (b)(6) the training for technicians and investigators working on dangerous pathogens will certainly be in demand.

Despite Limitations, WIV Researchers Produce SARS Discoveries

6. (SBU) The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study, (b)(6) (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS-coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like coronaviruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention. (b)(5) (b)(5) WIV scientists are allowed to study the SARS-like coronaviruses isolated from bats while they are precluded from studying human-disease causing SARS coronavirus in their new BSL-4 lab until permission for such work is granted by the NHFCP.

1. Hu B, Zeng L-P, Yang X-L, Ge X-Y, Zhang W, Li B, et al. (2017) Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus. PLoS Pathog 13(11): e1006698. https://doi.org/10.1371/journal.ppat.1006698

Signature:	BRANSTAD
Drafted By:	(b)(6)
Cleared By:	
Approved By:	
Released By:	
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We await your response at the earliest opportunity.

Yours sincerely,

Dr. Peter Daszak
President

(t) (b) (6); (e) (b) (6)
cc. Dr. Aleksei A. Chmura (Chief-of-Staff)

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Peter Daszak (b) (6)
Sent: Sunday, April 11, 2021 4:36 PM
To: 'Lauer, Michael (NIH/OD) [E]' (b) (6)
Cc: Aleksei Chmura (b) (6); 'Lauer, Michael (NIH/OD) [E]' (b) (6)
Subject: Regarding 2R01AI110964-06
Importance: High

Dear Dr. Lauer,

Please find attached a detailed response to your two previous letters.

I hope you will take our response in the way it was intended – a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
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USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6)

Subject: Re: Regarding 2R01AI110964-06

Dear Dr. Daszak

Attached please find two letters that I sent you previously.

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Peter Daszak (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: Aleksei Chmura (b) (6) ***[Peter Daszak:]*** REDACTED>
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. ***[Peter Daszak:]*** **REDACTED** joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Hauguel, Teresa (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Post, Diane (NIH/NIAID) [E]
Subject: RE: Call with Alan
Date: Saturday, April 10, 2021 9:19:33 AM
Attachments: Grant Info for Alan.docx

Forgot to attach

Teresa M. Hauguel, Ph.D.
Acting Chief, Respiratory Diseases Branch
COR, Collaborative Influenza Vaccine Innovation Centers (CIVICs)
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Rockville, MD 20852
Phone: (b) (6)
Email: (b) (6)

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Saturday, April 10, 2021 9:18 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Post, Diane (NIH/NIAID) [E] (b) (6)
Subject: RE: Call with Alan

(b) (6) but let's try to connect this morning if possible. I started to pull some information together (attached) that is probably much more detailed than is needed but it was a place to start. You may already have a lot of this pulled together so I won't do anymore until we talk.

Does 10am work?

Teresa M. Hauguel, Ph.D.
Acting Chief, Respiratory Diseases Branch
COR, Collaborative Influenza Vaccine Innovation Centers (CIVICs)
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Rockville, MD 20852
Phone: (b) (6)
Email: (b) (6)

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Saturday, April 10, 2021 8:47 AM
To: Hauguel, Teresa (NIH/NIAID) [E] (b) (6)
Cc: Post, Diane (NIH/NIAID) [E] (b) (6)

Subject: Re: Call with Alan

Feeling better this am! I can jump on a call anytime you're both free.

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
Email: (b) (6)
Pronouns: He/Him/His

On Apr 9, 2021, at 4:28 PM, Hauguel, Teresa (NIH/NIAID) [E] (b) (6) wrote:

Hi Erik,

Diane and I had a chance to chat with Alan about exactly what he wants. Once you are feeling better let us know so we can jump on the phone to touch base.

Thanks,
Teresa

Teresa M. Hauguel, Ph.D.
Acting Chief, Respiratory Diseases Branch
COR, Collaborative Influenza Vaccine Innovation Centers (CIVICs)
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Rockville, MD 20852
Phone: (b) (6)
Email: (b) (6)

R01AI110964 (PI: Peter Daszak, EcoHealth Alliance)

(b) (5)

[redacted]

From:	Fowler, Karen (NIH/NIAID) [C] on behalf of Harper, Jill (NIH/NIAID) [E]
To:	Fenton, Matthew (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]; NIAID OCGR Leg
Subject:	Discuss Grassley Letter
Start:	Tuesday, March 30, 2021 4:30:00 PM
End:	Tuesday, March 30, 2021 5:00:00 PM
Location:	https://www.zoomgov.com/j/(b) (6)?pwd=M1BCaXBseHdKT1pCa0kyN0psV28rZz09
Attachments:	2021-03-08 CEG to ODNI HHS (COVID Origins).pdf 2021-03-18 CMR to Collins.pdf

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United States Senate
WASHINGTON, DC 20510

March 8, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Avril Haines
Director of National Intelligence

Mr. Norris Cochran
Acting Director
Department of Health and Human Services

Dear Director Haines and Acting Director Cochran:

On February 4, 2020, my oversight and investigations staff received a classified briefing from the Department of Health and Human Services (HHS), Office of National Security regarding the SARS-CoV-2 (hereinafter "coronavirus") threat and the status of the U.S. government's efforts to combat the spread of the deadly virus.[1] From the beginning, my goal has been to ensure a robust federal response to the threat and to better understand the origins of the virus. For example, there is still considerable debate about whether the coronavirus is a naturally occurring virus, a naturally occurring virus that escaped from a lab, or a laboratory manipulated virus that escaped from a lab.

In December 2020, a team of World Health Organization (WHO) researchers and scientists traveled to Wuhan, China to investigate the origins of coronavirus. However, according to recent reports, China refused to grant WHO researchers access to anonymized raw data from the earliest days of the outbreak which would help pinpoint the origins of the virus.[2] Instead, China produced self-generated summaries and analyses of the data which could have been manipulated by the communist Chinese government, effectively preventing a real review.[3]

In early February last year, I warned about China's reluctance to share data regarding the coronavirus outbreak.[4] I also noted that China's failure to cooperate made it more important for the Intelligence Community and HHS to work together to ensure information is efficiently

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[1] Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.
[2] Jeremy Page et al., *China Refuse to Give WHO Raw Data on Early COVID-19 Cases*, WALL ST. J. (Feb. 12, 2021), https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580.
[3] *Id.*
[4] Press Release, Grassley Urges More Information Sharing Between Health, Intelligence Agencies (Mar. 24, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-urges-more-information-sharing-between-health-intelligence-agencies; Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.

shared between them. The Trump administration ensured that federal health agencies had a seat at the table within the Intelligence Community and access to information relating to the pandemic. That cooperation and access must continue and be built upon to better combat the virus and determine its origins.

More than 500,000 Americans have died as a result of the coronavirus pandemic and trillions of taxpayer dollars have been spent to shore up our economy and take care of our citizens. Congress and the American public have a right to know and understand what work the government has done to determine the origins of the coronavirus. Accordingly, in light of your agency's role with respect to the pandemic, no later than March 22, 2021, please provide the following:

1. All information disseminated to the National Intelligence Council relating to the coronavirus pandemic.

2. All records relating to detailed genomic sequencing analyses for SARS-CoV-2 and related coronaviruses, including all records relating to research about the receptor binding domain of pangolin origin coronavirus and furin-cleavage site insertion.

3. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and any previous published and/or unpublished work by the Wuhan Institute of Virology on coronavirus chimeras.

4. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and genomic sequencing analyses on miners that were hospitalized in Yunnan Province in and around 2012.

5. All records relating to all analyses with respect to the capabilities of the Wuhan Institute of Virology to manipulate bat coronaviruses using reverse genetic technologies.

6. All records relating to illnesses at the Wuhan Institute of Virology among its personnel and scientific staff during the Fall of 2019. In your answer, please describe the type of work these employees were engaged in.

7. All records relating to work conducted at the Wuhan Institute of Virology by Chinese government agencies prior to and during Fall of 2019.

8. Please describe the steps you have taken to continue to incorporate the Department of Health and Human Services into missions involving threats to the nation's health care, including access to Intelligence Community information, and the steps you have taken to improve upon the information access provided by the Trump administration.

9. In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.

Please send all unclassified material directly to the Committee. In keeping with the requirements of Executive Order 13526, if any of the responsive documents do contain classified information, please segregate all unclassified material within the classified documents, provide all unclassified information directly to the Committee, and provide a classified addendum to the Office of Senate Security. Although the Committee complies with all laws and regulations governing the handling of classified information, it is not bound, absent its prior agreement, by any handling restrictions.

Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

March 18, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

We write to request information, assistance, and needed-leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.

The COVID-19 pandemic has been the worst public health crisis in the U.S. in about a hundred years. Over a year has passed since the deadly virus reached our shores and yet, the origin of the virus has yet to be determined. An independent, expert investigation of the origin of COVID-19 is of paramount importance to public health and biosecurity. As noted by Stanford Medical School Professor David Relman:

> A more complete understanding of the origins of COVID-19 clearly serves the interests of every person in every country on this planet. It will limit further recriminations and diminish the likelihood of conflict; it will lead to more effective responses to this pandemic, as well as efforts to anticipate and prevent the next one. It will also advance our discussions about risky science. And it will do something else: Delineating COVID-19's origin story will help elucidate the nature of our very precarious coexistence within the biosphere.[1]

Recently, the World Health Organization (WHO) attempted to investigate the origin of COVID-19. The WHO said that this investigative mission would be guided by the science, be

[1] David A. Relman, *Opinion: To stop the next pandemic, we need to unravel the origins of COVID-19*, PNAS (Nov. 2020), *available at* https://www.pnas.org/content/117/47/29246.

"open-minded," and "not exclude[e] any hypothesis."[2] Unfortunately, China did not provide complete access or independence for the critical WHO mission. On February 13, 2021, National Security Advisor Jake Sullivan issued the following statement:

> We have deep concerns about the way in which the early findings of the COVID-19 investigation were communicated and questions about the process used to reach them. It is imperative that this report be independent, with expert findings free from intervention or alteration by the Chinese government. To better understand this pandemic and prepare for the next one, China must make available its data from the earliest days of the outbreak.[3]

Because of rising tensions between the U.S. and China, the WHO scrapped plans for an interim report.[4] An international group of science experts, including specialists in virology, microbiology, and zoology, asked for a new review.[5]

The NIH, as a premier scientific institution, must lead in order to foster a transparent, independent, and science-based investigation into the origin of the COVID-19 pandemic. Such an effort must meet the WHO's stated goals of an open-minded investigation that does not exclude any plausible hypothesis.[6] In addition, the NIH is well-positioned to gather and provide information through oversight of its grants and other federal awards. Thus, the NIH is in a unique position to investigate the possibility that the pandemic stemmed from a laboratory accident or leak, especially regarding the Wuhan Institute of Virology (WIV).

NIH raised concerns over a possible link between WIV and the COVID-19 outbreak during its review of federal awards to EcoHealth Alliance, a global environmental health nonprofit organization dedicated to protecting wildlife and public health from the emergence of disease. Of the $13.7 million in federal awards that NIH authorized for EcoHealth Alliance, 17

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[2] Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), *available at* https://www.nature.com/articles/d41586-020-03165-9.
[3] The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/.
[4] Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), *available at* https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines
[5] Jaime Metzl, et al, *Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19* (March 4, 2021), *available at* https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).pdf. The co-organizer of the letter and a WHO advisor on human genome editing, Jaime Metzl, PhD, said there is an eighty-five percent chance the pandemic started with an accidental leak from the WIV or Wuhan CDC laboratory, *available at* https://jamiemetzl.com/origins-of-sars-cov-2/. ("I have no definitive way of proving this thesis but the evidence is, in my view, extremely convincing. If forced to place odds on the confidence of my hypothesis, I would say there's an 85% chance the pandemic started with an accidental leak from the Wuhan Institute of Virology or Wuhan CDC and a 15% chance it began in some other way (in fairness, here is an article making the case for a zoonotic jump "in the wild"). If China keeps preventing a full and unrestricted international forensic investigation into the origins of the pandemic, I believe it is fair to deny Beijing the benefit of the doubt.")
[6] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

projects sponsored by the National Institute of Allergy and Infectious Disease (NIAID) have provided over $7.9 million in federal awards for research of viral emergence from bats in Southeast Asia.[7] EcoHealth Alliance passed some of its funding to the WIV, and in 2020, NIH made efforts to obtain information from EcoHealth Alliance about WIV related to concerns about the origins of COVID-19. In April 2020, NIH wrote to EcoHealth Alliance and Columbia University about an NIH-funded project entitled, "Understanding the Risk of Bat Coronavirus Emergency:"

> It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ('WIV'). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs. It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.[8]

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.[9] Among other revelations, it reported the following:

- The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses. This raises questions about the credibility of WIV senior researcher Shi Zhengli's public claim that there was "zero infection" among the WIV's staff and students of SARS-CoV-2 or SARS-related viruses.[10]

- Starting in at least 2016, WIV researchers conducted experiments involving RaTG13, the bat coronavirus identified by the WIV in January 2020 as the closest sample to SARS-CoV-2 (96.2 percent similar).[11] There was no indication that this research was suspended at any time prior to the COVID-19 outbreak.

- The WIV has a published record of conducting "gain-of-function" research to engineer chimeric viruses.[12] But the WIV has not been transparent or consistent about its record of

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[7] NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), *available at* https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts.
[8] Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), *available at* https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/.
[9] U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), *available at* https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html.
[10] *Id.*
[11] *Id.*
[12] *Id.*

studying viruses similar to the COVID-19 virus, including "RaTG13," which was sampled from a cave in Yunnan Province in 2013 after several miners died of SARS-like illness.[13]

- WHO investigators must have access to the records of the WIV's work on bat and other coronaviruses before the COVID-19 outbreak. As part of a thorough inquiry, they must have a full accounting of why the WIV altered and then removed online records of its work with RaTG13 and other viruses.[14]

- Despite the WIV presenting itself as a civilian institution, the U.S. has determined that the WIV has collaborated on projects with China's military.[15] The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.[16]

- The U.S. and other donors who funded or collaborated on civilian research at the WIV have a right and obligation to determine whether any of our research funding was diverted to secret Chinese military projects at the WIV.[17]

Notably, the State Department's former lead investigator who oversaw the Task Force into the COVID-19 virus origin stated recently that he not only believes the virus escaped from the WIV, but that it may have been the result of research that the Chinese military, or People's Liberation Army, was doing on a bioweapon.[18]

Accordingly, it is imperative to determine not only where SARS-CoV-2 originated, but also how and if NIH's funding and research to projects at the WIV could have contributed to SARS CoV-2. To assist our requests and inquiry, please provide the following by April 19, 2021:

1. An assessment from a classified U.S. Defense Intelligence Agency (DIA) report included the possibility that the origins of SARS CoV-2 could have emerged accidentally from a laboratory in Wuhan, China due to unsafe laboratory practices.[19] The DIA report cited U.S. government and Chinese researchers who found "about 33 percent of the original 41 identified cases did not have direct exposure" to the market.[20] That, along with what is known of the WIV's work in past few years, raised reasonable suspicion that the

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[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

[18] Jennifer Griffin, Former top State Dept. investigator says COVID-19 outbreak may have resulted from bioweapons research accident, Fox News (March 13, 2021), *available at* https://www.foxnews.com/world/top-state-official-coronavirus-bioweapon-accident

[19] Fred Guterl, Naveed Jamali and Tom O'Connor, *The Controversial Experiments ad Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), *available at* https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503.
[20] *Id.*

pandemic may have been caused by a lab error, not a wet market.[21] Further, a WHO inspector on the recent mission noted that "we know not all of those first 174 early COVID-19 cases visited the market, including the man diagnosed in December 2019 with the earliest onset date."[22] What information does the NIH have on the earliest COVID-19 cases?

2. According to an editorial on February 23, 2021, in *The Wall Street Journal* by former Secretary of State Mike Pompeo and Miles Yu, "[China's] army of scientists claim to have discovered almost 2,000 new viruses in a little over a decade."[23] How many of these discovered viruses does the NIH have information on and were any of these viruses discovered at the WIV?

3. According to *The Wall Street Journal* editorial mentioned in the previous question, some have alleged that the WIV's virus-carrying animals were sold as pets and may even show up at local wet markets.[24] Is the NIH aware of these allegations? If so, please provide any information the NIH has related to these allegations.

4. Please provide all information that NIH has about laboratory accidents and/or biosafety practices at the WIV since January 1, 2015.

5. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about communications and events at the WIV from August 2019 to the present.

6. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about their communications with China-based NIH, Chinese National Science Foundation, CDC, and China CDC about events at the WIV from August 2019 to the present.

State Department Cables

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[21] *Id.*

[22] Dominic Dwyer, I was the Australian doctor on the WHO's COVID-19 mission to China. Here's what we found about the origins of the coronavirus, THE CONVERSATION (Feb. 21, 2021), *available at*https://www.theguardian.com/commentisfree/2021/feb/22/i-was-on-the-whos-covid-mission-to-china-heres-what-we-found. *See also* Jeremy Page and Drew Hinshaw, *China Refuses to Give WHO Raw Data on Early Covid-19 Cases*, THE WALL STREET JOURNAL (Feb. 12, 2021), *available at* https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580#:~:text=BEIJING%E2%80%94Chinese%20authorities%20refused%20to,over%20the%20lack%20of%20detail. ("Chinese authorities refused to provide World Health Organization investigators with raw, personalized data on early Covid-19 cases that could help them determine how and when the coronavirus first began to spread in China, according to WHO investigators who described heated exchanges over the lack of detail. The Chinese authorities turned down requests to provide such data on 174 cases of Covid-19 that they have identified from the early phase of the outbreak in the Chinese city of Wuhan in December 2019. Investigators are part of a WHO team that this week completed a monthlong mission in China aimed at determining the origins of the pandemic.")

[23] *Id.*

[24] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab,* THE WALL STREET JOURNAL (Feb. 23, 2021), available at https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

7. What information does NIH have about the WIV's responses to the 2018 U.S. Department of State cables (attached to this letter) regarding safety concerns?

8. The April 2018 cable from the U.S. Department of State stated that the WIV planned to invite University of Texas Medical Branch Galveston (UTMBG) researchers to do research in Wuhan's labs. Please provide any information NIH received that indicates whether the WIV invited UTMBG researchers, and whether UTMBG researchers conducted any research in Wuhan's labs.

    a. If there was such research, please provide information and any documents related to this research.

9. Why was it pertinent to the NIH investigation that the "nonprofit [EcoHealth Alliance] must provide the "WIV's responses to the 2018 Department of State cables regarding safety concerns"?[25]

    a. Did EcoHealth Alliance provide this information? If so, how did NIH use the information to further its investigation?

<u>EcoHealth Alliance, Columbia University Health Sciences</u>

10. Was the 2019 NIH federal award to EcoHealth Alliance reviewed and approved by the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) committee?[26]

    a. If so, please provide the documentation with the committee's decision.

    b. Please also provide the names of the individuals who were members of the committee at the time.

11. Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.

12. In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with "program goals and agency priorities."[27] Please specify the work that was done by the EcoHealth Alliance that did

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[25] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[26] National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), *available at* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html.
[27] *Id.*

not align with the agency's program goals and priorities, and when that work was conducted.

a. Was an evaluation of EcoHealth Alliance's work and whether it aligned with the agency's program goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?

13. In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology…has been conducting research at its facilities in China that pose serious bio-safety concerns."[28] What are the sources for those reports to NIH and what were the specific allegations reported?

14. Why did the NIH request that EcoHealth Alliance provide a sample of the pandemic coronavirus that the WIV used to determine its genetic sequence for SARS CoV-2?[29]

a. Why is this information important to NIH's investigation?

b. Has NIH obtained the sample and if so, what evaluations have been done, and for what purpose?

c. If NIH has not yet obtained the sample, what are the planned studies and evaluations NIH will conduct with the sample when it is obtained?

15. What is the nature of NIH's concerns about purported restrictions at the WIV including "diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019[,]" about the WIV lab or virus origin?[30]

a. What is the basis of information to NIH about the purported restrictions at the WIV?

b. What are the other purported restrictions at the WIV in October 2019?

16. After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions.[31]

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[28] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.
[29] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[30] *Id.*
[31] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

a. Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement.

b. What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?

c. One condition for the federal award reinstatement was for EcoHealth Alliance to arrange for an outside inspection of the WIV and its records, "with specific attention to addressing the question of whether WIV staff had SARS-CoV-2their possession prior to December 2019."[32] Why is it pertinent to the NIH's investigation if staff at WIV had SARS-CoV-2 in their possession prior to December 2019? What is the potential significance if the staff did have the virus in their possession prior to December 2019?

d. What information does NIH have that was used for the basis of requesting that the EcoHealth Alliance "must 'explain the apparent disappearance' of a scientist who worked in the Wuhan lab," and on social media was rumored to be "patient zero" of the pandemic?[33]

i. What is the potential significance about the whereabouts of this scientist and the photo being removed from the website?

17. Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University.

a. In an April 2020 email, Dr. Lauer advised Naomi Schrag of Columbia University that it would be helpful for NIH "to know about all China-based participants in this work since the Type 1 grant started in 2014 - who they were and how much money they received."[34] Why did NIH request that Columbia University provide information about all of the China-based participants?

i. What is the pertinence of the timeframe starting in 2014 for the requested information?

ii. Did Columbia University provide the NIH with the requested information about all of the China-based participants from all grantees since 2014? If so, please provide the information1. If not, why not?

Federal Funding Records

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[32] *Id.*
[33] *Id.*
[34] Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), *available at* https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say.

18. Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support.[35]

19. What is the total amount of NIH federal funding per year from 2017 through 2021 that has directly or indirectly supported the WIV scientists or research through grant recipients, including to EcoHealth Alliance; Wildlife Trust, Inc.; Columbia University Health Sciences; Trustees of Columbia University; University of North Carolina Chapel Hill; Vanderbilt University; University of Virginia; and Oregon Health and Science University?[36]

20. According to a report in *The Washington Post* on April 14, 2020, the WIV issued a news release in English about the final visit from U.S. Embassy scientist diplomats in Beijing, which occurred on March 27, 2018.[37] Does the NIH have a copy of this news release? If so, please provide a copy.

21. For NIH award recipients that have provided support to the WIV since January 1, 2012, please provide annual reports, trip reports related to the WIV, documentation of any survey or field trips by the WIV, and interim data summaries from the WIV.

22. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 where foreign sites for all Type 1 and Type 2 awards have been documented as involving the WIV.

23. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 for NIH domestic grantee awards with a foreign component involving the WIV.

24. Please provide the name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility.

25. Please provide the name(s) of the NIH Scientific Review Officers responsible for reviewing and approving any NIH financial awards to EcoHealth Alliance and any other funding recipients that supported the WIV.

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[35] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[36] National Institutes of Health, Research Portfolio online Reporting Tools, NIH RePorter *available at* https://report.nih.gov/ (last accessed March 6, 2020).

[37] Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), *available at* https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.[38] Please provide any information the NIH has on the number of bat samples and animals at the WIV.

    a. Did any NIH scientists who are fluent in Mandarin review the Chinese scientific literature on the WIV research related to coronaviruses that is dated before February 1, 2020?

27. Does the NIH have the unpublished sequences of bat coronaviruses that were maintained in the WIV database before December 30, 2019, or before the database was removed from the internet?[39] Does NIH have the full sequences of the eight viruses sampled in the Yunnan province on an EcoHealth Alliance bat-virus sampling trip in 2015?

    a. Please provide NIH's analysis if the sequences have been analyzed.

    b. If NIH does not have the sequences, can NIH get this information from the EcoHealth Alliance or from other NIH-funded sources?

28. Please provide the original version of "Origin and cross-species transmission of bat coronaviruses in China" that was submitted to *Nature* by EcoHealth Alliance on October 6, 2019, published August 25, 2020, and funded in part by NIAID (award number R01AI110964).[40] If NIH does not have the October 6, 2019 report, can NIH obtain it from EcoHealth Alliance for this response? If so, please provide the report.

29. Have NIH, EcoHealth Alliance, or other NIH award recipient(s) been denied permission or access to results of any WIV research, which indirectly received financial support from NIH awards? If so, please provide the date(s), individuals involved, and circumstances of each denial.

We request that the NIH provide the requested documents and information in a coordinated response from all stakeholders and the appropriate divisions within NIH, including but not limited to subject matter experts from NIH's Division of Security and Emergency Response, the Office of Management Assessment, the Center for Scientific Review, the National Institute of Allergy and Infectious Diseases, and the Office of Extramural Research. After the requested information has been provided, we ask that the NIH provide a briefing to the Minority Committee staff to discuss the information that the NIH has related to the origins of SARS-CoV-2, including any potential links to the WIV. Finally, we request that you appoint an NIH working group representing an appropriate diversity of scientific disciplines to collect data and

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[38] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), *available at* https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

[39] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

[40] Latinne, A., Hu, B., Olival, K.J. et al,. *Origin and cross-species transmission of bat coronaviruses in China*, Nature (Aug. 25, 2020), *available at* https://www.nature.com/articles/s41467-020-17687-3#Ack1.

information related to COVID-19 origins (including the WIV), and that the NIH working group coordinate and consult with foreign scientific agencies involved in similar work.

Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Attachment

Cc: The Honorable Frank Pallone, Chairman
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

From: Arms, Erin (NIH/NIAID) [E]
To: Fenton, Matthew (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]
Cc: NIAID OCGR Leg; DDSM Correspondences; Herrod, Lisa (NIH/NIAID) [C]
Subject: RE: FYI - scheduled for tomorrow (3/30) at 4:30-5 p.m.: Availability to discuss Sen. Grassley letter on origins of SARS-CoV-2
Date: Monday, March 29, 2021 4:04:32 PM
Attachments: 2021-03-18 CMR to Collins.pdf

Hello,

In preparation for our meeting tomorrow we wanted you to also be aware of the attached related letter.

Thanks,
Erin

From: Arms, Erin (NIH/NIAID) [E]
Sent: Monday, March 29, 2021 11:48 AM
To: Selgrade, Sara (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Leg (b) (6); DDSM Correspondences (b) (6); Herrod, Lisa (NIH/NIAID) [C] (b) (6)
Subject: FYI - scheduled for tomorrow (3/30) at 4:30-5 p.m.: Availability to discuss Sen. Grassley letter on origins of SARS-CoV-2

Hello,

Thank you to everyone for your flexibility as we worked to schedule this meeting. You should all have received a calendar invite from Karen Fowler on behalf of Dr. Harper for tomorrow from 4:30 - 5:00 p.m.

Please let me know if you did not receive the invite.

Thank you,
Erin

From: Selgrade, Sara (NIH/NIAID) [E] (b) (6)
Sent: Friday, March 26, 2021 10:01 AM
To: Fenton, Matthew (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6)

Cc: NIAID OCGR Leg (b) (6); DDSM Correspondences (b) (6); Herrod, Lisa (NIH/NIAID) [C] (b) (6)

Subject: Please advise: Availability to discuss Sen. Grassley letter on origins of SARS-CoV-2

Greetings,

Background

We have received the attached letter from Sen. Chuck Grassley (R-IA; Ranking Member, Senate Judiciary Committee) to the Office of the Director of National Intelligence (ODNI) and HHS. The letter focuses on federal government efforts related to the origin of the SARS-CoV-2 pandemic, and asks several specific questions related to the Wuhan Institute of Virology.

NIH has been asked by the HHS Office of the Assistant Secretary for Legislation (ASL) to provide input on questions 8 and 9. NIH OER and NIAID have been asked to weigh in.

Action Item

We thought it would be helpful to discuss the letter to better understand background and potential input from NIAID. Please provide your availability to discuss on Monday and Tuesday next week (March 29 and 30).

If there are other key staff that should join the discussion, please let us know.

Thanks,
Sara

Sara Selgrade, Ph.D.
Section Chief for Legislative Activities
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
Bldg. 31, Room 7A17, MSC 2520
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FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

March 18, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

We write to request information, assistance, and needed-leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.

The COVID-19 pandemic has been the worst public health crisis in the U.S. in about a hundred years. Over a year has passed since the deadly virus reached our shores and yet, the origin of the virus has yet to be determined. An independent, expert investigation of the origin of COVID-19 is of paramount importance to public health and biosecurity. As noted by Stanford Medical School Professor David Relman:

> A more complete understanding of the origins of COVID-19 clearly serves the interests of every person in every country on this planet. It will limit further recriminations and diminish the likelihood of conflict; it will lead to more effective responses to this pandemic, as well as efforts to anticipate and prevent the next one. It will also advance our discussions about risky science. And it will do something else: Delineating COVID-19's origin story will help elucidate the nature of our very precarious coexistence within the biosphere.[1]

Recently, the World Health Organization (WHO) attempted to investigate the origin of COVID-19. The WHO said that this investigative mission would be guided by the science, be

[1] David A. Relman, *Opinion: To stop the next pandemic, we need to unravel the origins of COVID-19*, PNAS (Nov. 2020), *available at* https://www.pnas.org/content/117/47/29246.

"open-minded," and "not exclude[e] any hypothesis."[2] Unfortunately, China did not provide complete access or independence for the critical WHO mission. On February 13, 2021, National Security Advisor Jake Sullivan issued the following statement:

> We have deep concerns about the way in which the early findings of the COVID-19 investigation were communicated and questions about the process used to reach them. It is imperative that this report be independent, with expert findings free from intervention or alteration by the Chinese government. To better understand this pandemic and prepare for the next one, China must make available its data from the earliest days of the outbreak.[3]

Because of rising tensions between the U.S. and China, the WHO scrapped plans for an interim report.[4] An international group of science experts, including specialists in virology, microbiology, and zoology, asked for a new review.[5]

The NIH, as a premier scientific institution, must lead in order to foster a transparent, independent, and science-based investigation into the origin of the COVID-19 pandemic. Such an effort must meet the WHO's stated goals of an open-minded investigation that does not exclude any plausible hypothesis.[6] In addition, the NIH is well-positioned to gather and provide information through oversight of its grants and other federal awards. Thus, the NIH is in a unique position to investigate the possibility that the pandemic stemmed from a laboratory accident or leak, especially regarding the Wuhan Institute of Virology (WIV).

NIH raised concerns over a possible link between WIV and the COVID-19 outbreak during its review of federal awards to EcoHealth Alliance, a global environmental health nonprofit organization dedicated to protecting wildlife and public health from the emergence of disease. Of the $13.7 million in federal awards that NIH authorized for EcoHealth Alliance, 17

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[2] Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), *available at* https://www.nature.com/articles/d41586-020-03165-9.
[3] The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/.
[4] Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), *available at* https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines
[5] Jaime Metzl, et al, *Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19* (March 4, 2021), *available at* https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).pdf. The co-organizer of the letter and a WHO advisor on human genome editing, Jaime Metzl, PhD, said there is an eighty-five percent chance the pandemic started with an accidental leak from the WIV or Wuhan CDC laboratory, *available at* https://jamiemetzl.com/origins-of-sars-cov-2/. ("I have no definitive way of proving this thesis but the evidence is, in my view, extremely convincing. If forced to place odds on the confidence of my hypothesis, I would say there's an 85% chance the pandemic started with an accidental leak from the Wuhan Institute of Virology or Wuhan CDC and a 15% chance it began in some other way (in fairness, here is an article making the case for a zoonotic jump "in the wild"). If China keeps preventing a full and unrestricted international forensic investigation into the origins of the pandemic, I believe it is fair to deny Beijing the benefit of the doubt.")
[6] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

projects sponsored by the National Institute of Allergy and Infectious Disease (NIAID) have provided over $7.9 million in federal awards for research of viral emergence from bats in Southeast Asia.[7] EcoHealth Alliance passed some of its funding to the WIV, and in 2020, NIH made efforts to obtain information from EcoHealth Alliance about WIV related to concerns about the origins of COVID-19. In April 2020, NIH wrote to EcoHealth Alliance and Columbia University about an NIH-funded project entitled, "Understanding the Risk of Bat Coronavirus Emergency:"

> It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ('WIV'). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs. It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.[8]

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.[9] Among other revelations, it reported the following:

- The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses. This raises questions about the credibility of WIV senior researcher Shi Zhengli's public claim that there was "zero infection" among the WIV's staff and students of SARS-CoV-2 or SARS-related viruses.[10]

- Starting in at least 2016, WIV researchers conducted experiments involving RaTG13, the bat coronavirus identified by the WIV in January 2020 as the closest sample to SARS-CoV-2 (96.2 percent similar).[11] There was no indication that this research was suspended at any time prior to the COVID-19 outbreak.

- The WIV has a published record of conducting "gain-of-function" research to engineer chimeric viruses.[12] But the WIV has not been transparent or consistent about its record of

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[7] NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), *available at* https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts.
[8] Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), *available at* https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/.
[9] U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), *available at* https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html.
[10] *Id.*
[11] *Id.*
[12] *Id.*

studying viruses similar to the COVID-19 virus, including "RaTG13," which was sampled from a cave in Yunnan Province in 2013 after several miners died of SARS-like illness.[13]

- WHO investigators must have access to the records of the WIV's work on bat and other coronaviruses before the COVID-19 outbreak. As part of a thorough inquiry, they must have a full accounting of why the WIV altered and then removed online records of its work with RaTG13 and other viruses.[14]

- Despite the WIV presenting itself as a civilian institution, the U.S. has determined that the WIV has collaborated on projects with China's military.[15] The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.[16]

- The U.S. and other donors who funded or collaborated on civilian research at the WIV have a right and obligation to determine whether any of our research funding was diverted to secret Chinese military projects at the WIV.[17]

Notably, the State Department's former lead investigator who oversaw the Task Force into the COVID-19 virus origin stated recently that he not only believes the virus escaped from the WIV, but that it may have been the result of research that the Chinese military, or People's Liberation Army, was doing on a bioweapon.[18]

Accordingly, it is imperative to determine not only where SARS-CoV-2 originated, but also how and if NIH's funding and research to projects at the WIV could have contributed to SARS CoV-2. To assist our requests and inquiry, please provide the following by April 19, 2021:

1. An assessment from a classified U.S. Defense Intelligence Agency (DIA) report included the possibility that the origins of SARS CoV-2 could have emerged accidentally from a laboratory in Wuhan, China due to unsafe laboratory practices.[19] The DIA report cited U.S. government and Chinese researchers who found "about 33 percent of the original 41 identified cases did not have direct exposure" to the market.[20] That, along with what is known of the WIV's work in past few years, raised reasonable suspicion that the

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[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

[18] Jennifer Griffin, Former top State Dept. investigator says COVID-19 outbreak may have resulted from bioweapons research accident, Fox News (March 13, 2021), *available at* https://www.foxnews.com/world/top-state-official-coronavirus-bioweapon-accident

[19] Fred Guterl, Naveed Jamali and Tom O'Connor, *The Controversial Experiments ad Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), *available at* https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503.
[20] *Id.*

pandemic may have been caused by a lab error, not a wet market.[21] Further, a WHO inspector on the recent mission noted that "we know not all of those first 174 early COVID-19 cases visited the market, including the man diagnosed in December 2019 with the earliest onset date."[22] What information does the NIH have on the earliest COVID-19 cases?

2. According to an editorial on February 23, 2021, in *The Wall Street Journal* by former Secretary of State Mike Pompeo and Miles Yu, "[China's] army of scientists claim to have discovered almost 2,000 new viruses in a little over a decade."[23] How many of these discovered viruses does the NIH have information on and were any of these viruses discovered at the WIV?

3. According to *The Wall Street Journal* editorial mentioned in the previous question, some have alleged that the WIV's virus-carrying animals were sold as pets and may even show up at local wet markets.[24] Is the NIH aware of these allegations? If so, please provide any information the NIH has related to these allegations.

4. Please provide all information that NIH has about laboratory accidents and/or biosafety practices at the WIV since January 1, 2015.

5. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about communications and events at the WIV from August 2019 to the present.

6. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about their communications with China-based NIH, Chinese National Science Foundation, CDC, and China CDC about events at the WIV from August 2019 to the present.

State Department Cables

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[21] *Id.*

[22] Dominic Dwyer, I was the Australian doctor on the WHO's COVID-19 mission to China. Here's what we found about the origins of the coronavirus, THE CONVERSATION (Feb. 21, 2021), *available at*https://www.theguardian.com/commentisfree/2021/feb/22/i-was-on-the-whos-covid-mission-to-china-heres-what-we-found. *See also* Jeremy Page and Drew Hinshaw, *China Refuses to Give WHO Raw Data on Early Covid-19 Cases*, THE WALL STREET JOURNAL (Feb. 12, 2021), *available at* https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580#:~:text=BEIJING%E2%80%94Chinese%20authorities%20refused%20to,over%20the%20lack%20of%20detail. ("Chinese authorities refused to provide World Health Organization investigators with raw, personalized data on early Covid-19 cases that could help them determine how and when the coronavirus first began to spread in China, according to WHO investigators who described heated exchanges over the lack of detail. The Chinese authorities turned down requests to provide such data on 174 cases of Covid-19 that they have identified from the early phase of the outbreak in the Chinese city of Wuhan in December 2019. Investigators are part of a WHO team that this week completed a monthlong mission in China aimed at determining the origins of the pandemic.")

[23] *Id.*

[24] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab,* THE WALL STREET JOURNAL (Feb. 23, 2021), available at https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

7. What information does NIH have about the WIV's responses to the 2018 U.S. Department of State cables (attached to this letter) regarding safety concerns?

8. The April 2018 cable from the U.S. Department of State stated that the WIV planned to invite University of Texas Medical Branch Galveston (UTMBG) researchers to do research in Wuhan's labs. Please provide any information NIH received that indicates whether the WIV invited UTMBG researchers, and whether UTMBG researchers conducted any research in Wuhan's labs.

    a. If there was such research, please provide information and any documents related to this research.

9. Why was it pertinent to the NIH investigation that the "nonprofit [EcoHealth Alliance] must provide the "WIV's responses to the 2018 Department of State cables regarding safety concerns"?[25]

    a. Did EcoHealth Alliance provide this information? If so, how did NIH use the information to further its investigation?

<u>EcoHealth Alliance, Columbia University Health Sciences</u>

10. Was the 2019 NIH federal award to EcoHealth Alliance reviewed and approved by the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) committee?[26]

    a. If so, please provide the documentation with the committee's decision.

    b. Please also provide the names of the individuals who were members of the committee at the time.

11. Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.

12. In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with "program goals and agency priorities."[27] Please specify the work that was done by the EcoHealth Alliance that did

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[25] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[26] National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), *available at* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html.
[27] *Id.*

not align with the agency's program goals and priorities, and when that work was conducted.

a. Was an evaluation of EcoHealth Alliance's work and whether it aligned with the agency's program goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?

13. In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology…has been conducting research at its facilities in China that pose serious bio-safety concerns."[28] What are the sources for those reports to NIH and what were the specific allegations reported?

14. Why did the NIH request that EcoHealth Alliance provide a sample of the pandemic coronavirus that the WIV used to determine its genetic sequence for SARS CoV-2?[29]

a. Why is this information important to NIH's investigation?

b. Has NIH obtained the sample and if so, what evaluations have been done, and for what purpose?

c. If NIH has not yet obtained the sample, what are the planned studies and evaluations NIH will conduct with the sample when it is obtained?

15. What is the nature of NIH's concerns about purported restrictions at the WIV including "diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019[,]" about the WIV lab or virus origin?[30]

a. What is the basis of information to NIH about the purported restrictions at the WIV?

b. What are the other purported restrictions at the WIV in October 2019?

16. After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions.[31]

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[28] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.
[29] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[30] *Id.*
[31] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

a. Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement.

b. What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?

c. One condition for the federal award reinstatement was for EcoHealth Alliance to arrange for an outside inspection of the WIV and its records, "with specific attention to addressing the question of whether WIV staff had SARS-CoV-2their possession prior to December 2019."[32] Why is it pertinent to the NIH's investigation if staff at WIV had SARS-CoV-2 in their possession prior to December 2019? What is the potential significance if the staff did have the virus in their possession prior to December 2019?

d. What information does NIH have that was used for the basis of requesting that the EcoHealth Alliance "must 'explain the apparent disappearance' of a scientist who worked in the Wuhan lab," and on social media was rumored to be "patient zero" of the pandemic?[33]

i. What is the potential significance about the whereabouts of this scientist and the photo being removed from the website?

17. Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University.

a. In an April 2020 email, Dr. Lauer advised Naomi Schrag of Columbia University that it would be helpful for NIH "to know about all China-based participants in this work since the Type 1 grant started in 2014 - who they were and how much money they received."[34] Why did NIH request that Columbia University provide information about all of the China-based participants?

i. What is the pertinence of the timeframe starting in 2014 for the requested information?

ii. Did Columbia University provide the NIH with the requested information about all of the China-based participants from all grantees since 2014? If so, please provide the information1. If not, why not?

Federal Funding Records

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[32] *Id.*
[33] *Id.*
[34] Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), *available at* https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say.

18. Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support.[35]

19. What is the total amount of NIH federal funding per year from 2017 through 2021 that has directly or indirectly supported the WIV scientists or research through grant recipients, including to EcoHealth Alliance; Wildlife Trust, Inc.; Columbia University Health Sciences; Trustees of Columbia University; University of North Carolina Chapel Hill; Vanderbilt University; University of Virginia; and Oregon Health and Science University?[36]

20. According to a report in *The Washington Post* on April 14, 2020, the WIV issued a news release in English about the final visit from U.S. Embassy scientist diplomats in Beijing, which occurred on March 27, 2018.[37] Does the NIH have a copy of this news release? If so, please provide a copy.

21. For NIH award recipients that have provided support to the WIV since January 1, 2012, please provide annual reports, trip reports related to the WIV, documentation of any survey or field trips by the WIV, and interim data summaries from the WIV.

22. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 where foreign sites for all Type 1 and Type 2 awards have been documented as involving the WIV.

23. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 for NIH domestic grantee awards with a foreign component involving the WIV.

24. Please provide the name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility.

25. Please provide the name(s) of the NIH Scientific Review Officers responsible for reviewing and approving any NIH financial awards to EcoHealth Alliance and any other funding recipients that supported the WIV.

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[35] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[36] National Institutes of Health, Research Portfolio online Reporting Tools, NIH RePorter *available at* https://report.nih.gov/ (last accessed March 6, 2020).

[37] Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), *available at* https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.[38] Please provide any information the NIH has on the number of bat samples and animals at the WIV.

    a. Did any NIH scientists who are fluent in Mandarin review the Chinese scientific literature on the WIV research related to coronaviruses that is dated before February 1, 2020?

27. Does the NIH have the unpublished sequences of bat coronaviruses that were maintained in the WIV database before December 30, 2019, or before the database was removed from the internet?[39] Does NIH have the full sequences of the eight viruses sampled in the Yunnan province on an EcoHealth Alliance bat-virus sampling trip in 2015?

    a. Please provide NIH's analysis if the sequences have been analyzed.

    b. If NIH does not have the sequences, can NIH get this information from the EcoHealth Alliance or from other NIH-funded sources?

28. Please provide the original version of "Origin and cross-species transmission of bat coronaviruses in China" that was submitted to *Nature* by EcoHealth Alliance on October 6, 2019, published August 25, 2020, and funded in part by NIAID (award number R01AI110964).[40] If NIH does not have the October 6, 2019 report, can NIH obtain it from EcoHealth Alliance for this response? If so, please provide the report.

29. Have NIH, EcoHealth Alliance, or other NIH award recipient(s) been denied permission or access to results of any WIV research, which indirectly received financial support from NIH awards? If so, please provide the date(s), individuals involved, and circumstances of each denial.

We request that the NIH provide the requested documents and information in a coordinated response from all stakeholders and the appropriate divisions within NIH, including but not limited to subject matter experts from NIH's Division of Security and Emergency Response, the Office of Management Assessment, the Center for Scientific Review, the National Institute of Allergy and Infectious Diseases, and the Office of Extramural Research. After the requested information has been provided, we ask that the NIH provide a briefing to the Minority Committee staff to discuss the information that the NIH has related to the origins of SARS-CoV-2, including any potential links to the WIV. Finally, we request that you appoint an NIH working group representing an appropriate diversity of scientific disciplines to collect data and

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[38] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), *available at* https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

[39] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

[40] Latinne, A., Hu, B., Olival, K.J. et al,. *Origin and cross-species transmission of bat coronaviruses in China*, Nature (Aug. 25, 2020), *available at* https://www.nature.com/articles/s41467-020-17687-3#Ack1.

information related to COVID-19 origins (including the WIV), and that the NIH working group coordinate and consult with foreign scientific agencies involved in similar work.

Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Attachment

Cc: The Honorable Frank Pallone, Chairman
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

From: Miers, Sarah (NIH/NIAID) [E]
To: Erbelding, Emily (NIH/NIAID) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Chen, Ping (NIH/NIAID) [E]
Cc: NIAID BUGS
Subject: FYI for now -- Committee on Energy and Commerce letter re: origins of pandemic
Date: Friday, March 19, 2021 8:43:57 AM
Attachments: 398508 Rodgers #2 corr.pdf
398508 Rodgers #4 Att.pdf

Good morning –

Dr. Collins has received a letter from the minority members of the House Committee on Energy and Commerce regarding the origins of the pandemic. For now, the response is being developed by the NIH Office of Extramural Research, but it seems likely that we, along with DEA, will be asked to provide information. I wanted to share the questions in the first pdf attachment with you now, although we have no action item at this time.

Sarah

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Thursday, March 18, 2021 at 5:07 PM
To: NIAID DEA DART (b) (6), NIAID BUGS (b) (6)
Cc: "Auchincloss, Hugh (NIH/NIAID) [E]" (b) (6), "Embry, Alan (NIH/NIAID) [E]" (b) (6), "Harper, Jill (NIH/NIAID) [E]" (b) (6), "Billet, Courtney (NIH/NIAID) [E]" (b) (6), NIAID OCGR Correspondence (b) (6), NIAID OCGR Leg (b) (6)
Subject: FYI- Committee on Energy and Commerce letter re: origins of pandemic

FYI ONLY

Attached is a letter from the Committee on Energy and Commerce to Dr. Collins. They are writing about an independent scientific investigation into the origins of the COVID-19 pandemic.

The response is being drafted by OER. We may be asked to provide input (along with OLPA) for the response.

Thanks,
Kara

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

March 18, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

We write to request information, assistance, and needed-leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.

The COVID-19 pandemic has been the worst public health crisis in the U.S. in about a hundred years. Over a year has passed since the deadly virus reached our shores and yet, the origin of the virus has yet to be determined. An independent, expert investigation of the origin of COVID-19 is of paramount importance to public health and biosecurity. As noted by Stanford Medical School Professor David Relman:

> A more complete understanding of the origins of COVID-19 clearly serves the interests of every person in every country on this planet. It will limit further recriminations and diminish the likelihood of conflict; it will lead to more effective responses to this pandemic, as well as efforts to anticipate and prevent the next one. It will also advance our discussions about risky science. And it will do something else: Delineating COVID-19's origin story will help elucidate the nature of our very precarious coexistence within the biosphere.[1]

Recently, the World Health Organization (WHO) attempted to investigate the origin of COVID-19. The WHO said that this investigative mission would be guided by the science, be

[1] David A. Relman, *Opinion: To stop the next pandemic, we need to unravel the origins of COVID-19*, PNAS (Nov. 2020), *available at* https://www.pnas.org/content/117/47/29246.

"open-minded," and "not exclude[e] any hypothesis."[2] Unfortunately, China did not provide complete access or independence for the critical WHO mission. On February 13, 2021, National Security Advisor Jake Sullivan issued the following statement:

> We have deep concerns about the way in which the early findings of the COVID-19 investigation were communicated and questions about the process used to reach them. It is imperative that this report be independent, with expert findings free from intervention or alteration by the Chinese government. To better understand this pandemic and prepare for the next one, China must make available its data from the earliest days of the outbreak.[3]

Because of rising tensions between the U.S. and China, the WHO scrapped plans for an interim report.[4] An international group of science experts, including specialists in virology, microbiology, and zoology, asked for a new review.[5]

The NIH, as a premier scientific institution, must lead in order to foster a transparent, independent, and science-based investigation into the origin of the COVID-19 pandemic. Such an effort must meet the WHO's stated goals of an open-minded investigation that does not exclude any plausible hypothesis.[6] In addition, the NIH is well-positioned to gather and provide information through oversight of its grants and other federal awards. Thus, the NIH is in a unique position to investigate the possibility that the pandemic stemmed from a laboratory accident or leak, especially regarding the Wuhan Institute of Virology (WIV).

NIH raised concerns over a possible link between WIV and the COVID-19 outbreak during its review of federal awards to EcoHealth Alliance, a global environmental health nonprofit organization dedicated to protecting wildlife and public health from the emergence of disease. Of the $13.7 million in federal awards that NIH authorized for EcoHealth Alliance, 17

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[2] Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), *available at* https://www.nature.com/articles/d41586-020-03165-9.
[3] The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/.
[4] Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), *available at* https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines
[5] Jaime Metzl, et al, *Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19* (March 4, 2021), *available at* https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).pdf. The co-organizer of the letter and a WHO advisor on human genome editing, Jaime Metzl, PhD, said there is an eighty-five percent chance the pandemic started with an accidental leak from the WIV or Wuhan CDC laboratory, *available at* https://jamiemetzl.com/origins-of-sars-cov-2/. ("I have no definitive way of proving this thesis but the evidence is, in my view, extremely convincing. If forced to place odds on the confidence of my hypothesis, I would say there's an 85% chance the pandemic started with an accidental leak from the Wuhan Institute of Virology or Wuhan CDC and a 15% chance it began in some other way (in fairness, here is an article making the case for a zoonotic jump "in the wild"). If China keeps preventing a full and unrestricted international forensic investigation into the origins of the pandemic, I believe it is fair to deny Beijing the benefit of the doubt.")
[6] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

projects sponsored by the National Institute of Allergy and Infectious Disease (NIAID) have provided over $7.9 million in federal awards for research of viral emergence from bats in Southeast Asia.[7] EcoHealth Alliance passed some of its funding to the WIV, and in 2020, NIH made efforts to obtain information from EcoHealth Alliance about WIV related to concerns about the origins of COVID-19. In April 2020, NIH wrote to EcoHealth Alliance and Columbia University about an NIH-funded project entitled, "Understanding the Risk of Bat Coronavirus Emergency:"

> It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ('WIV'). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs. It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.[8]

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.[9] Among other revelations, it reported the following:

- The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses. This raises questions about the credibility of WIV senior researcher Shi Zhengli's public claim that there was "zero infection" among the WIV's staff and students of SARS-CoV-2 or SARS-related viruses.[10]

- Starting in at least 2016, WIV researchers conducted experiments involving RaTG13, the bat coronavirus identified by the WIV in January 2020 as the closest sample to SARS-CoV-2 (96.2 percent similar).[11] There was no indication that this research was suspended at any time prior to the COVID-19 outbreak.

- The WIV has a published record of conducting "gain-of-function" research to engineer chimeric viruses.[12] But the WIV has not been transparent or consistent about its record of

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[7] NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), *available at* https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts.
[8] Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), *available at* https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/.
[9] U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), *available at* https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html.
[10] *Id.*
[11] *Id.*
[12] *Id.*

studying viruses similar to the COVID-19 virus, including "RaTG13," which was sampled from a cave in Yunnan Province in 2013 after several miners died of SARS-like illness.[13]

- WHO investigators must have access to the records of the WIV's work on bat and other coronaviruses before the COVID-19 outbreak. As part of a thorough inquiry, they must have a full accounting of why the WIV altered and then removed online records of its work with RaTG13 and other viruses.[14]

- Despite the WIV presenting itself as a civilian institution, the U.S. has determined that the WIV has collaborated on projects with China's military.[15] The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.[16]

- The U.S. and other donors who funded or collaborated on civilian research at the WIV have a right and obligation to determine whether any of our research funding was diverted to secret Chinese military projects at the WIV.[17]

Notably, the State Department's former lead investigator who oversaw the Task Force into the COVID-19 virus origin stated recently that he not only believes the virus escaped from the WIV, but that it may have been the result of research that the Chinese military, or People's Liberation Army, was doing on a bioweapon.[18]

Accordingly, it is imperative to determine not only where SARS-CoV-2 originated, but also how and if NIH's funding and research to projects at the WIV could have contributed to SARS CoV-2. To assist our requests and inquiry, please provide the following by April 19, 2021:

1. An assessment from a classified U.S. Defense Intelligence Agency (DIA) report included the possibility that the origins of SARS CoV-2 could have emerged accidentally from a laboratory in Wuhan, China due to unsafe laboratory practices.[19] The DIA report cited U.S. government and Chinese researchers who found "about 33 percent of the original 41 identified cases did not have direct exposure" to the market.[20] That, along with what is known of the WIV's work in past few years, raised reasonable suspicion that the

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[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

[18] Jennifer Griffin, Former top State Dept. investigator says COVID-19 outbreak may have resulted from bioweapons research accident, Fox News (March 13, 2021), *available at* https://www.foxnews.com/world/top-state-official-coronavirus-bioweapon-accident

[19] Fred Guterl, Naveed Jamali and Tom O'Connor, *The Controversial Experiments ad Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), *available at* https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503.
[20] *Id.*

pandemic may have been caused by a lab error, not a wet market.[21] Further, a WHO inspector on the recent mission noted that "we know not all of those first 174 early COVID-19 cases visited the market, including the man diagnosed in December 2019 with the earliest onset date."[22] What information does the NIH have on the earliest COVID-19 cases?

2. According to an editorial on February 23, 2021, in *The Wall Street Journal* by former Secretary of State Mike Pompeo and Miles Yu, "[China's] army of scientists claim to have discovered almost 2,000 new viruses in a little over a decade."[23] How many of these discovered viruses does the NIH have information on and were any of these viruses discovered at the WIV?

3. According to *The Wall Street Journal* editorial mentioned in the previous question, some have alleged that the WIV's virus-carrying animals were sold as pets and may even show up at local wet markets.[24] Is the NIH aware of these allegations? If so, please provide any information the NIH has related to these allegations.

4. Please provide all information that NIH has about laboratory accidents and/or biosafety practices at the WIV since January 1, 2015.

5. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about communications and events at the WIV from August 2019 to the present.

6. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about their communications with China-based NIH, Chinese National Science Foundation, CDC, and China CDC about events at the WIV from August 2019 to the present.

State Department Cables

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[21] *Id.*

[22] Dominic Dwyer, I was the Australian doctor on the WHO's COVID-19 mission to China. Here's what we found about the origins of the coronavirus, THE CONVERSATION (Feb. 21, 2021), *available at*https://www.theguardian.com/commentisfree/2021/feb/22/i-was-on-the-whos-covid-mission-to-china-heres-what-we-found. *See also* Jeremy Page and Drew Hinshaw, *China Refuses to Give WHO Raw Data on Early Covid-19 Cases*, THE WALL STREET JOURNAL (Feb. 12, 2021), *available at* https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580#:~:text=BEIJING%E2%80%94Chinese%20authorities%20refused%20to,over%20the%20lack%20of%20detail. ("Chinese authorities refused to provide World Health Organization investigators with raw, personalized data on early Covid-19 cases that could help them determine how and when the coronavirus first began to spread in China, according to WHO investigators who described heated exchanges over the lack of detail. The Chinese authorities turned down requests to provide such data on 174 cases of Covid-19 that they have identified from the early phase of the outbreak in the Chinese city of Wuhan in December 2019. Investigators are part of a WHO team that this week completed a monthlong mission in China aimed at determining the origins of the pandemic.")

[23] *Id.*

[24] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab,* THE WALL STREET JOURNAL (Feb. 23, 2021), available at https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

7. What information does NIH have about the WIV's responses to the 2018 U.S. Department of State cables (attached to this letter) regarding safety concerns?

8. The April 2018 cable from the U.S. Department of State stated that the WIV planned to invite University of Texas Medical Branch Galveston (UTMBG) researchers to do research in Wuhan's labs. Please provide any information NIH received that indicates whether the WIV invited UTMBG researchers, and whether UTMBG researchers conducted any research in Wuhan's labs.

    a. If there was such research, please provide information and any documents related to this research.

9. Why was it pertinent to the NIH investigation that the "nonprofit [EcoHealth Alliance] must provide the "WIV's responses to the 2018 Department of State cables regarding safety concerns"?[25]

    a. Did EcoHealth Alliance provide this information? If so, how did NIH use the information to further its investigation?

<u>EcoHealth Alliance, Columbia University Health Sciences</u>

10. Was the 2019 NIH federal award to EcoHealth Alliance reviewed and approved by the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) committee?[26]

    a. If so, please provide the documentation with the committee's decision.

    b. Please also provide the names of the individuals who were members of the committee at the time.

11. Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.

12. In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with "program goals and agency priorities."[27] Please specify the work that was done by the EcoHealth Alliance that did

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[25] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[26] National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), *available at* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html.
[27] *Id.*

not align with the agency's program goals and priorities, and when that work was conducted.

a. Was an evaluation of EcoHealth Alliance's work and whether it aligned with the agency's program goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?

13. In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology…has been conducting research at its facilities in China that pose serious bio-safety concerns."[28] What are the sources for those reports to NIH and what were the specific allegations reported?

14. Why did the NIH request that EcoHealth Alliance provide a sample of the pandemic coronavirus that the WIV used to determine its genetic sequence for SARS CoV-2?[29]

a. Why is this information important to NIH's investigation?

b. Has NIH obtained the sample and if so, what evaluations have been done, and for what purpose?

c. If NIH has not yet obtained the sample, what are the planned studies and evaluations NIH will conduct with the sample when it is obtained?

15. What is the nature of NIH's concerns about purported restrictions at the WIV including "diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019[,]" about the WIV lab or virus origin?[30]

a. What is the basis of information to NIH about the purported restrictions at the WIV?

b. What are the other purported restrictions at the WIV in October 2019?

16. After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions.[31]

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[28] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.
[29] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[30] *Id.*
[31] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

a. Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement.

b. What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?

c. One condition for the federal award reinstatement was for EcoHealth Alliance to arrange for an outside inspection of the WIV and its records, "with specific attention to addressing the question of whether WIV staff had SARS-CoV-2their possession prior to December 2019."[32] Why is it pertinent to the NIH's investigation if staff at WIV had SARS-CoV-2 in their possession prior to December 2019? What is the potential significance if the staff did have the virus in their possession prior to December 2019?

d. What information does NIH have that was used for the basis of requesting that the EcoHealth Alliance "must 'explain the apparent disappearance' of a scientist who worked in the Wuhan lab," and on social media was rumored to be "patient zero" of the pandemic?[33]

i. What is the potential significance about the whereabouts of this scientist and the photo being removed from the website?

17. Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University.

a. In an April 2020 email, Dr. Lauer advised Naomi Schrag of Columbia University that it would be helpful for NIH "to know about all China-based participants in this work since the Type 1 grant started in 2014 - who they were and how much money they received."[34] Why did NIH request that Columbia University provide information about all of the China-based participants?

i. What is the pertinence of the timeframe starting in 2014 for the requested information?

ii. Did Columbia University provide the NIH with the requested information about all of the China-based participants from all grantees since 2014? If so, please provide the information1. If not, why not?

Federal Funding Records

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[32] *Id.*
[33] *Id.*
[34] Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), *available at* https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say.

18. Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support.[35]

19. What is the total amount of NIH federal funding per year from 2017 through 2021 that has directly or indirectly supported the WIV scientists or research through grant recipients, including to EcoHealth Alliance; Wildlife Trust, Inc.; Columbia University Health Sciences; Trustees of Columbia University; University of North Carolina Chapel Hill; Vanderbilt University; University of Virginia; and Oregon Health and Science University?[36]

20. According to a report in *The Washington Post* on April 14, 2020, the WIV issued a news release in English about the final visit from U.S. Embassy scientist diplomats in Beijing, which occurred on March 27, 2018.[37] Does the NIH have a copy of this news release? If so, please provide a copy.

21. For NIH award recipients that have provided support to the WIV since January 1, 2012, please provide annual reports, trip reports related to the WIV, documentation of any survey or field trips by the WIV, and interim data summaries from the WIV.

22. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 where foreign sites for all Type 1 and Type 2 awards have been documented as involving the WIV.

23. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 for NIH domestic grantee awards with a foreign component involving the WIV.

24. Please provide the name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility.

25. Please provide the name(s) of the NIH Scientific Review Officers responsible for reviewing and approving any NIH financial awards to EcoHealth Alliance and any other funding recipients that supported the WIV.

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[35] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[36] National Institutes of Health, Research Portfolio online Reporting Tools, NIH RePorter *available at* https://report.nih.gov/ (last accessed March 6, 2020).

[37] Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), *available at* https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.[38] Please provide any information the NIH has on the number of bat samples and animals at the WIV.

    a. Did any NIH scientists who are fluent in Mandarin review the Chinese scientific literature on the WIV research related to coronaviruses that is dated before February 1, 2020?

27. Does the NIH have the unpublished sequences of bat coronaviruses that were maintained in the WIV database before December 30, 2019, or before the database was removed from the internet?[39] Does NIH have the full sequences of the eight viruses sampled in the Yunnan province on an EcoHealth Alliance bat-virus sampling trip in 2015?

    a. Please provide NIH's analysis if the sequences have been analyzed.

    b. If NIH does not have the sequences, can NIH get this information from the EcoHealth Alliance or from other NIH-funded sources?

28. Please provide the original version of "Origin and cross-species transmission of bat coronaviruses in China" that was submitted to *Nature* by EcoHealth Alliance on October 6, 2019, published August 25, 2020, and funded in part by NIAID (award number R01AI110964).[40] If NIH does not have the October 6, 2019 report, can NIH obtain it from EcoHealth Alliance for this response? If so, please provide the report.

29. Have NIH, EcoHealth Alliance, or other NIH award recipient(s) been denied permission or access to results of any WIV research, which indirectly received financial support from NIH awards? If so, please provide the date(s), individuals involved, and circumstances of each denial.

We request that the NIH provide the requested documents and information in a coordinated response from all stakeholders and the appropriate divisions within NIH, including but not limited to subject matter experts from NIH's Division of Security and Emergency Response, the Office of Management Assessment, the Center for Scientific Review, the National Institute of Allergy and Infectious Diseases, and the Office of Extramural Research. After the requested information has been provided, we ask that the NIH provide a briefing to the Minority Committee staff to discuss the information that the NIH has related to the origins of SARS-CoV-2, including any potential links to the WIV. Finally, we request that you appoint an NIH working group representing an appropriate diversity of scientific disciplines to collect data and

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[38] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), *available at* https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

[39] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

[40] Latinne, A., Hu, B., Olival, K.J. et al,. *Origin and cross-species transmission of bat coronaviruses in China*, Nature (Aug. 25, 2020), *available at* https://www.nature.com/articles/s41467-020-17687-3#Ack1.

information related to COVID-19 origins (including the WIV), and that the NIH working group coordinate and consult with foreign scientific agencies involved in similar work.

Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Attachment

Cc: The Honorable Frank Pallone, Chairman
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

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MRN:	18 BEIJING 138
Date/DTG:	Jan 19, 2018 / 190739Z JAN 18
From:	AMEMBASSY BEIJING
Action:	WASHDC, SECSTATE *ROUTINE*
E.O.:	13526
TAGS:	SHLH, ETRD, ECON, PGOV, CN
Captions:	SENSITIVE
Reference:	17 WUHAN 48
Subject:	China Opens First Bio Safety Level 4 Laboratory

1. (SBU) **Summary and Comment:** The Chinese Academy of Sciences (CAS) has recently established what is reportedly China's first Biosafety Level 4 (BSL-4) laboratory in Wuhan. This state-of-the-art facility is designed for prevention and control research on diseases that require the highest level of biosafety and biosecurity containment. Ultimately, scientists hope the lab will contribute to the development of new antiviral drugs and vaccines, but its current productivity is limited by a shortage of the highly trained technicians and investigators required to safely operate a BSL-4 laboratory and a lack of clarity in related Chinese government policies and guidelines. (b)(5)

(b)(5)

(b)(5) **End Summary and Comment.**

China Investing in Infectious Disease Control

2. (U) Between November 2002 and July 2003, China faced an outbreak of Severe Acute Respiratory Syndrome (SARS), which, according to the World Health Organization, resulting in 8,098 cases and leading to 774 deaths reported in 37 countries. A majority of cases occurred in China, where the fatality rate was 9.6%. This incident convinced China to prioritize international cooperation for infectious disease control. An aspect of this prioritization was China's work with the Jean Merieux BSL-4 Laboratory in Lyon, France, to build China's first high containment laboratory at Wuhan's Institute of Virology (WIV), an institute under the auspices of the Chinese Academy of Sciences (CAS). Construction took 11 years and $44 million USD, and construction on the facility was completed on January 31, 2015. Following

two years of effort, which is not unusual for such facilities, the WIV lab was accredited in February 2017 by the China National Accreditation Service for Conformity Assessment. It occupies four floors and consists of over 32,000 square feet. WIV leadership now considers the lab operational and ready for research on class-four pathogens (P4), among which are the most virulent viruses that pose a high risk of aerosolized person-to-person transmission.

Unclear Guidelines on Virus Access and a Lack of Trained Talent Impede Research

3. (SBU) In addition to accreditation, the lab must also receive permission from the National Health and Family Planning Commission (NHFPC) to initiate research on specific highly contagious pathogens. According to some WIV scientists, it is unclear how NHFPC determines what viruses can or cannot be studied in the new laboratory. To date, WIV has obtained permission for research on three viruses: Ebola virus, Nipah virus, and Xinjiang hemorrhagic fever virus (a strain of Crimean Congo hemorrhagic fever found in China's Xinjiang Province). Despite this permission, however, the Chinese government has not allowed the WIV to import Ebola viruses for study in the BSL-4 lab. Therefore, WIV scientists are frustrated and have pointed out that they won't be able to conduct research project with Ebola viruses at the new BSL-4 lab despite of the permission.

(b)(6)

(b)(6) Thus, while the BSL-4 lab is ostensibly fully accredited, its utilization is limited by lack of access to specific organisms and by opaque government review and approval processes. As long as this situation continues, Beijing's commitment to prioritizing infectious disease control - on the regional and international level, especially in relation to highly pathogenic viruses, remains in doubt.

(b)(6) noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this, (b)(6) they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China. As China is building more BSL-4 labs, including one in Harbin Veterinary Research Institute subordinated to the Chinese Academy of Agricultural Sciences (CAAS) for veterinary research use, (b)(6) the training for technicians and investigators working on dangerous pathogens will certainly be in demand.

Despite Limitations, WIV Researchers Produce SARS Discoveries

6. (SBU) The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study, (b)(5) (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS-coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like coronaviruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention. (b)(5) (b)(5) WIV scientists are allowed to study the SARS-like coronaviruses isolated from bats while they are precluded from studying human-disease causing SARS coronavirus in their new BSL-4 lab until permission for such work is granted by the NHFCP.

1. Hu B, Zeng L-P, Yang X-L, Ge X-Y, Zhang W, Li B, et al. (2017) Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus. PLoS Pathog 13(11): e1006698. https://doi.org/10.1371/journal.ppat.1006698

Signature:	BRANSTAD
Drafted By:	(b)(6)
Cleared By:	
Approved By:	
Released By:	
Info:	CHINA POSTS COLLECTIVE *ROUTINE*
Dissemination Rule:	Archive Copy

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MRN:	18 WUHAN 38
Date/DTG:	Apr 19, 2018 / 190551Z APR 18
From:	AMCONSUL WUHAN
Action:	WASHDC, SECSTATE *ROUTINE*
E.O.:	13526
TAGS:	SHLH, PGOV, CN, PREL, TBIO, KGHI, CDC, EAID, KHIV, IN, JP, TW, TSPL, PINS, SENV
Captions:	SENSITIVE
Reference:	A) 18 BEIJING 138 B) 17 BEIJING 2458 C) 11 MUMBAI 630 D) 17 TOKYO 716 E) 13 SEOUL 790
Subject:	China Virus Institute Welcomes More U.S. Cooperation on Global Health Security

1. (SBU) **Summary with Comment:** China's Wuhan Institute of Virology, a global leader in virus research, is a key partner for the United States in protecting global health security. Its role as operator of the just-launched Biosafety Level 4 (or "P4") lab -- the first such lab in China -- opens up even more opportunities for expert exchange, especially in light of the lab's shortage of trained staff (Ref A). (b)(5)

(b)(5)

(b)(5) **End Summary with Comment.**

2. (U) Wuhan Institute of Virology researchers and staff gave an overview of the lab and current cooperation with the United States to visiting Environment, Science, Technology and Health Counsellor Rick Switzer and Consulate Wuhan Consul General Jamie Fouss in late March. In the last year, the institute has also hosted visits from the National Institutes of Health (NIH), National Science Foundation, and experts from the University of Texas Medical Branch in Galveston. The institute reports to the Chinese Academy of Sciences in Beijing.

P4 Lab is Open and Transparent, Officials Emphasize

3. (SBU) The Wuhan P4 lab, referring to labs with the highest level of safety precautions, became fully operational and began working with live viruses early this year. Institute officials said they believed it is the only operational P4 lab in Asia aside from a U.S. Centers for Disease

Control (CDC)-supported facility in Pune, India (Ref C). China plans to stand up a second P4 lab in Harbin. Institute officials said Japan's biosafety labs are "old" and lack cutting-edge equipment, so they consider Japan's labs to be "P3 Plus" (*Note*: the Japanese government says it has one P4-level lab in the Tokyo suburbs, though its activities are limited, and Japan is building a new P4 lab in Nagasaki, see Ref D. Taiwan operates at least one P4 lab. South Korea was close to opening a P4 lab as of last year, see Ref E. *End Note.*) Wuhan's lab is located about 20 miles from the city center in Zhengdian district, and the institute plans to gradually consolidate its other training, classroom and lab facilities at that location.

4. (U) Officials described the lab as a "regional node" in the global biosafety system and said it would play an emergency response role in an epidemic or pandemic. The lab's English brochure highlighted a national security role, saying that it "is an effective measure to improve China's availability in safeguarding national bio-safety if [a] possible biological warfare or terrorist attack happens."

5. (SBU) Institute officials said there would be "limited availability" for international and domestic scientists who had gone through the necessary approval process to do research at the lab. They stressed that the lab aimed to be a "worldwide, open platform" for virology. They said they welcomed U.S. Centers for Disease Control (CDC) experts, noting that the Chinese Academy of Sciences was not strong on human disease expertise, having only focused on it in the last 15 years, after the SARS outbreak. A Wuhan-based French consulate official who works on science and technology cooperation with China also emphasized that the lab, which was initiated in 2004 as a France-China joint project, was meant to be "open and transparent" to the global scientific community. "The intent was to set up a lab to international standards, and open to international research," he said. French experts have provided guidance and biosafety training to the lab, which will continue, the French official said. Institute officials said that France provided the lab's design and much of its technology, but that it is entirely China-funded and has been completely China-run since a "handover" ceremony in 2016.

6. (U) In addition to French assistance, experts from the NIH-supported P4 lab at the University of Texas Medical Branch in Galveston have trained Wuhan lab technicians in lab management and maintenance, institute officials said. The Wuhan institute plans to invite scientists from the Galveston lab to do research in Wuhan's lab. One Wuhan Institute of Virology researcher trained for two years at the Galveston lab, and the institute also sent one scientist to U.S. CDC headquarters in Atlanta for six months' work on influenza.

NIH-Supported Research Revises SARS Origin Story

7. (U) NIH was a major funder, along with the Natural Science Foundation of China (NSFC), of SARS research by the Wuhan Institute of Virology's [redacted] This lends weight to the theory that SARS originated in bat populations before jumping first to civet cats (likely via bat feces) and then to humans, [redacted]

(b)(6) (b)(6) team has provided support in statistical modeling to assess the risk of more coronaviruses like SARS crossing over to human populations.

Ready to Help with the Global Virome Project

8. (U) Institute officials expressed strong interest in the Global Virome Project (GVP), and said Chinese funding for the project would likely come from Chinese Academy of Sciences funding already earmarked for One Belt, One Road-related initiatives. The GVP aims to launch this year as an international collaborative effort to identify within ten years virtually all of the planet's viruses that have pandemic or epidemic potential and the ability to jump to humans. "We hope China will be one of the leading countries to initiate the Global Virome Project," one Wuhan Institute of Virology official said. China attended a GVP unveiling meeting in January in Thailand and is waiting for more details on the initiative. The officials said that the Chinese government funds projects similar to GVP to investigate the background of viruses and bacteria. This essentially constituted China's own Virome Project, officials said, but they noted the program currently has no official name.

9. (SBU) The Wuhan Institute of Virology's (b)(6) is the (b)(6) (b)(6) (b)(6) which is designed to show "proof of concept" and be a forerunner to the Global Virome Project. (b)(6) with the EcoHealth Alliance (a New York City-based NGO that is working with the University of California, Davis to manage the (b)(6) recently planned to visit Wuhan to meet with (b)(6) (b)(6) noted that China has expressed interest in building the GVP database, which would put China in a leadership position. Other countries have confidence in China's ability to build such a database, but are skeptical on whether China could remain transparent as a "gatekeeper" for this information (b)(6) said. (b)(6) expressed frustration with the slow progress so far in launching GVP, noting that the effort lacked funding sources, needed to hire a CEO, and would have to boost its profile at G7, G20 and other high-level international meetings.

U.S.-China Workshop Explores Research Partnerships

10. (U) The Institute also has ongoing collaboration with the U.S. National Science Foundation, including a just-concluded workshop in Shenzhen, involving about 40 scientists from the United States and China, on the topic of the "Ecology and Evolution of Infectious Diseases." Co-sponsored by the Natural Science Foundation of China (NSFC), (b)(6) (b)(6) (b)(6) The workshop explored opportunities for U.S.-China research cooperation in areas like using "big data" to predict emerging infectious diseases, climate change's effect on vector-borne diseases, and pathogen transmission between wildlife, domestic animals and humans.

11. (SBU) Some workshop participants also expressed skepticism about the Global Virome Project's (GVP) approach, saying that gaining a predictive understanding of viruses with pandemic potential would require going beyond the GVP's strategy of sample collection, to take an "ecological" approach that considers the virome beyond vertebrate systems to identify

mechanisms driving pathogen evolution. A follow-on workshop will be held in June at the University of Berkeley. NSF and NSFC hope to jointly announce a funding call for collaborative projects later this year.

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Approved By:	
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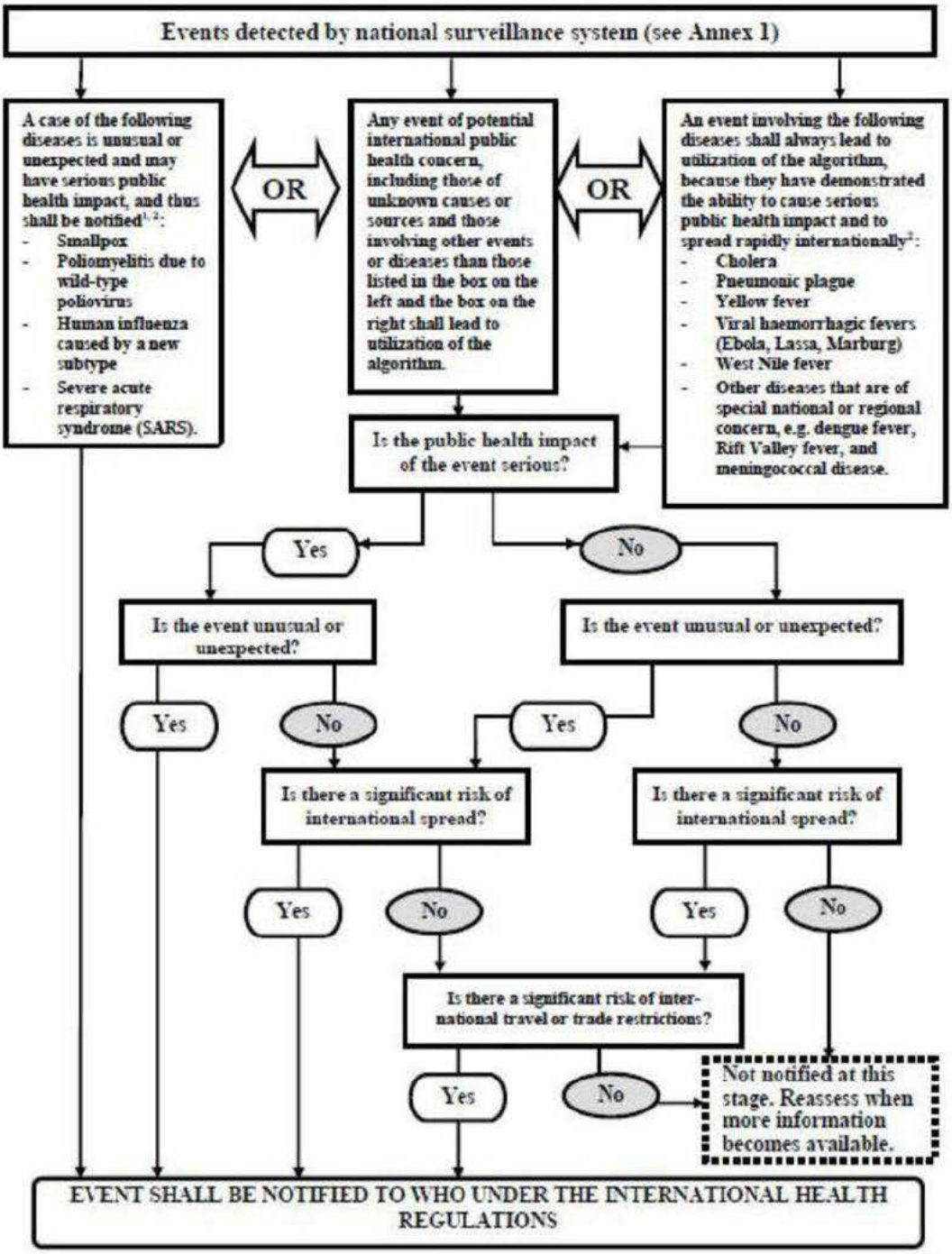
ANNEX 2

DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN



[1] As per WHO case definitions.
[2] The disease list shall be used only for the purposes of these Regulations.

From: Peter Daszak
To: Stemmy, Erik (NIH/NIAID) [E]; Alison Andre; Aleksei Chmura; Erbelding, Emily (NIH/NIAID) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]
Subject: RE: Status of R01AI110964-6 Understanding the Risk of Bat Coronavirus Emergence
Date: Thursday, February 25, 2021 12:49:08 PM

Other times that would work include:

Wed 3rd 9am – 1pm
Thurs 4th 9am-2pm

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, February 25, 2021 12:26 PM
To: Alison Andre (b) (6); Peter Daszak (b) (6); Aleksei Chmura (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Post, Diane (NIH/NIAID) [E] (b) (6)
Subject: RE: Status of R01AI110964-6 Understanding the Risk of Bat Coronavirus Emergence

Hi Alison,

I don't think we can align our calendars on the 5th. What about 10am and Wednesday March 10th?

Erik

From: Alison Andre (b) (6)
Sent: Thursday, February 25, 2021 12:02 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Peter Daszak (b) (6); Aleksei Chmura (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Post, Diane (NIH/NIAID) [E] (b) (6)
Subject: Re: Status of R01AI110964-6 Understanding the Risk of Bat Coronavirus Emergence

Dear Erik and All,

Apologies for the delay – Peter is in transit and will be for much of next week. Is a call on Friday March 5th possible? Peter's available anytime 11:00am ET and later.

Best.
Alison

Alison Andre
Executive Assistant to the President

EcoHealth Alliance
520 Eighth Ave – Suite 1200
New York, NY 10018

(b) (6) (direct)
1.212.380.4465 (fax)
www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

From: Aleksei Chmura (b) (6)
Date: Thursday, February 25, 2021 at 10:51 AM
To: Alison Andre (b) (6)
Subject: Re: Status of R01AI110964-6 Understanding the Risk of Bat Coronavirus Emergence

Alison,

Can you please step in, let them know Peter will be in transit and with poor connectivity (truly!), and set up something for Friday, next week. It is very urgent, but we need Peter seated, visible, and in front of his laptop for this Zoom call. Taking the call from the slopes or a car would not be good. Thursday seems impossible, so… it is up to you, though!

Cheers,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)
www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

Begin forwarded message:

From: "Stemmy, Erik (NIH/NIAID) [E]" (b) (6)
Date: February 24, 2021 at 10:21:59 EST
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6), "Erbelding, Emily (NIH/NIAID) [E]" (b) (6), "Cassetti, Cristina (NIH/NIAID) [E]" (b) (6), "Post, Diane (NIH/NIAID) [E]" (b) (6)
Subject: RE: Status of R01AI110964-6 Understanding the Risk of Bat Coronavirus Emergence

Hi Peter,
We've had a chance to check on this internally. Would you be able to have a quick call with us? Looks like the next time I can get the folks on our end together is Monday 3/1 from 1:30-2pm. Let me know if that works and I'll set up a zoom.

Thanks!
Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
Email: (b) (6)
Pronouns: He/Him/His

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.
****
NOTE: This material is intended for the individual or entity to which it is addressed. It

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From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, February 16, 2021 6:10 PM
To: Peter Daszak (b) (6)
Cc: Aleksei Chmura (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6)
Subject: Re: Status of R01AI110964-6 Understanding the Risk of Bat Coronavirus Emergence

Hi Peter,
Thanks for letting us know. We'll look in to it and get back to you.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
Email: (b) (6)
Pronouns: He/Him/His

> On Feb 16, 2021, at 5:57 PM, Peter Daszak (b) (6) wrote:
>
> Hi Erik,
>
> We received an email (below) from Garcia-Malone Gorka of the Office of Director letting us know that they have confirmed there are no pending investigations into the Wuhan Institute of Virology, and that the grant is funded. Because of that email, I'm writing to ask if you can confirm that we can move ahead with a continuation of our 5-yr award R01AI110964 and spend funds against the budget.

We're really hopeful that this is the case, and everyone at EcoHealth Alliance is looking forward to continuing this critical work.

Looking forward to hearing news from you!

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Garcia-Malene, Gorka (NIH/OD) [E] (b) (6)
Sent: Tuesday, January 26, 2021 12:20:51 PM
To: Matthew R.Torsiello
Cc: Nels T. Lippert; Andrew N. Krinsky; Bartok, Lauren (NIH/NIAID) [E]; NIH FOIA
Subject: [EXT] FW: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

Good afternoon, Mr. Torsiello –

I'd like to insert myself into the unfolding FOIA conversation in hopes of providing some helpful context. Our records show that this competing renewal has in fact been funded. In addition, any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations

into that organization. If we can agree on the above, all that would remain is to receive your proposed redactions to the records sought under the FOIA request.

Please let me know if there are any questions. I look forward to facilitating the Pre-Disclosure Notification process as efficiently as possible.

Best regards.

Gorka Garcia-Malene |FOIA Officer for the National Institutes of Health

From: Matthew R.Torsiello (b) (6)
Sent: Monday, January 25, 2021 5:21 PM
To: Bartok, Lauren (NIH/NIAID) [E] (b) (6)
Cc: Nels T. Lippert (b) (6); Andrew N. Krinsky (b) (6)
Subject: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

Dear Ms. Bartok:

As you may recall, this firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance"), with respect to certain FOIA requests, including the instant request, FOIA Case No. 55702. The instant request seeks the same documents sought last year in FOIA Case No. 53996, regarding the research project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01AI110964. A copy of our prior letter regarding FOIA 53996 is available via the link provided below using the password NIH12345. On the grounds set forth in the letter, FOIA 53996 was denied in its entirety.

Likewise, FOIA 55702 should be denied and the grant documents should be withheld. First, grant 2R01AI110964-06 remains an unfunded competing renewal grant that is the subject of a pending first-level appeal and, thus, the materials are not subject to disclosure under NIH Grants Policy Statement §2.3.11.2.2. Moreover, in the context of the appeal, NIH has made multiple requests for further information regarding The Wuhan Institute of Virology ("WIV"), which requests indicate that a law enforcement investigation concerning WIV remains ongoing. Second, as demonstrated by the recent attack on the US Capital fueled by disinformation and conspiracy theories, the need to protect the privacy of EcoHealth Alliance's employees and affiliates is more important than ever. Last, while EcoHealth Alliance did not initially identify that the grant proposal contained confidential-commercial and propriety information, this is not dispositive. Moreover, since the filing of the

renewal application, there has been a global COVID-19 pandemic, which has sparked international and highly competitive research in the area of bat coronaviruses.

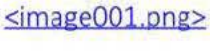
At the very least, the responsive documents will require significant redactions. While the grant documents were previously reviewed and redacted in connection with FOIA 53996, we require a further opportunity to review the documents to confirm, *inter alia*, that all personnel information has been removed given the heightened risk of harm in this unprecedented political environment. Accordingly, EcoHealth Alliance respectfully requests a forty-five (45) day extension of time to respond to FOIA 55702, to allow sufficient time for EcoHealth Alliance to conduct a further review of the responsive documents and provide an updated letter response that incorporates recent developments and specific justifications for additional redactions.

Please confirm that NIH will deny FOIA 55702 in its entirety or that NIH is agreeable to EcoHealth Alliance's request for an extension of time to provide a particularized response to FOIA 55702. Please also confirm NIH's receipt of this email.

Thank you.

Best,
Matthew R. Torsiello

FOIA Case No. 53996 - EcoHealth Alliance's Letter Response to FOIA Request, dated June 5, 2020 (With Exhibits)
https://tarterkrinsky-my.sharepoint.com/:b:/p/mtorsiello/EYHsvmSBaINAk6mAgJfyl-gByaIrZFhCEBLGOnHjfTjMOw?e=mZHyA8



Matthew R.Torsiello | Associate
D: (b) (6) | F: 212-216-8001
(b) (6) | Bio
Tarter Krinsky & Drogin LLP
1350 Broadway | New York | NY | 10018
www.tarterkrinsky.com | LinkedIn
COVID-19 RESOURCE CENTER

However, because of anticipated delays in receiving regular mail and other deliveries, please e-mail copies of anything you send by regular mail or delivery, including issuing remittances electronically, until further notice. Please contact Katrinia Soares at reception@tarterkrinsky.com or by phone at 212-216-8000 with any questions. Thank you in advance for your courtesies during these unprecedented times.

NOTE: If regular mailing or other specific transmission type is required by terms of a contract, order or statute, please comply with those obligations and transmit the materials by the means set forth in the agreement, order or statute as well as by email.

Tarter Krinsky & Drogin LLP, Attorneys-at-Law.

Tarter Krinsky & Drogin is fully operational. All attorneys and staff have been and will continue to be working remotely and TKD has put measures in place to ensure our services continue uninterrupted. However, because of anticipated delays in receiving regular mail and other deliveries, please e-mail copies of anything you send by regular mail or delivery, including issuing remittances electronically, until further notice. Please contact Katrinia Soares at reception@tarterkrinsky.com or by phone at 212-216-8000 with any questions. Thank you in advance for your courtesies during these unprecedented times.

NOTE: If regular mailing or other specific transmission type is required by terms of a contract, order or statute, please comply with those obligations and transmit the materials by the means set forth in the agreement, order or statute as well as by email.

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This email is an informal communication that is not meant to be legally binding upon the sender unless expressly noted to the contrary.

From: Miers, Sarah (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: Re: ACTION BY 12PM TODAY: Review response to Sen. Johnson on Wuhan Institute of Virology
Date: Monday, February 22, 2021 11:21:11 AM

Got it, thank you. That's good information to have although it won't satisfy a certain subgroup of the media.

From: "Stemmy, Erik (NIH/NIAID) [E]" (b) (6)
Date: Monday, February 22, 2021 at 11:20 AM
To: "Miers, Sarah (NIH/NIAID) [E]" (b) (6)
Subject: RE: ACTION BY 12PM TODAY: Review response to Sen. Johnson on Wuhan Institute of Virology

Yep, I'm sure DEA would have the correct numbers. Should be easier for them to pull it by institution than me. My only point with Daszak's email was that while they did budget for WIV in the renewal, they didn't set up the subcontract so no actual USG funds were there during the emergence of SARS-CoV-2.

From: Miers, Sarah (NIH/NIAID) [E] (b) (6)
Sent: Monday, February 22, 2021 11:18 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: Re: ACTION BY 12PM TODAY: Review response to Sen. Johnson on Wuhan Institute of Virology

Thanks, Erik. Do you feel comfortable deferring to DEA? You don't have to, I can ask the legislative office to set up a quick call.

From: "Stemmy, Erik (NIH/NIAID) [E]" (b) (6)
Date: Monday, February 22, 2021 at 11:13 AM
To: "Miers, Sarah (NIH/NIAID) [E]" (b) (6)
Subject: RE: ACTION BY 12PM TODAY: Review response to Sen. Johnson on Wuhan Institute of Virology

(b) (5)

From: Miers, Sarah (NIH/NIAID) [E] (b) (6)
Sent: Monday, February 22, 2021 11:05 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: Re: ACTION BY 12PM TODAY: Review response to Sen. Johnson on Wuhan Institute of Virology

DEA says the figure includes all the funding we provided. So not necessarily an answer to your

question.

From: "Stemmy, Erik (NIH/NIAID) [E]" (b) (6)
Date: Monday, February 22, 2021 at 10:57 AM
To: "Miers, Sarah (NIH/NIAID) [E]" (b) (6)
Subject: RE: ACTION BY 12PM TODAY: Review response to Sen. Johnson on Wuhan Institute of Virology

Hi Sarah,
Just one comment, does that figure include $ since the competing renewal in 2019? Daszak has said they didn't send any funds other there before the award was cancelled.

Erik

From: Miers, Sarah (NIH/NIAID) [E] (b) (6)
Sent: Monday, February 22, 2021 9:45 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: FW: ACTION BY 12PM TODAY: Review response to Sen. Johnson on Wuhan Institute of Virology

Hi Eric, quick turnaround request. Please see below. Are you okay with this draft statement from the legislative office/Gray Handley? (b) (5)

From: "Selgrade, Sara (NIH/NIAID) [E]" (b) (6)
Date: Monday, February 22, 2021 at 9:28 AM
To: NIAID BUGS (b) (6)
Cc: NIAID OCGR Leg (b) (6), "Billet, Courtney (NIH/NIAID) [E]" (b) (6), "Harper, Jill (NIH/NIAID) [E]" (b) (6), "Handley, Gray (NIH/NIAID) [E]" (b) (6), NIAID DEA DART (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6)
Subject: ACTION BY 12PM TODAY: Review response to Sen. Johnson on Wuhan Institute of Virology

Hello DMID,

Background
We received an inquiry from Committee staff to Sen. Ron Johnson (R-WI; Ranking Member, Senate Homeland Security and Governmental Affairs Committee) about a 2018 State Department cable regarding the Wuhan Institute of Virology.

> **Inquiry from staff to Sen. Johnson**
> *We received an inquiry from Sen. Johnson's staffers on HSGAC about the Wuhan Institute of Virology. They are interested in discussing HHS's role in the development of an April 2018*

State Department cable regarding the United States' role in research occurring at a lab at China's Wuhan Institute of Virology. Specifically, the staffers would like to discuss HHS's awareness of the types of research at this lab and any U.S. funding for those studies.

The Office of the HHS Assistant Secretary for Legislation (ASL) had reached out to NIH OLPA for input. NIH OLPA contacted OER/Dr. Lauer, who recommended reaching out to NIAID to answer the question.

On behalf of NIAID, Gray Handley suggested the response below. The funding figure highlighted below was provided by DEA and reflects subawards to the Wuhan Institute of Virology from the EcoHealth Alliance grant R01AI110964.

DRAFT NIAID Response

(b) (5)

[redacted]

Action Item

Please review the draft response and provide any edits to OCGR-Leg by noon today, Monday Feb. 22nd.

Once a response is cleared by NIAID, we will suggest that NIH OER and the HHS Office of Global Affairs (OGA) review the response before it is provided to Sen. Johnson's office.

Thank you for your help with this congressional request. Please let us know if you have any questions or would like to discuss further.

Thanks,
Sara

Sara Selgrade, Ph.D.
Section Chief for Legislative Activities
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
Bldg. 31, Room 7A17, MSC 2520
Bethesda, MD 20892-2520
Phone: (b) (6)
(b) (6)

From:	Lauer, Michael (NIH/OD) [E]
To:	Aleksei Chmura; Peter Daszak
Cc:	Stemmy, Erik (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; Bulls, Michelle G. (NIH/OD) [E]; Compliance Review; Ta, Kristin (NIH/OD) [E]
Subject:	Re: PLEASE READ -- Re: Please read and acknowledge receipt -- update regarding 2R01AI110964-06
Date:	Friday, October 23, 2020 2:57:44 PM
Attachments:	NIH Response to EcoHealth Response to Suspension_10_23_20.pdf

Dear Dr. Chmura and Dr. Daszak

Please see attached.

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 October 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

I am following up on Mr. Krinsky's August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. ("EcoHealth") responding to NIH's suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no *current* connection to the Project or EcoHealth's research, and EcoHealth had not issued any subawards in connection with the Grant *at the time of the suspension*.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth's grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that "Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China." EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV's facilities, EcoHealth described WIV as China's premier institute for virological research" and touted WIV's "fully equipped biosafety level 3 laboratory" and "a newly opened BLS-4 laboratory." In support of the application, Dr. Zheng Li Shi's personal statement indicated that "My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains." The application stated that "Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3

lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations."

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV's work in the following annual amounts for years 1 through 5:

	-Yr 1	-Yr 2	-Yr 3	-Yr 4	-Yr 5
Total Direct Costs	$123,699	$128,718	$147,335	$147,335	$147,335
F&A Costs @ 8%	$9,896	$10,297	$11,787	$11,787	$11,787
TOTAL COSTS	$133,595	$139,015	$159,122	$159,122	$159,122

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) ("The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities."). Moreover, EcoHealth was required to "Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]" 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]." Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV's lab safety and EcoHealth's oversight of its subrecipient, and an inspection of WIV's laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this

project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that "NIAID is not authorized under 45 CFR§§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates."

These provisions are irrelevant to NIH's requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH's concerns. Moreover, as a granting agency, NIH is required to "manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]" 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to "make site visits as warranted by program needs." 45 C.F.R. § 75.342. As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH's authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV's facility to conduct an inspection. EcoHealth's responses have not satisfied NIH's concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:

1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.10.23 13:34:25 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)

From: Post, Diane (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: FW: Scientific Advances: Daszak paper
Date: Friday, October 23, 2020 12:00:22 PM
Attachments: Origins of SARS CoV-2SM BLSM.docx

From: Mendez, Susana (NIH/NIAID) [E] (b) (6)
Sent: Friday, October 23, 2020 11:35 AM
To: Post, Diane (NIH/NIAID) [E] (b) (6); Barbara Laughon (b) (6); Ramachandra, Lakshmi (NIH/NIAID) [E] (b) (6)
Subject: Scientific Advances: Daszak paper

Hi Diane,

Please find attached the Scientific Advances write up for the Daszak publication. Please let us know if you need anything else.

Susana

Susana Mendez, DVM PhD
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases, NIAID, NIH
5601 Fishers Lane, Room 8E25
Rockville, MD 20892
(b) (6) (phone)
(b) (6) (cell)
(b) (6)

DMID SCIENCE ADVANCES

Title of Advance:

Tracking the origins and evolution of SARS-CoV-2

Background:

In January 2020 a novel coronavirus, SARS-CoV-2, was identified as the causative agent of an outbreak of viral pneumonia centered around Wuhan, Hubei, China. The disease, called COVID-19, was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. SARS-CoV2 was rapidly characterized as being closely related to several bat coronaviruses and to severe acute respiratory syndrome coronavirus (SARS-CoV), which caused an outbreak of disease in 2003. SAR-CoV-2, however, is more readily transmitted from human to human. With rapid and efficient transmission, as well as the high rates of severe disease and death, there is an urgent need to understand the source of the virus.

Advance:

China harbors more than 100 species of bats, some of which have been identified as evolutionary sources of coronavirus (CoVs). In this study, over 780 partial CoV genetic sequences were identified from 41 species of bats. The authors used a statistical genetic program to reconstruct transmission history and analyze virus spread to help understand how CoVs evolve, circulate, and transmit among bat genera, and helped identify bat hosts and regions where the risk of CoV spillover is the highest.

These phylogenetic analyses showed that most bat genera included in this study (10/16) were infected with both α- and β-CoVs. The study also found that SARS-CoV-2 is likely derived from a clade of viruses originating in horseshoe bats (Rhinolophus spp.) from the Yunnan province. This bat genus appeared to play a key role in the evolution and cross-species transmission of α-CoVs and was involved in more inter-family and inter-genus host switching than any other genus of bats.

The stable and long-term persistence of bats and other mammals throughout the quaternary ice age in China may explain the deep macroevolutionary diversity of bat-CoVs in these regions. The authors only sampled within China and could not rule out an origin for the clade of viruses that are progenitors of SARS-CoV-2 from neighboring Southeast Asian countries. In conclusion, this paper shows that αCoVs have a higher propensity to switch host within their natural bat reservoirs and have a high cross-species transmission potential and risk of spillover.

Public Impact Statement/Significance:

Understanding how COVID-19 emerged is critical to prepare for future pandemics. In this study, the authors identified the host taxa and geographic regions that define hotspots of CoV phylogenetic diversity in China. The findings suggest that future sampling and viral discovery

should target hotspots of CoV diversification in Southern and South western China, as well as neighboring countries where similar bat species live. This project contributed to our understanding of what factors allow CoVs to evolve and jump into the human population by studying viral diversity in their bat reservoirs.

NIAID Support:

R01AI110964, Peter Daszak, Ecohealth Alliance, Inc., Understanding the Risk of Bat Coronavirus Emergence (PA-18-484). FY 2019.

Press Releases and Media:
https://www.ecohealthalliance.org/2020/08/statement-on-the-latest-development-regarding-ecohealth-alliances-coronavirus-research-funding

Emerging Pandemic Diseases: How we got to COVID-19
David M. Morens, Anthony S. Fauci
Cell. 2020 Sep 3; 182(5): 1077–1092. Published online 2020 Aug 15. doi: 10.1016/j.cell.2020.08.021

The Origin of COVID-19 and Why It Matters
David M. Morens, Joel G. Breman, Charles H. Calisher, Peter C. Doherty, Beatrice H. Hahn, Gerald T. Keusch, Laura D. Kramer, James W. LeDuc, Thomas P. Monath, Jeffery K. Taubenberger
Am J Trop Med Hyg. 2020 Sep; 103(3): 955–959. Published online 2020 Jul 22. doi:10.4269/ajtmh.20-0849

Publication Citation and Pubmed Link:
Latinne *et al.* Origin and cross-species transmission of bat coronaviruses in China. Nat Commun. 2020 Aug 25;11(1):4235. https://www.ncbi.nlm.nih.gov/pubmed/32843626

Contact Information:
Erik Stemmy, RDB, erik.stemmy@nih.gov

From: Post, Diane (NIH/NIAID) [E]
To: Bozick, Brooke (NIH/NIAID) [E]; Cooper, Michael (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Gordon, Jennifer (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]; Kim, Sonnie (NIH/NIAID) [E]; Krafft, Amy (NIH/NIAID) [E]; Lampley, Rebecca (NIH/NIAID) [C]; Lane, Chelsea (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Zendt, Mackenzie (NIH/NIAID) [E]
Subject: Science Advances
Date: Wednesday, October 21, 2020 1:44:31 PM
Attachments: Science Advances Submissions FY20(2) April-Sept write up.xlsx

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Hi Everyone,

Attached are the advances that Alan choose to go forward. TB is working on drafts for us (so thankful!!). They will be reaching out to the indicated POC with any questions and will have drafts for you to review on Friday. The 3 animal model manuscripts will be combined into 1 advance.

Thanks everyone!
Diane

Diane J. Post, Ph.D.
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FY20 Round - April 1, 2020 until September 30, 2020.

RANK	Publication Title (Link to full text)	Contact PI	PI Affiliation	Journal	Write-Up	Commentary (Link)	NIAID News Release (Link)	Topic	Pathogen	Impact Statement	Outcome	Support	Contact PO
	Structure-based design of prefusion-stabilized SARS-CoV-2 spikes	Jason S. McLellan	UT-Austin	Science				SARS-CoV-2 Structure/vaccines	SARS-CoV-2			R01AI127521	Erik Stemmy
	Origin and cross-species transmission of bat coronaviruses in China	Peter Daszak	EcoHealth Alliance	Nature Communications				SARS-CoV-2 Origin	SARS-CoV-2			R01AI110964	Erik Stemmy
	Different genetic barriers for resistance to HA stem antibodies in influenza H3 and H1 viruses	Ian Wilson	TSRI	Science				Influenza broadly neutralizing antibodies	Influenza			75N93019C00051, R56AI127371 (IAW), K99AI139445 (NCW), R01AI127893 (JDB), F30AI136326 (tML)	Teresa Hauguel, Brooke Bozick, Chelsea Lane
	Molecular Diagnosis of a Novel Coronavirus (2019-nCoV) Causing an Outbreak of Pneumonia	Leo Poon	University of Hong Kong	Clin. Chem				SARS-CoV-2 Assay Development	SARS-CoV-2			HHSN272201400006C	Marciela DeGrace and Erik Stemmy
	A Mouse-Adapted SARS-CoV-2 Induces Acute Lung Injury and Mortality in Standard Laboratory Mice	Ralph Baric	University of North Carolina at Chapel Hill	Cell				SARS-CoV-2 pathogenesis	SARS-CoV-2			1U19 AI142759, 5R01AI132178, N/100625, and AI108197 as well as an animal models contract from the NIH (HHSN272201700036I 75N93020F00001)	Erik Stemmy
	Pathogenesis and transmission of SARS-CoV-2 in golden hamsters	Hui-Ling Yen	University of Hong Kong	Nature				SARS-CoV-2 animal models	SARS-CoV-2			HHSN272201400006C	Marciela DeGrace and Erik Stemmy
	Syrian hamsters as a small animal model for SARS-CoV-2 infection and countermeasure development	Yoshi Kawaoka	University of Wisconsin-Madison	PNAS				SARS-CoV-2 animal models	SARS-CoV-2			HHSN272201400008C	Marciela DeGrace and Erik Stemmy

FY20 Round - April 1, 2020 until September 30, 2020.

Publication Title (Link to full text)	Contact PI	PI Affiliation	Journal	Write-Up	Commentary (Link)	NIAID News Release (Link)	Topic	Pathogen	Impact Statement	Outcome	Support	Contact PO
Sex, age, and hospitalization drive antibody responses in a COVID-19 convalescent plasma donor population	Sabra Klein	Hopkins	J Clin Investigation				SARS-CoV-2 immune responses and sex differences	SARS-CoV-2			HHSN272201400007C	Marciela DeGrace and Erik Stemmy

From: Post, Diane (NIH/NIAID) [E]
To: Embry, Alan (NIH/NIAID) [E]
Cc: RDBViral
Subject: RDBViral Science Advances
Date: Tuesday, October 20, 2020 2:29:39 PM
Attachments: Science Advances Submissions FY20(2) April-Sept.xlsx

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Hi Alan,

Attached here is a list of the RDB Viral science advances. We have one women's health advance (can always rely on Sabra!). We did add a couple of flu advances that were really high impact. Take a look and let us know if you have any questions.

Thank you
Diane

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FY20 Round - April 1, 2020 until September 30, 2020.

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	Structure-based design of prefusion-stabilized SARS-CoV-2 spikes	Jason S. McLellan	UT-Austin	Science				SARS-CoV-2 Structure/vaccines	SARS-CoV-2			R01AI127521	Erik Stemmy
	Introductions and early spread of SARS-CoV2 in the New York City area	Harm van Bakel	Mt. Sinai	Science				SARS-CoV-2 genomics and natural history	SARS-CoV-2			HHSN272201400008C	Marciela DeGrace and Erik Stemmy
	Origin and cross-species transmission of bat coronaviruses in China	Peter Daszak	EcoHealth Alliance	Nature Communications				SARS-CoV-2 Origin	SARS-CoV-2			R01AI110964	Erik Stemmy
	A Mouse-Adapted SARS-CoV-2 Induces Acute Lung Injury and Mortality in Standard Laboratory Mice	Ralph Baric	University of North Carolina at Chapel Hill	Cell				SARS-CoV-2 pathogenesis	SARS-CoV-2			1U19 AI142759, 5R01AI132178, AI100625, and AI108197 as well as an animal models contract from the NIH (HHSN272201700036I 75N93020F00001)	Erik Stemmy
	A serological assay to detect SARS-CoV-2 seroconversion in humans	Florian Krammer	Mt Sinai	Nature Medicine				SARS-CoV-2 Assay Development	SARS-CoV-2			HHSN272201400008C	Marciela DeGrace and Erik Stemmy
	Remdesivir Inhibits SARS-CoV-2 in Human Lung Cells and Chimeric SARS-CoV Expressing the SARS-CoV-2 RNA Polymerase in Mice	Timothy P Sheahan	University of North Carolina at Chapel Hill	Cell Reports				SARS-CoV-2 Therapeutics	SARS-CoV-2			1U19AI142759, R01AI132178, R01AI132178-04S1, R01AI108197, T32AI007151	Erik Stemmy
	Different genetic barriers for resistance to HA stem antibodies in influenza H3 and H1 viruses	Ian Wilson	TSRI	Science				Influenza broadly neutralizing antibodies	Influenza			75N93019C00051 R56AI127371 (IAW) K99AI139440 (NCW) R01 AI127893 (JDB) F30AI136326 (JML)	Teresa Hauguel Brooke Bozick Chelsea Lane
	Influenza A virus is transmissible via aerosolized fomites	Nicole Bouvier	Mt. Sinai	Nature Communications				Influenza transmission	Influenza			R01 AI110703	Brooke Bozick
	Site-specific glycan analysis of the SARS-CoV-2 spike	Max Crispin	University of Southampton	Science				SARS-CoV-2 Structure/vaccines	SARS-CoV-2			R01AI127521	Erik Stemmy
	Effects of a major deletion in the SARS-CoV-2 genome on the severity of infection and the inflammatory response: an observational cohort study	Gavin JD Smith	Duke-NUS Medical School	Lancet				SARS-CoV-2 genomics and natural history	SARS-CoV-2			HHSN272201400006C	Marciela DeGrace and Erik Stemmy
	Pathogenesis and transmission of SARS-CoV-2 in golden hamsters	Hui Lin Yen	University of Hong Kong	Nature				SARS-CoV-2 animal models	SARS-CoV-2			HHSN272201400006C	Marciela DeGrace and Erik Stemmy
	Syrian hamsters as a small animal model for SARS-CoV-2 infection and countermeasure development	Yoshi Kawaoka	University of Wisconsin-Madison	PNAS				SARS-CoV-2 animal models	SARS-CoV-2			HHSN272201400008C	Marciela DeGrace and Erik Stemmy
	Molecular Diagnosis of a Novel Coronavirus (2019-nCoV) Causing an Outbreak of Pneumonia	Leo Poon	University of Hong Kong	Clin. Chem				SARS-CoV-2 Assay Development	SARS-CoV-2			HHSN272201400006C	Marciela DeGrace and Erik Stemmy
	An Alphavirus-derived replicon RNA vaccine induces SARS-CoV2 neutralizing antibody and T cell responses in mice and nonhuman primate	Deborah Fuller	University of Washington	Sci Transl Med				SARS-CoV-2 vaccine development	SARS-CoV-2			HHSN272201400006C	Marciela DeGrace and Erik Stemmy

FY20 Round - April 1, 2020 until September 30, 2020.

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Sex, age, and hospitalization drive antibody responses in a COVID-19 convalescent plasma donor population	Sabra Klein	Hopkins	J Clin Investigation				SARS-CoV-2 immune responses and sex differences	SARS-CoV-2			HHSN272201400007C	Marciela DeGrace and Erik Stemmy

From: Post, Diane (NIH/NIAID) [E]
To: RDBViral
Subject: Section meeting tomorrow
Date: Monday, October 19, 2020 10:09:37 PM
Attachments: IMPT FW IDCRC Respiratory Diseases Expert Working Group Clinical Priorities.msg
IDCRC Ad-Hoc Coronavirus Expert Working Group Establishment of DMID Clinical Priorities for the IDCRC.msg
List of Proteins included in the 16-0107 Protein Microarray Study.msg
Science Advances Submissions FY20(2) April-Sept.xlsx

Hi Everyone!

We will have section meeting tomorrow. Lots to get through so we will bypass the check in question (I know you all are going to be disappointed). Agenda is below. Please let me know if there are additional things you'd like to discuss.

VRD Section Meeting 10/20/2020

1. Science advances
2. Clinical priorities for the IDCRC
3. Protein Microarray study
4. Return to Workspace (see below)
5. Coronavirus updates
6. Standing agenda items:
    a. Universal flu
    b. Clinical trials
    c. PCS
    d. CEIRS
    e. CIVICs
    f. RSV/Rhino
    g. Other items – Ethics training (Dec); FEVES survey
    h. Due dates:
        i. FEVES Survey
        ii. Anti-harassment training – Dec 14th
        iii. Ethics training (Dec)
        iv. DURC Inventory – Nov 4th

Return to Physical Workspaces

Today, NIH is opening an exceptions process to allow federal employees who are teleworking under challenging circumstances to apply to voluntarily return to the physical workspace as a part of Group C. I know that many of us miss seeing our colleagues in person and some would actually prefer to be on site. However, this special exception process is intended for those of you who told us in the recent survey that your work from home situation is preventing you from successfully completing your work and/or maintaining your wellbeing.

Staff who find themselves in these difficult situations and are interested in voluntarily

returning as a part of Group C must complete this application form. An initial application period will be open until October 28th, and future opportunities to apply will be dependent on local conditions as well as the number of initial applications received. This application process is open to federal employees, fellows, and trainees. Contractors are not eligible to apply to voluntarily return and should speak with their Contracting Officers for more information.

I want to emphasize that completing this application does not guarantee you will be able to return on site. Once an application is completed, it will be routed first to your supervisor for approval and then to a central Institute and Center point of contact for further review. It is possible that you may be approved to return on site, but not to your regular worksite as we seek to keep density low in areas that already have a large on-site presence. The Coronavirus Response Team will review summary data about the applications received to determine if we can safely support return requests. We anticipate the earliest that decision will be made is mid-November and will update you all with any new information.

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From: Roberts, Chris (NIH/NIAID) [E]
Sent: Wed, 14 Oct 2020 23:34:54 +0000
To: Ramachandra, Lakshmi (NIH/NIAID) [E];Embry, Alan (NIH/NIAID) [E];Post, Diane (NIH/NIAID) [E];Lu, Kristina (NIH/NIAID) [E]
Cc: Makhene, Mamodikoe (NIH/NIAID) [E]
Subject: IMPT: FW: IDCRC Respiratory Diseases Expert Working Group Clinical Priorities
Attachments: IDCRC Research Priorities.docx, Priorities IDCRC Respiratory.docx

Hi All,

We received a request from IDCRC, specifically the Respiratory Diseases WG, to provide an update of our clinical priorities for Respiratory Diseases. Please discuss with you sections and others as needed and provide in tracked changes any updates/edits/suggestions by COB October 23. I will compile and schedule a call for the week of the 26th to have a broader discussion. This will then have to be cleared by Emily prior to us presenting to the IDCRC WG sometime in November.

Please use the "Priorities IDCRC Respiratory Document" to track changes. The "IDCRC Research Priorities" is the entire IDCR clinical priorities list, but may be useful to see how other branches have listed priorities in the past. Of note, some of the priorities stemmed from the IDCRC kick-off meeting last year, and these may/may not need to be fine-tuned from a programmatic standpoint.

Thanks

Chris

From: Linda McNeil <LMcneil@fhi360.org>
Date: Tuesday, October 6, 2020 at 3:51 PM
To: "Roberts, Chris (NIH/NIAID) [E]" (b) (6), "Lu, Kristina (NIH/NIAID) [E]" (b) (6)
Cc: "Makhene, Mamodikoe (NIH/NIAID) [E]" (b) (6), Ginger Pittman <GPittman@fhi360.org>
Subject: IDCRC Respiratory Diseases Expert Working Group

Dear NIH Colleagues,

I am forwarding an email just recently sent to the Co-Chairs of the Respiratory Diseases EWG. At the January kick-off meeting for the IDCRC there were several breakout sessions/meetings where we had the opportunity to discuss the forthcoming year's scientific mission, goals and agenda. There were DMID representatives present at each of these sessions and then I understand there were also individual sessions the next day between IDCRC leadership and Branch chiefs. It is possible that you were not involved in these meetings. As we draw towards the end of the first year of activity our goal is to have each EWG have one meeting where time is focused on a review and discussion on the mission/agenda and priorities for the group. To do this we felt it would be wise to share what had been discussed back in January as the basis with you in the hopes that as a Branch you would be able to update and provide a new/refreshed agenda for discussion with your EWG fellows.

We would aim to have this discussion sometime in November. The FHI team, led by Ginger, will be informing the EWG members of this call.

I apologize if I am sending this to the wrong individuals – I realize that our EWGs do not necessarily align directly with each of the Branches and those individuals representing the Branches on the calls may not be best placed to undertake this exercise. However, I am hopeful that you will be able to work with the appropriate individual(s) internally. The two attached documents, also shared with the Co-Chairs, are from the January meeting.

Please if this poses difficulties let me know. One group has already completed this exercise and may be able to provide some clarification – the STI EWG has completed their overview.

Kind regards, Linda

From: Linda McNeil
Sent: Monday, October 5, 2020 9:27 PM
To: Hana M El Sahly <Hana.ElSahly@bcm.edu>; Lisa A. Jackson <lisa.a.jackson@kp.org>
Cc: Ginger Pittman <GPittman@fhi360.org>; Shilysha Davis-Dublin (SDavis-Dublin@fhi360.org) <SDavis-Dublin@fhi360.org>
Subject: IDCRC Respiratory Diseases Expert Working Group

Dear Drs. El Sahly and Jackson,

Thank you once again for agreeing to serve as Co-Chairs of this EWG. While it has been good that your EWG has had some concepts to work thru and review we would like to have one of your meetings, before the end of our first year, devoted to a discussion and update of the priorities that were set or outlined at the January 2020 kick-off meeting.

Attached is a summary of the discussions that took place during the January 2020 meeting for your reference – the one attachment is the set where it is easy to define those for the Respiratory Diseases group and the second is a comprehensive set covering all. We will ask the assigned Respiratory Diseases DMID representatives to review, update and provide a short presentation of revised DMID priorities/mission at the planned EWG meeting.

The January 2021 Annual IDCRC meeting will also be an excellent opportunity to refine the collective path forward for the IDCRC.

Copied on this email are Ginger and Shilysha, from your FHI 360 team who will work with you to devise this particular agenda. If you have suggestions, questions, or concerns, please just give me a call.

Kind regards, Linda

Linda McNeil MA PMP | Assoc Director, Science Facilitation Dept; Project Director STI CTG & IDCRC

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Infectious Diseases Clinical Research Consortium

Priorities Draft

Emerging Infections		
Disease	Focus	Source of Priority
Novel emerging viruses	Vaccines for Phase I/II trials Novel platforms Natural History Studies	Virology Branch
Chikungunya	mAbs/therapeutics in Phase I trials	Virology Branch
Zika	Development of CHIMs	Virology Branch
Dengue	Development of CHIMs	Virology Branch
AFM due to enterovirus	Vaccines and Passive immunization strategies	Kickoff Meeting Breakout group & Virology Branch
S. aureus	Passive immunization strategies	Kickoff Meeting Breakout group
Flaviviruses	Passive immunization strategies	Kickoff Meeting Breakout group
Tickborne Diseases	Therapeutics	Bacteriology and Mycology Branch
Lyme disease	Prevention and Therapeutics	Bacteriology and Mycology Branch
Coccidioidomycosis	Antifungal resistance Therapeutics	Bacteriology and Mycology Branch
Candida auris	Antifungal resistance Therapeutics Vaccine	Enteric and STI Branch Bacteriology and Mycology Branch
Pathogen-agnostic: Establish common protocols that can be used for rapid responses to emerging threats, much like a DARPA-sprint		Kickoff Meeting Breakout group
AMR bacterial vaccines: *S. aureus/C. auris*, NTM (would fall under RDB), *E. coli* UTI Building a biorepository		Kickoff Meeting Breakout group & Bacteriology and Mycology Branch (re: ?NTM, Mycobacterium excluded from IDCRC RFA)
Testing novel methods of vaccination (e.g., nanoparticles, microneedle patch)		Kickoff Meeting Breakout group & Virology Branch
Broad-platform based technologies (Pan-species vaccines, mRNA/DNA vaccines, Common vectored vaccines)		Kickoff Meeting Breakout group
Antibacterial resistance (especially hospital-based, critically ill populations): optimizing current drugs, new antibiotic candidate trials, phage trials		Bacteriology and Mycology Branch

Infectious Diseases Clinical Research Consortium

Priorities Draft

Enteric		
Disease	Focus	Source of Priority
Shigella species	Vaccines in high risk populations	Enteric and STI Branch Kickoff Meeting Breakout group
Campylobacter	Vaccines	Enteric and STI Branch
Non-typhoidal *Salmonella*	Vaccines Epidemiology CHIMs studies	Enteric and STI Branch Kickoff Meeting Breakout group
C. difficile	New treatment modalities: Phase I safety study of Monoclonal Antibodies Landscape Analysis	Enteric and STI Branch Kickoff Meeting Breakout group
Norovirus	Development of CHIMs Outbreak control	Virology Branch Kickoff Meeting Breakout group
Rotavirus	Vaccines and strategies in developing countries	Kickoff Meeting Breakout group
Cryptosporidium	Therapeutics POC diagnostics.	Mentioned by Enteric and STI Branch but falls under Parasitology and International Programs Branch; Kickoff Meeting Breakout group
Hepatitis and Rotavirus		Mentioned by Enteric and STI Branch but falls under Virology Branch

Infectious Diseases Clinical Research Consortium

Priorities Draft

Malaria and Tropical Diseases		
Diseases:	Focus	Source of Priority
Malaria	Vaccines: multiple candidates for different stages of the disease Drugs: monoclonal antibodies CHIM studies Immunology: understanding of antibody as well as T cell immunity in the blood and tissues Considerations for local versus international studies	Parasitology and International Programs Branch and Kickoff Meeting Breakout group
Schistosomiasis	Vaccines & Drugs Diagnostics	Parasitology and International Programs Branch Kickoff Meeting Breakout group
Filariases	Vaccines & Drugs	Parasitology and International Programs Branch and Kickoff Meeting Breakout group
STH	Vaccines & Drugs	Parasitology and International Programs Branch
Leishmaniasis	Vaccines & Drugs	Parasitology and International Programs Branch and Kickoff Meeting Breakout group
Chagas	Vaccines	Kickoff Meeting Breakout group
Other parasitic diseases	Novel vector control Diagnostics Salivary protein vaccine	Parasitology and International Programs Branch Kickoff Meeting Breakout group
Special Considerations	CHIM and International Sites	Parasitology and International Programs Branch

Infectious Diseases Clinical Research Consortium

Priorities Draft

Respiratory Diseases		
Disease	Focus	Source of Priority
Influenza	Improved seasonal and universal vaccine candidates	Respiratory Diseases Branch Clinical Priorities
RSV	Vaccines	Respiratory Diseases Branch Clinical Priorities
Emerging respiratory viruses	Vaccines Rapid response assessments	Respiratory Diseases Branch Clinical Priorities
Pertussis	Vaccine	Respiratory Diseases Branch Clinical Priorities
GAS	Vaccine	Respiratory Diseases Branch Clinical Priorities
Pneumonia	Vaccine	Respiratory Diseases Branch Clinical Priorities
GBS	Vaccine	Respiratory Diseases Branch Clinical Priorities
TB	Novel Vaccine and therapeutic candidates	Respiratory Diseases Branch Clinical Priorities DMID (although TB excluded from IDCRC RFA)
Human challenge studies: Influenza, RSV, emerging resp viruses		Respiratory Diseases Branch Clinical Priorities
Can existing, licensed influenza vaccines (e.g., high dose and adjuvanted vaccines) benefit younger age-groups? *(Phase II trials, Head to head evaluations, including standard seasonal vaccines, broad immunologic assessments, potentially include a challenge component)*		Kickoff Meeting Respiratory EWG
For pre-pandemic influenza vaccines (e.g., H5N1, H7N9), how much cross-protection against drifted strains is induced by adjuvanted vaccines? *(Build on prior studies, advanced immunologic assessments, also evaluate priming with adjuvanted vs non-adjuvanted)*		Kickoff Meeting Respiratory EWG
What novel seasonal vaccine constructs and approaches show promise? *(Phase I/II trials, initially healthy adults, evaluate heterologous prime-boost and strategies utilizing combinations of vaccines and delivery methods, evaluate novel adjuvants, broad immunologic assessments, eventually compare with the best available conventional vaccines)*		Kickoff Meeting Breakout group
How does NA content in standard seasonal vaccines influence non-HAI responses? *(Phase I/II studies in varied populations)*		Kickoff Meeting Breakout group
How are the immune responses to vaccination and infection influenced by prior history (e.g., birth cohort and immune status) and		Kickoff Meeting Breakout group

other factors (e.g., genetics)? (*Human challenge studies, longitudinal cohort studies)*	
What are the correlates of protection to standard and novel seasonal influenza vaccines? *(Human challenge studies, longitudinal cohort studies of natural infection, system biology approaches)*	Kickoff Meeting Breakout group
How does maternal vaccination influence infant responses to vaccines and risk of infection? *(Phase II trials of maternal vaccination with limited follow-up of infants evaluating immunologic responses, longitudinal cohort studies enrolling pregnant women with multi-year follow up of infants and assessment of natural infection risk, immunologic parameters, and responses of infants to vaccinations after six months of age)*	Kickoff Meeting Breakout group
What is the duration of efficacy of conventional influenza vaccines (evaluation of waning immunity)? *(Varied age groups in Phase II trials, potentially human challenge models)*	Kickoff Meeting Breakout group
How does vaccine type and pattern of vaccine administration influence immunogenicity and efficacy? *(Multi-year prospective cohort study of young, healthy adults, evaluation of multiple vaccine types given in multiple patterns over time, follow up for multiple sequential influenza seasons, multiple immunologic parameters)*	Kickoff Meeting Breakout group
Does LAIV influence the immunogenicity of inactivated vaccines? *(Multi-season evaluation of young healthy adults given various sequences of LAIV and inactivated vaccines over time, multiple specimen types evaluated by broad immunologic assessments, comparisons of transcriptomic (other 'omic) signatures in non-invasive respiratory samples)*	Kickoff Meeting Breakout group

Infectious Diseases Clinical Research Consortium

Priorities Draft

STIs		
Disease	Focus	Source of Priority
Neisseria gonorrhoeae	Vaccines, (new, Bexero) Therapeutics, new antibiotics Rapid POC diagnostics with antibiotic susceptibility markers	Enteric and STI Branch
Chlamydia trachomatis	Vaccines Rapid POC diagnostics with antibiotic susceptibility markers	Enteric and Sexually Transmitted Branch
Syphilis	Vaccines Therapeutics, alternative treatments particularly for pregnant women New diagnostics	Enteric and Sexually Transmitted Infections Branch and Kickoff Meeting Breakout group
HSV	Vaccines Accurate diagnostics Therapeutics and treatment of resistance	Enteric and Sexually Transmitted Infections Branch Kickoff Meeting Breakout group
M. genitalium	Moxifloxacin R, Role of *M. genitalium* in genital health (natural history), How relevant for public health/diagnostics	Kickoff Meeting Breakout group
BV and other STIs/PID	Including women of reproductive age	Kickoff Meeting Breakout group
Cross fertilization with HIV networks (especially HPTN & HVTN)		Kickoff Meeting Breakout group

Infectious Diseases Clinical Research Consortium

Priorities Draft

Respiratory Diseases		
Disease	Focus	Source of Priority
Influenza	Improved seasonal and universal vaccine candidates	Respiratory Diseases Branch Clinical Priorities
RSV	Vaccines	Respiratory Diseases Branch Clinical Priorities
Emerging respiratory viruses	Vaccines Rapid response assessments	Respiratory Diseases Branch Clinical Priorities
Pertussis	Vaccine	Respiratory Diseases Branch Clinical Priorities
GAS	Vaccine	Respiratory Diseases Branch Clinical Priorities
Pneumonia	Vaccine	Respiratory Diseases Branch Clinical Priorities
GBS	Vaccine	Respiratory Diseases Branch Clinical Priorities
TB	Novel Vaccine and therapeutic candidates	Respiratory Diseases Branch Clinical Priorities DMID (although TB excluded from IDCRC RFA)
Human challenge studies: Influenza, RSV, emerging resp viruses		Respiratory Diseases Branch Clinical Priorities
Can existing, licensed influenza vaccines (e.g., high dose and adjuvanted vaccines) benefit younger age-groups? *(Phase II trials, Head to head evaluations, including standard seasonal vaccines, broad immunologic assessments, potentially include a challenge component)*		Kickoff Meeting Respiratory EWG
For pre-pandemic influenza vaccines (e.g., H5N1, H7N9), how much cross-protection against drifted strains is induced by adjuvanted vaccines? *(Build on prior studies, advanced immunologic assessments, also evaluate priming with adjuvanted vs non-adjuvanted)*		Kickoff Meeting Respiratory EWG
What novel seasonal vaccine constructs and approaches show promise? *(Phase I/II trials, initially healthy adults, evaluate heterologous prime-boost and strategies utilizing combinations of vaccines and delivery methods, evaluate novel adjuvants, broad immunologic assessments, eventually compare with the best available conventional vaccines)*		Kickoff Meeting Breakout group
How does NA content in standard seasonal vaccines influence non-HAI responses? *(Phase I/II studies in varied populations)*		Kickoff Meeting Breakout group
How are the immune responses to vaccination and infection influenced by prior history (e.g., birth cohort and immune status) and		Kickoff Meeting Breakout group

other factors (e.g., genetics)? (*Human challenge studies, longitudinal cohort studies)*	
What are the correlates of protection to standard and novel seasonal influenza vaccines? *(Human challenge studies, longitudinal cohort studies of natural infection, system biology approaches)*	Kickoff Meeting Breakout group
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What is the duration of efficacy of conventional influenza vaccines (evaluation of waning immunity)? *(Varied age groups in Phase II trials, potentially human challenge models)*	Kickoff Meeting Breakout group
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Does LAIV influence the immunogenicity of inactivated vaccines? *(Multi-season evaluation of young healthy adults given various sequences of LAIV and inactivated vaccines over time, multiple specimen types evaluated by broad immunologic assessments, comparisons of transcriptomic (other 'omic) signatures in non-invasive respiratory samples)*	Kickoff Meeting Breakout group

From: Roberts, Chris (NIH/NIAID) [E]
Sent: Wed, 14 Oct 2020 23:32:33 +0000
To: Post, Diane (NIH/NIAID) [E];Beigel, John (NIH) [E];Embry, Alan (NIH/NIAID) [E]
Subject: IDCRC Ad-Hoc Coronavirus Expert Working Group: Establishment of DMID Clinical Priorities for the IDCRC
Attachments: IDCRC Research Priorities.docx, Priorities IDCRC COVID.docx

Hi Diane, Alan and John,

We received a request from IDCRC, specifically the COVID WG, to provide an update of our clinical priorities for the IDCRC with respect to COVID19 and Coronavirus. We may ultimately decide that all of this should be incorporated into RDB's clinical priorities, but as COVID priorites are DMID wide, they are looking for some specific guidance on coronavirus priorities for this WG, as we will likely maintain the WG through next year. Please discuss with your sections or others as needed and provide suggestions by COB October 23 back to me, so that have time to further refine, have a broader discussion and get buy-in and feedback from Emily and Cristina. I will compile and schedule a call for the week of the 26th to have a discussion on this. As noted, Alan will have to clear through Emily prior to us presenting to the IDCRC WG sometime in November.

John: if you could perhaps focus on therapeutics, I think we (RDBviral-Diane and RDBclinical) can begin to get the vaccine priorities together as well as help identify any therapeutic gaps. Two documents are attached: The "IDCRC Research Priorities", which is the entire DMID clinical priorities list, may be useful to see how other branches have listed priorities in the past. Of note, some of the priorities stemmed from the IDCRC kick-off meeting last year, and these may/may not need to be fine-tuned from a programmatic standpoint.

Please use the attached document for suggestions: "Priorities IDCRC COVID"

Additional notes: We've learned through the EWG sessions, that guidance or "swim lane" of the IDCRC needs to be tailored somewhat and specific with respect to types, stage, risk groups and age groups of trials we envision supporting.

Thanks

Chris

From: Linda McNeil <LMcneil@fhi360.org>
Date: Tuesday, October 6, 2020 at 3:50 PM
To: "Roberts, Chris (NIH/NIAID) [E]" (b) (6), John Beigel (b) (6)>
Cc: Anne Rinaldi <ARinaldi@fhi360.org>
Subject: IDCRC Ad-Hoc Coronavirus Expert Working Group

Dear NIH Colleagues,

I am forwarding an email just recently sent to the Co-Chairs of the Ad-Hoc Coronavirus EWG. As outlined in the email below at the January kick-off meeting for the IDCRC there were several breakout sessions/meetings where we had the opportunity to discuss the forthcoming year's scientific mission, goals and agenda. There were DMID representatives present at each of these sessions and then I understand there were also individual sessions the next day between IDCRC leadership and Branch chiefs. There was no such meeting of course for Coronavirus. However as we draw towards the end of the first year of activity our goal is to have each EWG have one meeting where they take some time to review and discuss the mission/agenda and priorities for the group. In order to for this to be successful we would be relying heavily on our DMID colleagues to present the NIH view of current mission, priorities etc.

We would aim to have this discussion sometime in November on a routine EWG call.

I realize this request is slightly unusual in that there was no prior discussion with the IDCRC for this particular Ad-Hoc EWG, but I believe that within recent EWG calls there has been some talk of what the direction should be, and it is clear that the IDCRC is just a small component of the overall COVID work undertaken within DMID/NIH. A short presentation of where DMID sees the IDCRC fitting in, is I believe what is being sought, and certainly would be in line with what you both generally bring to the ongoing discussions on concepts.

Please if this poses difficulties let me know.

Kind regards, Linda

From: Linda McNeil
Sent: Monday, October 5, 2020 9:26 PM
To: Spearman, Paul (Paul) <paul.spearman@cchmc.org>; Hana M El Sahly <Hana.ElSahly@bcm.edu>
Cc: Anne Rinaldi <ARinaldi@fhi360.org>; Lauren Hale <LHale@fhi360.org>
Subject: IDCRC Ad-Hoc Coronavirus Expert Working Group

Dear Drs. Spearman and El Sahly,

Thank you once again for agreeing to serve as Co-Chairs of this Ad-Hoc EWG. Your EWG has been exceptionally busy since inception and only recently been able to take a break from a back-to-back schedule. For the other EWGs there were meetings at the January 2020 kick-off meeting where those of us who were joining the new IDCRC venture were given the opportunity to meet together with DMID representatives to discuss possible research priorities for the coming year. Naturally this EWG was not on the horizon and a research plan for COVID was not discussed. For each of the IDCRC EWG's we are asking that before the end of our first year they set aside one meeting to discuss what had been discussed as the plan and think/discuss new priorities/direction. We will ask the assigned Respiratory Diseases DMID representative (who is on your EWG) to provide a short presentation of revised DMID priorities/mission at the planned EWG meeting. We think that this would be a good review/exercise for the COVID Ad-Hoc EWG.

Attached is a summary of the discussions that took place during the January 2020 meeting for your reference – I am also attaching a short table that might be helpful in preparing for this call. I know this EWG has had some discussions on what the mission/agenda is; therapeutics (all vs some in particular); vaccines; and recently the issue of behavioral interventions has cropped up. – the one attachment is the set where it is easy to define those for the Respiratory Diseases group (the goal has always been to fold this ad-hoc EWG into Respiratory at some point but that seems in a way distant future!), but I thought I would send it, and the second is a comprehensive set covering all. The January 2021 Annual IDCRC meeting will also be an excellent opportunity to refine the collective path forward for the IDCRC.

Copied on this email are Anne and Lauren from your FHI 360 team who will work with you to devise this particular agenda. If you have suggestions, questions, or concerns, please just give me a call.

Kind regards, Linda

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Infectious Diseases Clinical Research Consortium

Priorities Draft

Emerging Infections		
Disease	Focus	Source of Priority
Novel emerging viruses	Vaccines for Phase I/II trials Novel platforms Natural History Studies	Virology Branch
Chikungunya	mAbs/therapeutics in Phase I trials	Virology Branch
Zika	Development of CHIMs	Virology Branch
Dengue	Development of CHIMs	Virology Branch
AFM due to enterovirus	Vaccines and Passive immunization strategies	Kickoff Meeting Breakout group & Virology Branch
S. aureus	Passive immunization strategies	Kickoff Meeting Breakout group
Flaviviruses	Passive immunization strategies	Kickoff Meeting Breakout group
Tickborne Diseases	Therapeutics	Bacteriology and Mycology Branch
Lyme disease	Prevention and Therapeutics	Bacteriology and Mycology Branch
Coccidioidomycosis	Antifungal resistance Therapeutics	Bacteriology and Mycology Branch
Candida auris	Antifungal resistance Therapeutics Vaccine	Enteric and STI Branch Bacteriology and Mycology Branch
Pathogen-agnostic: Establish common protocols that can be used for rapid responses to emerging threats, much like a DARPA-sprint		Kickoff Meeting Breakout group
AMR bacterial vaccines: *S. aureus/C. auris*, NTM (would fall under RDB), *E. coli* UTI Building a biorepository		Kickoff Meeting Breakout group & Bacteriology and Mycology Branch (re: ?NTM, Mycobacterium excluded from IDCRC RFA)
Testing novel methods of vaccination (e.g., nanoparticles, microneedle patch)		Kickoff Meeting Breakout group & Virology Branch
Broad-platform based technologies (Pan-species vaccines, mRNA/DNA vaccines, Common vectored vaccines)		Kickoff Meeting Breakout group
Antibacterial resistance (especially hospital-based, critically ill populations): optimizing current drugs, new antibiotic candidate trials, phage trials		Bacteriology and Mycology Branch

Infectious Diseases Clinical Research Consortium

Priorities Draft

Enteric		
Disease	Focus	Source of Priority
Shigella species	Vaccines in high risk populations	Enteric and STI Branch Kickoff Meeting Breakout group
Campylobacter	Vaccines	Enteric and STI Branch
Non-typhoidal *Salmonella*	Vaccines Epidemiology CHIMs studies	Enteric and STI Branch Kickoff Meeting Breakout group
C. difficile	New treatment modalities: Phase I safety study of Monoclonal Antibodies Landscape Analysis	Enteric and STI Branch Kickoff Meeting Breakout group
Norovirus	Development of CHIMs Outbreak control	Virology Branch Kickoff Meeting Breakout group
Rotavirus	Vaccines and strategies in developing countries	Kickoff Meeting Breakout group
Cryptosporidium	Therapeutics POC diagnostics.	Mentioned by Enteric and STI Branch but falls under Parasitology and International Programs Branch; Kickoff Meeting Breakout group
Hepatitis and Rotavirus		Mentioned by Enteric and STI Branch but falls under Virology Branch

Infectious Diseases Clinical Research Consortium

Priorities Draft

Malaria and Tropical Diseases		
Diseases:	Focus	Source of Priority
Malaria	Vaccines: multiple candidates for different stages of the disease Drugs: monoclonal antibodies CHIM studies Immunology: understanding of antibody as well as T cell immunity in the blood and tissues Considerations for local versus international studies	Parasitology and International Programs Branch and Kickoff Meeting Breakout group
Schistosomiasis	Vaccines & Drugs Diagnostics	Parasitology and International Programs Branch Kickoff Meeting Breakout group
Filariases	Vaccines & Drugs	Parasitology and International Programs Branch and Kickoff Meeting Breakout group
STH	Vaccines & Drugs	Parasitology and International Programs Branch
Leishmaniasis	Vaccines & Drugs	Parasitology and International Programs Branch and Kickoff Meeting Breakout group
Chagas	Vaccines	Kickoff Meeting Breakout group
Other parasitic diseases	Novel vector control Diagnostics Salivary protein vaccine	Parasitology and International Programs Branch Kickoff Meeting Breakout group
Special Considerations	CHIM and International Sites	Parasitology and International Programs Branch

Infectious Diseases Clinical Research Consortium

Priorities Draft

Respiratory Diseases		
Disease	Focus	Source of Priority
Influenza	Improved seasonal and universal vaccine candidates	Respiratory Diseases Branch Clinical Priorities
RSV	Vaccines	Respiratory Diseases Branch Clinical Priorities
Emerging respiratory viruses	Vaccines Rapid response assessments	Respiratory Diseases Branch Clinical Priorities
Pertussis	Vaccine	Respiratory Diseases Branch Clinical Priorities
GAS	Vaccine	Respiratory Diseases Branch Clinical Priorities
Pneumonia	Vaccine	Respiratory Diseases Branch Clinical Priorities
GBS	Vaccine	Respiratory Diseases Branch Clinical Priorities
TB	Novel Vaccine and therapeutic candidates	Respiratory Diseases Branch Clinical Priorities DMID (although TB excluded from IDCRC RFA)
Human challenge studies: Influenza, RSV, emerging resp viruses		Respiratory Diseases Branch Clinical Priorities
Can existing, licensed influenza vaccines (e.g., high dose and adjuvanted vaccines) benefit younger age-groups? *(Phase II trials, Head to head evaluations, including standard seasonal vaccines, broad immunologic assessments, potentially include a challenge component)*		Kickoff Meeting Respiratory EWG
For pre-pandemic influenza vaccines (e.g., H5N1, H7N9), how much cross-protection against drifted strains is induced by adjuvanted vaccines? *(Build on prior studies, advanced immunologic assessments, also evaluate priming with adjuvanted vs non-adjuvanted)*		Kickoff Meeting Respiratory EWG
What novel seasonal vaccine constructs and approaches show promise? *(Phase I/II trials, initially healthy adults, evaluate heterologous prime-boost and strategies utilizing combinations of vaccines and delivery methods, evaluate novel adjuvants, broad immunologic assessments, eventually compare with the best available conventional vaccines)*		Kickoff Meeting Breakout group
How does NA content in standard seasonal vaccines influence non-HAI responses? *(Phase I/II studies in varied populations)*		Kickoff Meeting Breakout group
How are the immune responses to vaccination and infection influenced by prior history (e.g., birth cohort and immune status) and		Kickoff Meeting Breakout group

other factors (e.g., genetics)? (*Human challenge studies, longitudinal cohort studies)*	
What are the correlates of protection to standard and novel seasonal influenza vaccines? *(Human challenge studies, longitudinal cohort studies of natural infection, system biology approaches)*	Kickoff Meeting Breakout group
How does maternal vaccination influence infant responses to vaccines and risk of infection? *(Phase II trials of maternal vaccination with limited follow-up of infants evaluating immunologic responses, longitudinal cohort studies enrolling pregnant women with multi-year follow up of infants and assessment of natural infection risk, immunologic parameters, and responses of infants to vaccinations after six months of age)*	Kickoff Meeting Breakout group
What is the duration of efficacy of conventional influenza vaccines (evaluation of waning immunity)? *(Varied age groups in Phase II trials, potentially human challenge models)*	Kickoff Meeting Breakout group
How does vaccine type and pattern of vaccine administration influence immunogenicity and efficacy? *(Multi-year prospective cohort study of young, healthy adults, evaluation of multiple vaccine types given in multiple patterns over time, follow up for multiple sequential influenza seasons, multiple immunologic parameters)*	Kickoff Meeting Breakout group
Does LAIV influence the immunogenicity of inactivated vaccines? *(Multi-season evaluation of young healthy adults given various sequences of LAIV and inactivated vaccines over time, multiple specimen types evaluated by broad immunologic assessments, comparisons of transcriptomic (other 'omic) signatures in non-invasive respiratory samples)*	Kickoff Meeting Breakout group

Infectious Diseases Clinical Research Consortium

Priorities Draft

STIs		
Disease	Focus	Source of Priority
Neisseria gonorrhoeae	Vaccines, (new, Bexero) Therapeutics, new antibiotics Rapid POC diagnostics with antibiotic susceptibility markers	Enteric and STI Branch
Chlamydia trachomatis	Vaccines Rapid POC diagnostics with antibiotic susceptibility markers	Enteric and Sexually Transmitted Branch
Syphilis	Vaccines Therapeutics, alternative treatments particularly for pregnant women New diagnostics	Enteric and Sexually Transmitted Infections Branch and Kickoff Meeting Breakout group
HSV	Vaccines Accurate diagnostics Therapeutics and treatment of resistance	Enteric and Sexually Transmitted Infections Branch Kickoff Meeting Breakout group
M. genitalium	Moxifloxacin R, Role of *M. genitalium* in genital health (natural history), How relevant for public health/diagnostics	Kickoff Meeting Breakout group
BV and other STIs/PID	Including women of reproductive age	Kickoff Meeting Breakout group
Cross fertilization with HIV networks (especially HPTN & HVTN)		Kickoff Meeting Breakout group

Infectious Diseases Clinical Research Consortium

Priorities Draft

Coronavirus		
Disease	Focus	Source of Priority

October 2020

From: Roberts, Chris (NIH/NIAID) [E]
Sent: Mon, 19 Oct 2020 17:55:57 +0000
To: RDBViral
Cc: Tibbals, Melinda (NIH/NIAID) [C];Ormanoski, Kathy (NIH/NIAID) [E]
Subject: List of Proteins included in the 16-0107 Protein Microarray Study
Attachments: 16-0107_Appendix B_22Oct2019_Protein List for Supplemental Array[3].pdf,
RE: 16-0107 slides to be printed

Hi All,

Here is the list of antigens incorporated in the microarray that was used to probe the H5N1 A/Indo AS03 and MF59 Mix and Match Studies. We included vaccine antigens for the 2013 and 2017 H7N9 trials as well as the H5N8 vaccine trials so that we could actually use these for probing the serological responses in those samples as well. The attached email lists (excel) a whole slew of other antigens that could be incorporated onto these arrays again as a deliverable to us. However, as Kathy pointed out, we can't change too many antigens out at this stage, based on timing and costs but if you feel strongly about having some additional antigens on the array we could quickly look into feasibility of incorporating them. Anyway, if you can get back to me by COB on Friday with any suggestions that would be great. Otherwise we will move forward with the Appendix B list.

Thanks
Chris

FINAL PROTEIN LIST FOR SUPPLEMENTARY MICROARRAY (version 22 October 2019)

(This list is composed of proteins from Sino Biologicals Inc., from Florian Krammer's Lab, and from James Crowe's Lab) DUPLICATE Protein duplicated in the array

Cat # (Sino Bio)	Full ID	Type	Clade	Isolate	Isolate	Geo	SN2	SN3	Year	Mol ID1	Mol ID2	Form1	Form2	Subtype	GenBank	Expression Syste	Other notes
11003-V04H2	A/VietNam/1203/2004	A	1	human	human	VietNam	1203		2004	HA	HA2			H5N1	AAW80737.1	Human cells	Fc tag (mouse)
11003-V06H1	A/VietNam/1203/2004	A	1	human	human	VietNam	1203		2004	HA	HA1			H5N1	AAW80717.1	Human cells	His & Fc tag (mouse)
11003-V06H3	A/VietNam/1203/2004	A	1	human	human	VietNam	1203		2004	HA	HA1+HA2	uncleaved		H5N1	AAW80717.1	Human cells	His & Fc tag (mouse)
11048-V06H1	A/Anhui/1/2005	A	2.3.4	human	human	Anhui	1		2005	HA	HA1+HA2	uncleaved		H5N1	ABD28180.1	Human cells	His & Fc tag (mouse)
11048-V08B	A/Anhui/1/2005	A	2.3.4	human	human	Anhui	1		2005	HA	HA1+HA2	uncleaved		H5N1	ABD28180.1	Baculovirus	His tag
11048-V08H1	A/Anhui/1/2005	A	2.3.4	human	human	Anhui	1		2005	HA	HA1+HA2	uncleaved		H5N1	ABD28180.1	Human cells	His tag
11048-V08H2	A/Anhui/1/2005	A	2.3.4	human	human	Anhui	1		2005	HA	HA1			H5N1	ABD28180.1	Human cells	His tag
11048-V08H4	A/Anhui/1/2005	A	2.3.4	human	human	Anhui	1		2005	HA	HA1+HA2	cleaved	Native	H5N1	ABD28180.1	Human cells	His tag
11048-VNAH2	A/Anhui/1/2005	A	2.3.4	human	human	Anhui	1		2005	HA	HA1			H5N1	ABD 28180.1	Human cells	
11052-V08H	A/Brisbane/59/2007	A		human	human	Brisbane	59		2007	HA	HA1+HA2	uncleaved	Native	H1N1	ACA28844.1	Human cells	His tag
11052-V08H1	A/Brisbane/59/2007	A		human	human	Brisbane	59		2007	HA	HA1			H1N1	ACA28844.1	Human cells	His tag
11055-V08B	A/California/04/2009	A		human	human	California	4		2009	HA	HA1+HA2	uncleaved	Native	H1N1	ACP41105.1	Baculovirus	His tag
11055-V08H	A/California/04/2009	A		human	human	California	4		2009	HA	HA1+HA2	uncleaved	Native	H1N1	ACP41105.1	Human cells	His tag
11055-V08H2	A/California/04/2009	A		human	human	California	4		2009	HA	HA1+HA2	cleaved (partial)		H1N1	ACP41105.1	Human cells	His tag
11055-V08H4	A/California/04/2009	A		human	human	California	4		2009	HA	HA1			H1N1	ACP41105.1	Human cells	His tag
11055-VNAB	A/California/04/2009	A		human	human	California	4		2009	HA	HA1+HA2 (HAG)			H1N1		Baculovirus	
11056-V08B	A/Brisbane/10/2007	A		human	human	Brisbane	10		2007	HA	HA1+HA2			H3N2	ABW23353.1	Baculovirus	His tag
11056-V08H	A/Brisbane/10/2007	A		human	human	Brisbane	10		2007	HA	HA1-HA2	uncleaved	Native	H3N2	ABW23353.1	Human cells	His tag
11056-V08H1	A/Brisbane/10/2007	A		human	human	Brisbane	10		2007	HA	HA1			H3N2	ABW23353.1	Human cells	His tag
11059-V08B1	A/bar-headed goose/Qinghai/14/2008	A	2.2	bar-hea	non-hui	Qinghai	14		2008	HA	HA1+HA2	uncleaved		H5N1	ACL28277.1	Baculovirus	His tag
11059-V08H1	A/bar-headed goose/Qinghai/14/2008	A	2.2	bar-hea	non-hui	Qinghai	14		2008	HA	HA1+HA2	uncleaved		H5N1	ACL28277.1	Human cells	His tag
11059-V08H2	A/bar-headed goose/Qinghai/14/2008	A	2.2	bar-hea	non-hui	Qinghai	14		2008	HA	HA1+HA2	cleaved	Native	H5N1	ACL28277.1	Human cells	His tag
11060-V08H1	A/Indonesia/5/2005	A	2.1.3.2	human	human	Indonesia	5		2005	HA	HA1+HA2	uncleaved		H5N1	ABW06108.1	Human cells	His tag
11060-V08H2	A/Indonesia/5/2005	A	2.1.3.2	human	human	Indonesia	5		2005	HA	HA1+HA2	cleaved	Native	H5N1	ABW06108.1	Human cells	His tag
11061-V08H1	A/turkey/Turkey/1/2005	A	2.2.1	turkey	non-hui	Turkey	1		2005	HA	HA1+HA2	uncleaved		H5N1	ABD73284.1	Human cells	His tag
11061-V08H2	A/turkey/Turkey/1/2005	A	2.2.1	turkey	non-hui	Turkey	1		2005	HA	HA1+HA2	cleaved	Native	H5N1	ABD73284.1	Human cells	His tag
11062-V08H1	A/Vietnam/1194/2004	A	1	human	human	Vietnam	1194		2004	HA	HA1+HA2	uncleaved		H5N1	AAT73273.1	Human cells	His tag
11062-V08H2	A/Vietnam/1194/2004	A	1	human	human	Vietnam	1194		2004	HA	HA1+HA2	cleaved	Native	H5N1	AAT73273.1	Human cells	His tag
11068-V08H	A/Brevig Mission/1/1918	A		human	human	Brevig Mis	1		1918	HA	HA1+HA2	uncleaved	Native	H1N1	AAD17229.1	Human cells	His tag
11068-V08H1	A/Brevig Mission/1/1918	A		human	human	Brevig Mis	1		1918	HA	HA1			H1N1	AAD17229.1	Human cells	His tag
11082-V08B	A/Netherlands/219/03	A		human	human	Netherlan	219		2003	HA	HA1+HA2		Native	H7N7	AAR02640.1	Baculovirus	His tag
11082-V08H1	A/Netherlands/219/03	A		human	human	Netherlan	219		2003	HA	HA1			H7N7	AAR02640.1	Human cells	His tag
11212-V08B	A/chicken/Netherlands/1/03	A		chicken	non-hui	Netherlan	1		2003	HA	HA1+HA2		Native	H7N7	AAR02635.1	Baculovirus	His tag
11212-V08H1	A/chicken/Netherlands/1/03	A		chicken	non-hui	Netherlan	1		2003	HA	HA1			H7N7	AAR02635.1	Human cells	His tag
11229-V08H	A/Hong Kong/1073/99	A		human	human	Hong Kon	1073		1999	HA	HA1-HA2		Native	H9N2	NP_859037.1	Human cells	His tag
11229-V08H1	A/HongKong/1073/99	A		human	human	HongKong	1073		1999	HA	HA1			H9N2	NP_859037.1	Human cells	His tag
11683-V08H	A/New Caledonia/20/99	A		human	human	New Calec	20		1999	HA	HA1+HA2	uncleaved		H1N1	AAP34324.1	Human cells	His tag
11683-V08H1	A/New Caledonia/20/99	A		human	human	New Calec	20		1999	HA	HA1			H1N1	AAP34324.1	Human cells	His tag
11685-V08H	A/duck/NZL/160/1976	A		duck	non-hui	NZL	160		1976	HA	HA1+HA2	uncleaved		H1N3	ABB20429.1	Human cells	His tag
11685-V08H1	A/duck/NZL/160/1976	A		duck	non-hui	NZL	160		1976	HA	HA1			H1N3	ABB20429.1	Human cells	His tag
11686-V08H1	A/chicken/Egypt/2253-1/2006	A	?	chicken	non-hui	Egypt	2253-1		2006	HA	HA1			H5N1	ABG81039.1	Human cells	His tag
11687-V08H	A/Ohio/UR06-0091/2007	A		human	human	Ohio	UR06-0091		2007	HA	HA1+HA2	uncleaved		H1N1	ABW40422.1	Human cells	His tag
11687-V08H1	A/Ohio/UR06-0091/2007	A		human	human	Ohio	UR06-0091		2007	HA	HA1			H1N1	ABW40422.1	Human cells	His tag
11689-V08H	A/Hong Kong/483/97	A	0	human	human	Hong Kon	483		1997	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	AAC32099.1	Human cells	His tag
11689-V08H1	A/Hong Kong/483/97	A	0	human	human	Hong Kon	483		1997	HA	HA1			H5N1	AAC32099.1	Human cells	His tag
11690-V08H	A/goose/Guiyang/337/2006	A	4	goose	non-hui	Guiyang	337		2006	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ABJ96698.1	Human cells	His tag
11690-V08H1	A/goose/Guiyang/337/2006	A	4	goose	non-hui	Guiyang	337		2006	HA	HA1			H5N1	ABJ96698.1	Human cells	His tag
11693-V08H	A/duck/Hong Kong/786/1979	A		duck	non-hui	Hong Kon	786		1979	HA	HA1+HA2	uncleaved		H10N3	BAF46762.1	Human cells	His tag
11694-V08H	A/Japanese white-eye/Hong Kong/1038/2006	A	2.3.4	Japanese	non-hui	Hong Kon	1038		2006	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ABJ96775.1	Human cells	His tag
11694-V08H1	A/Japanese white-eye/Hong Kong/1038/2006	A	2.3.4	Japanese	non-hui	Hong Kon	1038		2006	HA	HA1			H5N1	ABJ96775.1	Human cells	His tag
11696-V08H	A/duck/Hokkaido/167/2007	A	?	duck	non-hui	Hokkaido	167		2007	HA	HA1+HA2			H5N3	BAG07130.2	Human cells	His tag
11696-V08H1	A/duck/Hokkaido/167/2007	A	?	duck	non-hui	Hokkaido	167		2007	HA	HA1			H5N3	BAG07130.2	Human cells	His tag
11697-V08H	A/Egypt/2321-NAMRU3/2007	A	2.2.1	human	human	Egypt	2321-NAMRU3		2007	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ABP96850.1	Human cells	His tag
11697-V08H1	A/Egypt/2321-NAMRU3/2007	A	2.2.1	human	human	Egypt	2321-NAMRU3		2007	HA	HA1			H5N1	ABP96850.1	Human cells	His tag
11698-V08H	A/duck/Hunan/795/2002	A	2.1.1	duck	non-hui	Hunan	795		2002	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ACA47835.1	Human cells	His tag
11698-V08H1	A/duck/Hunan/795/2002	A	2.1.1	duck	non-hui	Hunan	795		2002	HA	HA1			H5N1	ACA47835.1	Human cells	His tag
11699-V08H	A/American green-winged teal/California/HKWF609/2007	A	LPAI	America	non-hui	California	HKWF609		2007	HA	HA1+HA2	uncleaved		H5N2	ACF47563.1	Human cells	His tag
11699-V08H1	A/American green-winged teal/California/HKWF609/2007	A	LPAI	America	non-hui	California	HKWF609		2007	HA	HA1			H5N2	ACF47563.1	Human cells	His tag
11700-V08H	A/Common magpie/Hong Kong/2256/2006	A	?	Commor	non-hui	Hong Kon	2256		2006	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ABJ96777.1	Human cells	His tag
11700-V08H1	A/Common magpie/Hong Kong/2256/2006	A	?	Commor	non-hui	Hong Kon	2256		2006	HA	HA1			H5N1	ABJ96777.1	Human cells	His tag
11701-V08H1	A/duck/Laos/3295/2006	A	2.3.4	duck	non-hui	Laos	3295		2006	HA	HA1			H5N1	ABG67978.1	Human cells	His tag
11702-V08H	A/Egypt/N05056/2009	A	?	human	human	Egypt	N05056		2009	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ACT15357.1	Human cells	His tag
11702-V08H1	A/Egypt/N05056/2009	A	?	human	human	Egypt	N05056		2009	HA	HA1			H5N1	ACT15357.1	Human cells	His tag
11708-V08H	A/Solomon Islands/3/2006	A		human	human	Solomon I	3		2006	HA	HA1+HA2	uncleaved		H1N1	ABU99109.1	Human cells	His tag
11708-V08H1	A/Solomon Islands/3/2006	A		human	human	Solomon I	3		2006	HA	HA1			H1N1	ABU99109.1	Human cells	His tag
11709-V08H	A/whooper swan/Mongolia/244/2005	A	2.2	whoope	non-hui	Mongolia	244		2005	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ACJ36881.1	Human cells	His tag
11709-V08H1	A/whooper swan/Mongolia/244/2005	A	2.2	whoope	non-hui	Mongolia	244		2005	HA	HA1			H5N1	ACJ36881.1	Human cells	His tag
11710-V08B	A/Cambodia/R0405050/2007	A	1.1	human	human	Cambodia	R0405050		2007	HA	HA1+HA2			H5N1		Baculovirus	His tag
11710-V08H	A/Cambodia/R0405050/2007	A	1.1	human	human	Cambodia	R0405050		2007	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ACI06178.1	Human cells	His tag
11710-V08H1	A/Cambodia/R0405050/2007	A	1.1	human	human	Cambodia	R0405050		2007	HA	HA1			H5N1	ACI06178.1	Human cells	His tag
11712-V08B	A/chicken/India/NIV33487/06	A	2.2	chicken	non-hui	India	NIV33487		2006	HA	HA1+HA2			H5N1	ABQ45856.1	Baculovirus	His tag
11712-V08H	A/chicken/India/NIV33487/06	A	2.2	chicken	non-hui	India	NIV33487		2006	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ABQ45856.1	Human cells	His tag
11712-V08H1	A/chicken/India/NIV33487/06	A	2.2	chicken	non-hui	India	NIV33487		2006	HA	HA1			H5N1	ABQ45856.1	Human cells	His tag
11713-V08H	A/Hong kong/213/2003	A	?	human	human	Hong kong	213		2003	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ABP51975.1	Human cells	His tag
11713-V08H1	A/Hong kong/213/2003	A	?	human	human	Hong kong	213		2003	HA	HA1		1 aa mut	H5N1	ABP51975.1	Human cells	His tag
11715-V08H	A/Wyoming/03/2003	A		human	human	Wyoming	3		2003	HA	HA1+HA2	uncleaved		H3N2	ABX10525.1	Human cells	His tag
11715-V08H1	A/Wyoming/03/2003	A		human	human	Wyoming	3		2003	HA	HA1			H3N2	ABX10525.1	Human cells	His tag
11716-V08H	B/Malaysia/2506/2004	B		human	human	Malaysia	2506		2004	HA	HA1+HA2	uncleaved		FluB	ACO05957.1	Human cells	His tag
11716-V08H1	B/Malaysia/2506/2004	B		human	human	Malaysia	2506		2004	HA	HA1			FluB	ACO05957.1	Human cells	His tag
11717-V08H	A/duck/NY/191255-59/2002	A		duck	non-hui	NY	191255-59		2002	HA	HA1+HA2	uncleaved		H5N8	AAP72011.1	Human cells	His tag
11717-V08H1	A/duck/NY/191255-59/2002	A		duck	non-hui	NY	191255-59		2002	HA	HA1			H5N8	AAP72011.1	Human cells	His tag
11972-V08B	A/Wisconsin/67/X-161/2005	A		human	human	Wisconsin	67	X-161	2005	HA	HA1+HA2			H3N2	ACF41911.1	Baculovirus	His tag
11972-V08H	A/Wisconsin/67/X-161/2005	A		human	human	Wisconsin	67	X-161	2005	HA	HA1+HA2	uncleaved		H3N2	AB037609.1	Human cells	His tag
11972-V08H1	A/Wisconsin/67/X-161/2005	A		human	human	Wisconsin	67	X-161	2005	HA	HA1			H3N2	AB037609.1	Human cells	His tag
40001-V08H	A/Duck/Hong Kong/p46/97	A	?	Duck	non-hui	Hong Kon	p46		1997	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	AAF02306.1	Human cells	His tag
40001-V08H1	A/Duck/Hong Kong/p46/97	A	?	Duck	non-hui	Hong Kon	p46		1997	HA	HA1			H5N1	AAF02306.1	Human cells	His tag
40004-V08H	A/Xinjiang/1/2006	A	?	human	human	Xinjiang	1		2006	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ACJ68614.1	Human cells	His tag
40004-V08H1	A/Xinjiang/1/2006	A	?	human	human	Xinjiang	1		2006	HA	HA1			H5N1	ACJ68614.1	Human cells	His tag
40014-V08H1	A/ostrich/South Africa/Ai1091/2006	A	?	ostrich	non-hui	South Afri	Ai1091		2006	HA	HA1			H5N2	ABQ24016.1	Human cells	His tag
40015-V08B	A/Hubei/1/2010	A	2.3.2.1a	human	human	Hubei	1		2010	HA	HA1+HA2			H5N1	AEO89181.1	Baculovirus	His tag
40015-V08H	A/Hubei/1/2010	A	2.3.2.1a	human	human	Hubei	1		2010	HA	HA1+HA2	cleaved		H5N1		Human cells	His tag
40022-V08H1	A/Vietnam/UT314131I/2008	A	?	human	human	Vietnam	UT314131I		2008	HA	HA1			H5N1	ADI83651.1	Human cells	His tag
40024-V08B	A/Goose/Guangdong/1/96	A	0	Goose	non-hui	Guangdon	1		1996	HA	HA1+HA2			H5N1	YP_308669.1	Baculovirus	His tag
40043-V08H	A/Perth/16/2009	A		human	human	Perth	16		2009	HA	HA1+HA2			H3N2	ACI71642.1	Human cells	His tag
40043-V08H1	A/Perth/16/2009	A		human	human	Perth	16		2009	HA	HA1			H3N2	ACI71642.1	Human cells	His tag
40044-V08H	A/common magpie/Hong Kong/5052/2007	A	2.3.2.1	commor	non-hui	Hong Kon	5052		2007	HA	HA1+HA2			H5N1	ACJ26242.1	Human cells	His tag
40044-V08H1	A/common magpie/Hong Kong/5052/2007	A	2.3.2.1	commor	non-hui	Hong Kon	5052		2007	HA	HA1			H5N1	ACJ26242.1	Human cells	His tag
40049-V08H1	A/Egypt/3300-NAMRU3/2008	A	2.2.1.1	human	human	Egypt	3300-NAMRU3		2008	HA	HA1			H5N1		Human cells	His tag
40060-V08H1	A/Hubei/1/2010	A	2.3.2.1a	human	human	Hubei	1		2010	HA	HA1			H5N1	AEO89181.1	Human cells	His tag
40064-V07H	A/Thailand/1(KAN-1)/2004	A	1	human	human	Thailand	1(KAN-1)		2004	NA	NA			H5N1		Human cells	His tag
40064-V07H-B	A/Thailand/1(KAN-1)/2004	A	1	human	human	Thailand	1(KAN-1)		2004	NA	NA (biotinylated)			H5N1		Baculovirus	His tag + Biotin
40065-V08H1	A/Thailand/1(KAN-1)/2004	A	1	human	human	Thailand	1(KAN-1)		2004	HA	HA1			H5N1		Human cells	His tag
40103-V08H	A/Anhui/1/2013	A		human	human	Anhui	1		2013	HA	HA1-HA2			H7N9	EPI439507	Human cells	His tag
40103-V08H1	A/Anhui/1/2013	A		human	human	Anhui	1		2013	HA	HA1			H7N9	AGJ51953.1	Human cells	His tag
40103-V08H4	A/Anhui/1/2013	A		human	human	Anhui	1		2013	HA	HA1+HA2	cleaved		H7N9	EPI439507	Human cells	His tag
40104-V08B	A/Shanghai/1/2013	A		human	human	Shanghai	1		2013	HA	HA1+HA2			H7N9		Baculovirus	His tag
40104-V08B1	A/Shanghai/1/2013	A		human	human	Shanghai	1		2013	HA	HA1			H7N9		Baculovirus	His tag
40104-V08H	A/Shanghai/1/2013	A		human	human	Shanghai	1		2013	HA	HA1+HA2			H7N9		Human cells	His tag
40104-V08H1	A/Shanghai/1/2013	A		human	human	Shanghai	1		2013	HA	HA1			H7N9		Human cells	His tag
40104-V08H4	A/Shanghai/1/2013	A		human	human	Shanghai	1		2013	HA	HA1+HA2	cleaved		H7N9		Human cells	His tag
40105-V08B	A/Hangzhou/1/2013	A		human	human	Hangzhou	1		2013	HA	HA1+HA2			H7N9	AGJ60301.1	Baculovirus	His tag
40105-V08H	A/Hangzhou/1/2013	A		human	human	Hangzhou	1		2013	HA	HA1+HA2			H7N9	AGJ60301.1	Human cells	His tag
40105-V08H1	A/Hangzhou/1/2013	A		human	human	Hangzhou	1		2013	HA	HA1			H7N9	AGJ60301.1	Human cells	His tag
40106-V08H	A/Pigeon/Shanghai/S1069/2013	A		Pigeon	non-hui	Shanghai	S1069		2013	HA	HA1+HA2			H7N9		Human cells	His tag
40109-V07H	A/Shanghai/1/2013	A		human	human	Shanghai	1		2013	NA	NA			H7N9		Human cells	His tag
40109-VNAHC	A/Shanghai/1/2013	A		human	human	Shanghai	1		2013	NA	NA (Active)			H7N9		Human cells	Active (pre-activity tested)
40111-V08B	A/Shanghai/2/2013	A		human	human	Shanghai	2		2013	NP	NP			H7N9	AGL44439.1	Baculovirus	His tag
40116-V08B	A/Hong Kong/1/1968	A		human	human	Hong Kon	1		1968	HA	HA1-HA2			H3N2	Q91MA7	Baculovirus	His tag
40116-V08H1	A/Hong Kong/1/1968	A		human	human	Hong Kon	1		1968	HA	HA1			H3N2	AAC51718.1	Human cells	His tag
40117-V08B	A/bar-headed goose/Qinghai/1A/2005	A	2.2	bar-hea	non-hui	Qinghai	1A		2005	HA	HA1-HA2			H5N1	ABI93441.1	Baculovirus	His tag
40117-V08H1	A/bar-headed goose/Qinghai/1A/2005	A	2.2	bar-hea	non-hui	Qinghai	1A		2005	HA	HA1			H5N1	ABI93441.1	Human cells	His tag

1	40119-V08B	A/Guiyang/1/1957	A		human	human	Guiyang	1		1957	HA	HA1+HA2			H2N2	ACD85231.1	Baculovirus	His tag
1	40119-V08H1	A/Guiyang/1/1957	A		human	human	Guiyang	1		1957	HA	HA1			H2N2	ACD85231.1	Human cells	His tag
1	40120-V08B	A/Fujian/411/2002	A		human	human	Fujian	411		2002	HA	HA1+HA2			H3N2	AFG72823.1	Baculovirus	His tag
1	40123-V08B	A/Hangzhou/3/2013	A		human	human	Hangzhou	3		2013	HA	HA1+HA2			H7N9	EPI442713	Baculovirus	His tag
1	40125-V08B	A/Zhejiang/1/2013	A		human	human	Zhejiang	1		2013	HA	HA1+HA2			H7N9	EPI443034	Baculovirus	His tag
1	40126-V08B	A/Shanghai/4664T/2013	A		human	human	Shanghai	4664T		2013	HA	HA1+HA2			H7N9	AGI60292.1	Baculovirus	His tag
1	40128-V08B	A/turkey/Italy/214845/2002	A		turkey	non-hu	Italy	214845		2002	HA	HA1+HA2			H7N3	CAF33017.1	Baculovirus	His tag
1	40128-V08H1	A/turkey/Italy/214845/2002	A		turkey	non-hu	Italy	214845		2002	HA	HA1			H7N3	CAF33017.1	Human cells	His tag
1	40129-V08H1	A/chicken/SK/HR-00011/2007	A		chicken	non-hu	SK	HR-00011		2007	HA	HA1			H7N3	ACA25329.1	Human cells	His tag
1	40134-V08B	A/USSR/90/1977	A		human	human	USSR	90		1977	HA	HA1+HA2			H1N1	P03453.2	Baculovirus	His tag
1	40134-V08H1	A/USSR/90/1977	A		human	human	USSR	90		1977	HA	HA1			H1N1	P03453	Human cells	His tag
1	40146-V08B	A/Hong Kong/CUHK31987/2011	A		human	human	Hong Kon	CUHK31987		2011	HA	HA1+HA2			H3N2	AGC13545.1	Baculovirus	His tag
1	40149-V08B	A/Sydney/5/1997	A		human	human	Sydney	5		1997	HA	HA1+HA2			H3N2	ACO95259.1	Baculovirus	His tag
1	40153-V08B	A/Babol/36/2005	A		human	human	Babol	36		2005	HA	HA1+HA2			H3N2		Baculovirus	His tag
1	40154-V08B	A/Moscow/10/1999	A		human	human	Moscow	10		1999	HA	HA1+HA2			H3N2	ABE73115.1	Baculovirus	His tag
1	40158-V08B	A/chicken/VietNam/NCVD-016/2008	A	7.1	chicken	non-hu	VietNam	NCVD-016		2008	HA	HA1+HA2			H5N1	ACO07033.1	Baculovirus	His tag
1	40158-V08B2	A/chicken/VietNam/NCVD-016/2008	A	7.1	chicken	non-hu	VietNam	NCVD-016		2008	HA	HA1+HA2	uncleaved	Mut clv site	H5N1	ACO07033.1	Baculovirus	His tag
1	40158-V08H1	A/chicken/VietNam/NCVD-016/2008	A	7.1	chicken	non-hu	VietNam	NCVD-016		2008	HA	HA1			H5N1	ACO07033.1	Human cells	His tag
1	40160-V08B	A/barnswallow/HongKong/D10-1161/2010	A	2.3.2.1b	barnswa	non-hu	HongKong	D10-1161		2010	HA	HA1+HA2			H5N1	AGC13463.1	Baculovirus	His tag
1	40160-V08B1	A/barnswallow/HongKong/D10-1161/2010	A	2.3.2.1b	barnswa	non-hu	HongKong	D10-1161		2010	HA	HA1+HA2	uncleaved	Mut clv site	H5N1		Baculovirus	His tag
1	40160-V08H1	A/barn swallow/Hong Kong/D10-1161/2010	A	2.3.2.1b	barn sw	non-hu	Hong Kon	D10-1161		2010	HA	HA1			H5N1	AGC13463.1	Human cells	His tag
1	40164-V08B2	A/turkey/Ireland/1378/1983	A	?	turkey	non-hu	Ireland	1378		1983	HA	HA2			H5N8	ABI85117.1	Baculovirus	His tag
1	40164-V08H1	A/turkey/Ireland/1378/1983	A	?	turkey	non-hu	Ireland	1378		1983	HA	HA1			H5N8	P11135	Human cells	His tag
1	40165-V08B	A/chicken/Italy/22A/1998	A	?	chicken	non-hu	Italy	22A		1998	HA	HA1+HA2			H5N9	ABR37720.1	Baculovirus	His tag
1	40165-V08H1	A/chicken/Italy/22A/1998	A	?	chicken	non-hu	Italy	22A		1998	HA	HA1			H5N9	ABR37720.1	Human cells	His tag
1	40168-V08B	A/mallard/Ohio/217/1998	A		mallard	non-hu	Ohio	217		1998	HA	HA1+HA2			H6N8	ABO52049.1	Baculovirus	His tag
1	40168-V08H1	A/mallard/Ohio/217/1998	A		mallard	non-hu	Ohio	217		1998	HA	HA1			H6N8	ABO52049.1	Human cells	His tag
1	40169-V08H1	A/turkey/Italy/4602/99	A		turkey	non-hu	Italy	4602		1999	HA	HA1			H7N1	CAD38286.1	Human cells	His tag
1	40170-V08B	A/ruddy turnstone/New Jersey/563/2006	A		ruddy tu	non-hu	New Jerse	563		2006	HA	HA1+HA2			H7N2	ACS68445.1	Baculovirus	His tag
1	40170-V08H1	A/ruddy turnstone/New Jersey/563/2006	A		ruddy tu	non-hu	New Jerse	563		2006	HA	HA1			H7N2	ACS68445.1	Human cells	His tag
1	40171-V08B	A/equine/Kentucky/1a/1975	A		equine	non-hu	Kentucky	1a		1975	HA	HA1+HA2			H7N7	ACI12085.1	Baculovirus	His tag
1	40172-V08B	A/mallard/Netherlands/33/2006	A		mallard	non-hu	Netherlan	33		2006	HA	HA1+HA2			H7N8	ACR59554.1	Baculovirus	His tag
1	40172-V08H1	A/mallard/Netherlands/33/2006	A		mallard	non-hu	Netherlan	33		2006	HA	HA1			H7N8	EPI182113	Human cells	His tag
1	40239-V08B	A/Shanghai/2/2013	A		human	human	Shanghai	2		2013	HA	HA1+HA2			H7N9		Baculovirus	His tag
1	40239-V08H	A/Shanghai/2/2013	A		human	human	Shanghai	2		2013	HA	HA1+HA2			H7N9		Human cells	His tag
1	40325-V08B	A/Zhejiang/DTID-ZJU10/2013	A		human	human	Zhejiang	DTID-ZJU10		2013	HA	HA1+HA2			H7N9	AHA11500.1	Baculovirus	His tag
1	40325-V08H	A/Zhejiang/DTID-ZJU10/2013	A		human	human	Zhejiang	DTID-ZJU10		2013	HA	HA1+HA2			H7N9	AHA11500.1	Human cells	His tag
1	40354-V08B	A/Texas/50/2012	A		human	human	Texas	50		2012	HA	HA1+HA2			H3N2	EPI537015	Baculovirus	His tag
1	40354-V08H1	A/Texas/50/2012	A		human	human	Texas	50		2012	HA	HA1			H3N2	AFH57070.1	Human cells	His tag
1	40372-V08B	A/chicken/Jilin/9/2004	A	?	chicken	non-hu	Jilin	9		2004	HA	HA1+HA2			H5N1	AAT76166.1	Baculovirus	His tag
1	40372-V08H1	A/chicken/Jilin/9/2004	A	?	chicken	non-hu	Jilin	9		2004	HA	HA1			H5N1		Human cells	His tag

162 TOTAL PROTEINS FROM SINO BIO

Comment: the five NS1 proteins are to be removed. These were originally from [illegible] in the RTS cell free reaction system obtained from Dan Motion.

	F Krammer Lab	Full ID	Type		Isolate	Isolate	Geo	SN2	SN3	Year	Mol ID1	Mol ID2	Form1	Form2	Subtype	GenBank	Expression Syst	Other notes
1	FKL	A/South Carolina/1/1918 (H1)	A		human	human	Sout Carol	1		1918	HA	HA0			H1N1		Baculovirus	His tag
1	FKL	A/William Smith Neurotropic/1933 (H1)	A		human	human	?			1933	HA	HA0			H1N1		Baculovirus	His tag
1	FKL	A/PR/8/1934 (H1)	A		human	human	Puerto Ric	8		1934	HA	HA0			H1N1		Baculovirus	His tag
1	FKL	A/Fort Monmouth/1/1947 (H1)	A		human	human	New Jerse	1		1947	HA	HA0			H1N1		Baculovirus	His tag
1	FKL	A/Denver/1/1957 (H1)	A		human	human	Colorado	1		1957	HA	HA0			H1N1		Baculovirus	His tag
1	FKL	A/USSR/1977 (H1)	A		human	human	Russia			1977	HA	HA0			H1N1		Baculovirus	His tag
1	FKL	A/Texas/36/1991 (H1)	A		human	human	Texas	36		1991	HA	HA0			H1N1		Baculovirus	His tag
1	FKL	A/New Caledonia/20/1999 (H1)	A		human	human	New Calec	20		1999	HA	HA0			H1N1		Baculovirus	His tag
1	FKL	A/California/04/2009 (H1)	A		human	human	California	4		2009	HA	HA0			pdmH1N1		Baculovirus	His tag
1	FKL	A/DR/7293/2013 (H1)	A		human	human	Dominicar	7293		2013	HA	HA0			pdmH1N1		Baculovirus	His tag
1	FKL	A/swine/Jiangsu/40/2011	A		swine	non-hu	China	40		2011	HA	HA0			avian-swine H1N1		Baculovirus	His tag
1	FKL	A/Michigan/45/15 (pdmH1N1)	A		human	human	Michigan	45		2015	HA	HA0			pdmH1N1		Baculovirus	His tag
1	FKL	A/Japan/305/1957 (H2)	A		human	human	Japan	305		1957	HA	HA0			H2N2		Baculovirus	His tag
1	FKL	A/mallard/Netherlands/5/1999 (H2)	A		mallard	non-hu	Netherlan	5		1999	HA	HA0			H2N9		Baculovirus	His tag
1	FKL	A/swine/Missouri/4296424/2006 (H2)	A		swine	non-hu	Missouri	4296424		2006	HA	HA0			H2N3		Baculovirus	His tag
1	FKL	A/Hong Kong/1/1968 (H3)	A		human	human	Hong Kon	1		1968	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/Alabama/1/1981 (H3)	A		human	human	Alabama	1		1981	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/Philippines/2/1982 (H3)	A		human	human	Philippine	2		1982	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/Panama/2007/1999 (H3)	A		human	human	Panama	2007		1999	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/Wyoming/3/2003 (H3)	A		human	human	Wyoming	3		2003	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/Wisconsin/67/2005 (H3)	A		human	human	Wisconsin	67		2005	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/Perth/16/2009 (H3)	A		human	human	Australia	16		2009	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/Victoria/361/2011 (H3)	A		human	human	Australia	361		2011	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/Indiana/10/2011 (H3v)	A		human	human	Indiana	10		2011	HA	HA0			H3N2v		Baculovirus	His tag
1	FKL	A/harbor seal/Massachusetts/1/2011 (H3)	A		seal	non-hu	Massachu	1		2011	HA	HA0			H3N8		Baculovirus	His tag
1	FKL	A/canine/Texas/12/2004 (H3 equine lineage-dog isolate)	A		dog	non-hu	Texas	12		2004	HA	HA0			H3		Baculovirus	His tag
1	FKL	A/canine/NY/120106.2/2011 H3 (H3 equine lineage-dog isolate)	A		dog	non-hu	New York	120106.2		2011	HA	HA0			H3		Baculovirus	His tag
1	FKL	A/Switzerland/9715293/2013 (H3)	A		human	human	Switzerlan	9715293		2013	HA	HA0			H3N2		Baculovirus	His tag
1	FKL	A/duck/Czech/1956 (H4)	A		duck	non-hu	Czech			1956	HA	HA0			H4N6		Baculovirus	His tag
1	FKL	A/Vietnam/1204/2004 (H5)	A		human	human	Vietnam	1204		2004	HA	HA0			H5N1		Baculovirus	His tag
1	FKL	A/Indonesia/05/2005 (H5)	A		human	human	Indonesia	5		2005	HA	HA0			H5N1		Baculovirus	His tag
1	FKL	A/chicken/Netherlands/14015531/2014 (H5 from novel H5N8)	A		chicken	non-hu	Netherlan	14015531		2014	HA	HA0			H5N8		Baculovirus	His tag
1	FKL	A/Northern Pintail/WA/40964/2014 (H5 from novel H5N2)	A		Northern pintail		Washingt	40964		2014	HA	HA0			H5N2		Baculovirus	His tag
1	FKL	A/Shenzen/1/16 (H5 from lethal human H5N6 case)	A		human	human	Shenzen/(	1		2016	HA	HA0			H5N6		Baculovirus	His tag
1	FKL	A/Taiwan/2/13 (H6)	A		human	human	Taiwan	2		2013	HA	HA0			H6N1		Baculovirus	His tag
1	FKL	A/mallard/Sweden/81/2002 (H6)	A		mallard	non-hu	Sweden	81		2002	HA	HA0			H6		Baculovirus	His tag
1	FKL	A/mallard/Netherlands/12/2000 (H7)	A		mallard	non-hu	Netherlan	12		2000	HA	HA0			H7N3		Baculovirus	His tag
1	FKL	A/rhea/North Carolina/39482/93 (H7)	A		rhea	non-hu	North Car	39482		1993	HA	HA0			H7N1		Baculovirus	His tag
1	FKL	A/chicken/Jalisco/12283/2012 (H7)	A		chicken	non-hu	Mexico	12283		2012	HA	HA0			H7N3		Baculovirus	His tag
1	FKL	A/Shanghai/1/2013 (H7)	A		human	human	China	1		2013	HA	HA0			H7N9		Baculovirus	His tag
1	FKL	A/Anhui/1/2013 (H7)	A		human	human	China	1		2013	HA	HA0			H7N9		Baculovirus	His tag
1	FKL	A/chicken/Italy/13474/1999 (H7)	A		chicken	non-hu	Italy	13474		1999	HA	HA0			H7		Baculovirus	His tag
1	FKL	A/chicken/BC/CN-6/2004 (H7)	A		chicken	non-hu	Canada	CN-6		2004	HA	HA0			H7N3		Baculovirus	His tag
1	FKL	A/feline/New York/16-040082-1/2016	A		cat	non-hu	New York	16-040082		2016	HA	HA0			H7N2		Baculovirus	His tag
1	FKL	A/mallard/Sweden/24/2002 (H8)	A		mallard	non-hu	Sweden	24		2002	HA	HA0			H8		Baculovirus	His tag
1	FKL	A/guinea fowl/Hong Kong/WF10/1999 (H9)	A		guinea f	non-hu	China	WF10		1999	HA	HA0			H9N2		Baculovirus	His tag
1	FKL	A/chicken/Hong Kong/G9/1997 (H9)	A		chicken	non-hu	China	G9		1997	HA	HA0			H9N2		Baculovirus	His tag
1	FKL	A/Jiangxi/Donghu/346/2013 (H10)	A		human	human	China	346		2013	HA	HA0			H10N8		Baculovirus	His tag
1	FKL	A/shoveler/Netherlands/18/1999 (H11)	A		shoveler	non-hu	Netherlan	18		1999	HA	HA0			H11		Baculovirus	His tag
1	FKL	A/mallard/Interior Alaska/7MP0167/2007 (H12)	A		mallard	non-hu	Alaska	7MP0167		2007	HA	HA0			H12		Baculovirus	His tag
1	FKL	A/black headed gull/Sweden/1/1999 (H13)	A		gull	non-hu	Sweden	1		1999	HA	HA0			H13		Baculovirus	His tag
1	FKL	A/mallard/Gurjev/263/1982 (H14)	A		mallard	non-hu	Kazakhsta	263		1982	HA	HA0			H14		Baculovirus	His tag
1	FKL	A/shearwater/West Australia/2576/1979 (H15)	A		shearwa	non-hu	Australia	2576		1979	HA	HA0			H15		Baculovirus	His tag
1	FKL	A/black headed gull/Sweden/5/1999 (H16)	A		gull	non-hu	Sweden	5		1999	HA	HA0			H16		Baculovirus	His tag
1	FKL	A/yellow shouldered bat/Guatemala/06/2010 (H17)	A		bat	non-hu	Guatemal	6		2010	HA	HA0			H17N10		Baculovirus	His tag
1	FKL	A/bat/Peru/33/2010 (H18)	A		bat	non-hu	Peru	33			HA	HA0			H18N11		Baculovirus	His tag
1	FKL	B/Lee/1940	B		human	human	New York			1940	HA	HA0			B		Baculovirus	His tag
1	FKL	B/Victoria/2/1987	B		human	human	Australia	2		1987	HA	HA0			B		Baculovirus	His tag
1	FKL	B/Yamagata/16/1988	B		human	human	Japan	16		1988	HA	HA0			B		Baculovirus	His tag
1	FKL	B/Wisconsin/1/2010	B		human	human	Wisconsin	1		2010	HA	HA0			B		Baculovirus	His tag
1	FKL	B/Florida/4/2006	B		human	human	Florida	4		2006	HA	HA0			B		Baculovirus	His tag
1	FKL	B/Malaysia/2506/2004	B		human	human	Malaysia	2506		2004	HA	HA0			B		Baculovirus	His tag
1	FKL	B/Massachusetts/2/2012	B		human	human	Massachu	2		2012	HA	HA0			B		Baculovirus	His tag
1	FKL	B/Phuket/3073/2013	B		human	human	Thailand	3073		2013	HA	HA0			B		Baculovirus	His tag
1	FKL	A/Vietnam/1204/2004 (N1)	A		human	human	Vietnam	1204		2004	NA				H5N1		Baculovirus	His tag
1	FKL	A/California/04/2009 (N1)	A		human	human	California	4		2009	NA				pdmH1N1		Baculovirus	His tag
1	FKL	A/PR/8/1934 (N1)	A		human	human	Puerto Ric	8		1934	NA				H1N1		Baculovirus	His tag
1	FKL	A/New Caledonia/20/1999 (N1)	A		human	human	New Calec	20		1999	NA				H1N1		Baculovirus	His tag
1	FKL	A/Singapore/1/1957 (N2)	A		human	human	Singapore	1		1957	NA				H3N2		Baculovirus	His tag
1	FKL	A/Hong Kong/1/1968 (N2)	A		human	human	Hong Kon	1		1968	NA				H3N2		Baculovirus	His tag
1	FKL	A/Panama/2007/1999 (N2)	A		human	human	Panama	2007		1999	NA				H3N2		Baculovirus	His tag
1	FKL	A/Victoria/361/2011 (N2)	A		human	human	Australia	361		2012	NA				H3N2		Baculovirus	His tag
1	FKL	A/Texas/50/2012 (N2)	A		human	human	Texas	50		2012	NA				H9N2		Baculovirus	His tag
1	FKL	A/chicken/Hong Kong/G9/1997 (N2)	A		chicken	non-hu	Hong Kon	G9		1997	NA				H2N3		Baculovirus	His tag
1	FKL	A/swine/Missouri/4296424/2006 (N3)	A		pig	non-hu	Missouri	4296424		2006	NA				N4		Baculovirus	His tag
1	FKL	A/mallard/Sweden/24/2002 (N4)	A		mallard	non-hu	Sweden	24		2002	NA				N5		Baculovirus	His tag
1	FKL	A/mallard/Sweden/86/2003 (N5)	A		mallard	non-hu	Sweden	86		2003	NA				N6		Baculovirus	His tag
1	FKL	A/mallard/Netherlands/1/1999 (N6)	A		mallard	non-hu	Netherlan	1		1999	NA				N7		Baculovirus	His tag
1	FKL	A/mallard/IA/10BM01929/2010 (N7)	A		mallard	non-hu	Alaska	10BM1929		2010	NA				H5N8		Baculovirus	His tag
1	FKL	A/chicken/Netherlands/14015531/2014 (N8 from novel H5N8)	A		chicken	non-hu	Netherlan	14015531		2014	NA				H17N10		Baculovirus	His tag
1	FKL	B/Yamagata/16/1988 (B-NA)	B		human	human	Japan	16		1988	NA				B		Baculovirus	His tag
1	FKL	B/Florida/4/2006 (B-NA)	B		human	human	Florida	4		2006	NA				B		Baculovirus	His tag
1	FKL	B/Malaysia/2506/2004 (B-NA)	B		human	human	Malaysia	2506		2004	NA				B		Baculovirus	His tag

1	FKL	B/Brisbane/60/2008 (B-NA)	B	human	human	Australia	60	2008	NA			B	Baculovirus	His tag
1	FKL	B/Wisconsin/1/2010 (B-NA)	B	human	human	Wisconsin	1	2010	NA			B	Baculovirus	His tag
1	FKL	cH6/1	A					X	HA			X	Baculovirus	His tag
1	FKL	cH9/1	A					X	HA			X	Baculovirus	His tag
1	FKL	H9 head-only	A					X	HA			X	Baculovirus	His tag
1	FKL	A/PR/8/34	A	human	human	Puert Rico	8	1934	NP			H1N1	baculovirus	His tag
1	FKL	A/Hubei/02285/2017	A					2017				H7N9		Yangtse River clade, low path
1	FKL	A/Guangdong/17SF003/2016	A					2016				H7N9		Yangtse River clade, high path
1	FKL	A/HongKong/2014/2017	A					2017				H7N9		Pearl River clade, low path
92	TOTAL PROTEINS FROM F. KRAMMER'S LAB													

	VANDERBILT	Full ID	Type	Isolate	Isolate	Geo	SN2	SN3	Year	Mol ID1	Mol ID2	Form1	Form2	Subtype	GenBank	Expression Syst	Other notes
1	J. Crowe lab	gyrfalcon/Washington/41088-6/2014 (H5N8)	A						2014	HA				H5N8			
1	J. Crowe lab	gyrfalcon/Washington/41088-6/2014 (H5N8)	A						2014	NA				H5N8			
2	TOTAL PROTEINS FROM VANDERBILT																

256 TOTAL PROTEINS ON SUPPLEMENTAL MICROARRAY

From: Felgner, Philip
Sent: Sun, 30 Aug 2020 20:51:03 -0400
To: Tibbals, Melinda (NIH/NIAID) [C];Felgner, Philip
Cc: Chen, Wilbur;Roberts, Chris (NIH/NIAID) [E];Luke, Catherine (NIH/NIAID) [E];Nakajima, Rie
Subject: RE: 16-0107 slides to be printed
Attachments: 20200821-New update.xls

Hi Melinda,
As you said, DMID is finalizing the antigen list for the 330 slides (5,280 arrays) that the UCI protein microarray facility still owes DMID. Our vendor has a longer list of 598 antigens (attached) that can be printed on DMID's next version of the influenza antigen array, and DMID may be interested to know what is available. There are 510 HA antigens available, 4 M1, 71 NA, 10 NP and 2 NS. The current array design can accommodate 280 antigens. Let me know which 280 antigens DMID would like the UCI protein microarray facility to print on DMID's final batch of arrays.
Phil

From: Tibbals, Melinda (NIH/NIAID) [C] (b) (6)
Sent: Tuesday, August 11, 2020 12:07 PM
To: Felgner, Philip <pfelgner@uci.edu>
Cc: Chen, Wilbur <Wilbur.Chen@som.umaryland.edu>; Roberts, Chris (NIH/NIAID) [E] (b) (6); Luke, Catherine (NIH/NIAID) [E] (b) (6)
Subject: 16-0107 slides to be printed

Hi, Phil,

I'm checking into where DMID could store the additional slides that will be printed as part of the 16-0107 study. Looking through my notes, there will be 330 slides. Can you confirm?

Once DMID finalizing the antigen list, how much time will you need to incorporate the request into your lab's work queue and print them before the task order ends Dec 31?
How should the slides be stored?
How long can the slides be stored and remain stable?
How much space do you expect will be needed to store the slides and how will they be shipped?

Thanks, Melinda

Melinda Tibbals
NIH/NIAID/DMID/RDB, ESTIB [C]
(b) (6)
(b) (6)

Somewhere something incredible is waiting to be known – Carl Sagan

Catalog No.	Launch date	Product name	HN type	antigen
10003-V06H1	2009-05-27	Influenza A H5N1 (A/VietNam/1203/2004) Hemagglutinin Protein (HA1 Subunit) (His & Fc Tag)	H5N1	HA
10003-V06H3	2009-05-27	Influenza A H5N1 (A/VietNam/1203/2004) Hemagglutinin / HA Protein (His & Fc Tag)	H5N1	HA
11048-V06H1	2009-07-13	Influenza A H5N1 (A/Anhui/1/2005) Hemagglutinin / HA Protein (His & Fc Tag)	H5N1	HA
11048-V08B	2013-04-22	Influenza A H5N1 (A/Anhui/1/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11048-V08H1	2009-07-13	Influenza A H5N1 (A/Anhui/1/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11048-V08H2	2009-07-13	Influenza A H5N1 (A/Anhui/1/2005) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11048-V08H4	2009-07-13	Influenza A H5N1 (A/Anhui/1/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11048-VNAH2	2010-02-11	Influenza A H5N1 (A/Anhui/1/2005) Hemagglutinin Protein (HA1 Subunit)	H5N1	HA
11052-V08H	2009-07-13	Influenza A H1N1 (A/Brisbane/59/2007) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11052-V08H1	2009-11-19	Influenza A H1N1 (A/Brisbane/59/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
11053-V01H2	2011-06-22	Influenza B (B/Florida/4/2006) Hemagglutinin Protein (HA2 Subunit) (Fc Tag)	Influenza B	HA
11053-V04H2	2011-06-22	Influenza B (B/Florida/4/2006) Hemagglutinin Protein (HA2 Subunit) (Fc Tag)	Influenza B	HA
11053-V08H	2009-07-13	Influenza B (B/Florida/4/2006) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
11053-V08H1	2009-12-18	Influenza B (B/Florida/4/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	Influenza B	HA
11055-V08B	2009-11-17	Influenza A H1N1 (A/California/04/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11055-V08B-B	2019-07-09	Influenza A H1N1 (A/California/04/2009) Hemagglutinin / HA Protein (His Tag), Biotinylated	H1N1	HA
11055-V08B1	2015-04-30	Influenza A H1N1 (A/California/04/2009) Hemagglutinin / HA-specific B cell probe (His Tag)	H1N1	HA
11055-V08H	2009-07-13	Influenza A H1N1 (A/California/04/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11055-V08H2	2009-10-23	Influenza A H1N1 (A/California/04/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11055-V08H4	2009-11-17	Influenza A H1N1 (A/California/04/2009) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
11055-VNAB	2014-08-13	Influenza A H1N1 (A/California/04/2009) Hemagglutinin / HA0 Protein (full length)	H1N1	HA
11055-VNAB-B	2019-10-17	Influenza A H1N1 (A/California/04/2009) Hemagglutinin / HA0 Protein (full length), Biotinylated	H1N1	HA
11056-V08B	2014-07-25	Influenza A H3N2 (A/Brisbane/10/2007) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
11056-V08H	2009-07-13	Influenza A H3N2 (A/Brisbane/10/2007) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
11056-V08H1	2009-12-18	Influenza A H3N2 (A/Brisbane/10/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N2	HA
11058-V01H	2009-10-22	Influenza A H1N1 (A/California/04/2009) Neuraminidase / NA (Fc Tag)	H1N1	NA
11058-V07B	2011-08-09	Influenza A H1N1 (A/California/04/2009) Neuraminidase / NA (His Tag)	H1N1	NA
11058-V08B	2019-01-09	Influenza A H1N1 (A/California/04/2009) Neuraminidase / NA (His Tag)	H1N1	NA
11058-VNAHC	2010-06-29	Influenza A H1N1 Neuraminidase / NA (Active)	H1N1	NA
11058-VNAHC1	2011-04-13	Influenza A H1N1 Neuraminidase / NA (H275Y) (Active)	H1N1	NA
11058-VNAHC2	2013-06-05	Influenza A H1N1 Neuraminidase / NA (N295S mutation) (Active)	H1N1	NA
11059-V08B1	2010-01-21	Influenza A H5N1 (A/bar-headed goose/Qinghai/14/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11059-V08H1	2009-10-23	Influenza A H5N1 (A/bar-headed goose/Qinghai/14/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11059-V08H2	2009-10-23	Influenza A H5N1 (A/bar-headed goose/Qinghai/14/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11060-V08B	2015-01-26	Influenza A H5N1 (A/Indonesia/5/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11060-V08B1	2015-04-30	Influenza A H5N1 (A/Indonesia/5/2005) Hemagglutinin / HA-specific B cell probe (His Tag)	H5N1	HA
11060-V08H1	2009-10-23	Influenza A H5N1 (A/Indonesia/5/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11060-V08H2	2009-10-23	Influenza A H5N1 (A/Indonesia/5/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11061-V08B	2015-04-30	Influenza A H5N1 (A/turkey/Turkey/1/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11061-V08H1	2009-10-23	Influenza A H5N1 (A/turkey/Turkey/1/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11061-V08H2	2009-10-23	Influenza A H5N1 (A/turkey/Turkey/1/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11062-V08B	2017-08-01	Influenza A H5N1 (A/Vietnam/1194/2004) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11062-V08B-B	2019-10-18	Influenza A H5N1 (A/Vietnam/1194/2004) Hemagglutinin / HA Protein (His Tag), Biotinylated	H5N1	HA
11062-V08H1	2009-10-23	Influenza A H5N1 (A/Vietnam/1194/2004) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11062-V08H2	2009-10-23	Influenza A H5N1 (A/Vietnam/1194/2004) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11068-V08H	2009-10-22	Influenza A H1N1 (A/Brevig Mission/1/1918) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11068-V08H1	2009-12-17	Influenza A H1N1 (A/Brevig Mission/1/1918) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
11082-V08B	2010-01-21	Influenza A H7N7 (A/Netherlands/219/2003) Hemagglutinin / HA Protein (His Tag)	H7N7	HA
11082-V08H1	2010-02-11	Influenza A H7N7 (A/Netherlands/219/2003) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N7	HA
11085-V08B	2014-03-27	Influenza A H1N1 (A/California/07/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11085-V08H	2009-11-19	Influenza A H1N1 (A/California/07/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11085-V08H-B	2019-06-11	Influenza A H1N1 (A/California/07/2009) Hemagglutinin / HA Protein (His Tag), Biotinylated	H1N1	HA
11088-V08H	2009-11-19	Influenza A H2N2 (A/Japan/305/1957) Hemagglutinin / HA Protein (His Tag)	H2N2	HA
11088-V08H1	2013-08-28	Influenza A H2N2 (A/Japan/305/1957) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H2N2	HA
11212-V08B	2010-01-21	Influenza A H7N7 (A/chicken/Netherlands/1/03) Hemagglutinin / HA Protein (His Tag)	H7N7	HA
11212-V08H1	2010-02-11	Influenza A H7N7 (A/chicken/Netherlands/1/03) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N7	HA
11229-V08H	2010-03-26	Influenza A H9N2 (A/Hong Kong/1073/99) Hemagglutinin / HA Protein (His Tag)	H9N2	HA
11229-V08H1	2013-12-16	Influenza A H9N2 (A/Hong Kong/1073/99) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H9N2	HA
11675-V08B	2010-05-06	Influenza A H1N1 Nucleoprotein / NP Protein (His Tag)	H1N1	NP
11676-V08B	2019-05-16	Influenza A H5N1 (A/Anhui/1/2005) Neuraminidase / NA (His Tag)	H5N1	NA
11676-VNAHC	2010-05-17	Influenza A H5N1 Neuraminidase / NA (Active)	H5N1	NA
11676-VNAHC1	2011-04-13	Influenza A H5N1 Neuraminidase / NA (H255Y) (Active)	H5N1	NA
11683-V08B1	2015-06-30	Influenza A H1N1 (A/New Caledonia/20/1999) Hemagglutinin / HA-specific B cell probe (His Tag)	H1N1	HA
11683-V08H	2010-08-12	Influenza A H1N1 (A/New Caledonia/20/1999) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11683-V08H1	2010-07-12	Influenza A H1N1 (A/New Caledonia/20/1999) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
11684-V08B	2014-12-05	Influenza A H1N1 (A/Puerto Rico/8/1934) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11684-V08H	2010-08-12	Influenza A H1N1 (A/Puerto Rico/8/1934) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11684-V08H1	2010-07-12	Influenza A H1N1 (A/Puerto Rico/8/1934) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
11685-V08B	2014-12-18	Influenza A H1N3 (A/duck/NZL/160/1976) Hemagglutinin / HA Protein (His Tag)	H1N3	HA
11685-V08H	2010-08-12	Influenza A H1N3 (A/duck/NZL/160/1976) Hemagglutinin / HA Protein (His Tag)	H1N3	HA
11685-V08H1	2010-07-12	Influenza A H1N3 (A/duck/NZL/160/1976) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N3	HA
11686-V08H1	2010-07-12	Influenza A H5N1 (A/chicken/Egypt/2253-1/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11687-V08H	2010-08-12	Influenza A H1N1 (A/Ohio/UR06-0091/2007) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11687-V08H1	2010-07-12	Influenza A H1N1 (A/Ohio/UR06-0091/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
11688-V08B	2014-12-05	Influenza A H2N2 (A/Canada/720/2005) Hemagglutinin / HA Protein (His Tag)	H2N2	HA
11688-V08H	2010-08-12	Influenza A H2N2 (A/Canada/720/2005) Hemagglutinin / HA Protein (His Tag)	H2N2	HA
11688-V08H1	2010-07-12	Influenza A H2N2 (A/Canada/720/2005) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H2N2	HA
11689-V08H	2010-08-13	Influenza A H5N1 (A/Hong Kong/483/1997) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11689-V08H1	2010-07-12	Influenza A H5N1 (A/Hong Kong/483/1997) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11690-V08H	2010-08-13	Influenza A H5N1 (A/goose/Guiyang/337/2006) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11690-V08H1	2010-07-12	Influenza A H5N1 (A/goose/Guiyang/337/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11692-V08B	2014-07-25	Influenza A H1N1 (A/WSN/1933) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11692-V08H	2010-07-12	Influenza A H1N1 (A/WSN/1933) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11692-V08H1	2010-07-12	Influenza A H1N1 (A/WSN/1933) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
11693-V08B	2014-07-25	Influenza A H10N3 (A/duck/Hong Kong/786/1979) Hemagglutinin / HA Protein (His Tag)	H10N3	HA
11693-V08H	2010-08-13	Influenza A H10N3 (A/duck/Hong Kong/786/1979) Hemagglutinin / HA Protein (His Tag)	H10N3	HA
11693-V08H1	2010-07-12	Influenza A H10N3 (A/duck/Hong Kong/786/1979) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H10N3	HA
11694-V08H	2010-09-27	Influenza A H5N1 (A/Japanese white-eye/Hong Kong/1038/2006) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11694-V08H1	2010-07-12	Influenza A H5N1 (A/Japanese white-eye/Hong Kong/1038/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11696-V08H	2010-08-12	Influenza A H5N3 (A/duck/Hokkaido/167/2007) Hemagglutinin / HA Protein (His Tag)	H5N3	HA
11696-V08H1	2010-08-12	Influenza A H5N3 (A/duck/Hokkaido/167/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N3	HA
11697-V08H	2010-08-12	Influenza A H5N1 (A/Egypt/2321-NAMRU3/2007) Hemagglutinin / HA Protein (His Tag)	H5N1	HA

11697-V08H1	2010-08-12	Influenza A H5N1 (A/Egypt/2321-NAMRU3/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11698-V08H	2010-08-12	Influenza A H5N1 (A/duck/Hunan/795/2002) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11698-V08H1	2010-08-12	Influenza A H5N1 (A/duck/Hunan/795/2002) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11699-V08H	2010-09-30	Influenza A H5N2 (A/American green-winged teal/California/HKWF609/2007) Hemagglutinin / HA Protein (His Tag)	H5N2	HA
11699-V08H1	2010-08-12	Influenza A H5N2 (A/American green-winged teal/California/HKWF609/2007) Hemagglutinin Protein (HA1 Subunit)	H5N2	HA
11700-V08H	2010-08-12	Influenza A H5N1 (A/Common magpie/Hong Kong/2256/2006) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11700-V08H1	2010-08-12	Influenza A H5N1 (A/Common magpie/Hong Kong/2256/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11701-V08H1	2010-08-12	Influenza A H5N1 (A/duck/Laos/3295/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11702-V08H	2010-08-12	Influenza A H5N1 (A/Egypt/N05056/2009) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11702-V08H1	2010-08-12	Influenza A H5N1 (A/Egypt/N05056/2009) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11703-V08H	2010-08-12	Influenza A H1N2 (A/swine/Guangxi/13/2006) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
11703-V08H1	2010-08-12	Influenza A H1N2 (A/swine/Guangxi/13/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N2	HA
11704-V08H	2010-08-12	Influenza A H11N9 (A/mallard/Alberta/294/1977) Hemagglutinin / HA Protein (His Tag)	H11N9	HA
11704-V08H1	2010-08-12	Influenza A H11N9 (A/mallard/Alberta/294/1977) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H11N9	HA
11705-V08B	2014-12-05	Influenza A H11N2 (A/duck/Yangzhou/906/2002) Hemagglutinin / HA Protein (His Tag)	H11N2	HA
11705-V08H	2010-08-12	Influenza A H11N2 (A/duck/Yangzhou/906/2002) Hemagglutinin / HA Protein (His Tag)	H11N2	HA
11705-V08H1	2010-08-12	Influenza A H11N2 (A/duck/Yangzhou/906/2002) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H11N2	HA
11706-V08H	2010-08-12	Influenza A H4N6 (A/Swine/Ontario/01911-1/99) Hemagglutinin / HA Protein (His Tag)	H4N6	HA
11706-V08H1	2010-09-27	Influenza A H4N6 (A/Swine/Ontario/01911-1/99) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H4N6	HA
11707-V08B	2014-10-10	Influenza A H3N2 (A/Aichi/2/1968) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
11707-V08H	2010-08-12	Influenza A H3N2 (A/Aichi/2/1968) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
11707-V08H1	2010-08-12	Influenza A H3N2 (A/Aichi/2/1968) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N2	HA
11708-V08B	2014-12-18	Influenza A H1N1 (A/Solomon Islands/3/2006) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11708-V08H	2010-08-12	Influenza A H1N1 (A/Solomon Islands/3/2006) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
11708-V08H1	2010-08-12	Influenza A H1N1 (A/Solomon Islands/3/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
11709-V08H	2010-08-13	Influenza A H5N1 (A/whooper swan/Mongolia/244/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11709-V08H1	2011-03-25	Influenza A H5N1 (A/whooper swan/Mongolia/244/2005) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11710-V08B	2014-07-25	Influenza A H5N1 (A/Cambodia/R0405050/2007) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11710-V08H	2010-08-12	Influenza A H5N1 (A/Cambodia/R0405050/2007) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11710-V08H1	2010-08-12	Influenza A H5N1 (A/Cambodia/R0405050/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11711-V08B	2015-03-24	Influenza A H16N3 (A/black-headed gull/Sweden/5/99) Hemagglutinin / HA Protein (His Tag)	H16N3	HA
11711-V08H	2010-08-13	Influenza A H16N3 (A/black-headed gull/Sweden/5/99) Hemagglutinin / HA Protein (His Tag)	H16N3	HA
11711-V08H1	2010-08-13	Influenza A H16N3 (A/black-headed gull/Sweden/5/99) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H16N3	HA
11712-V08B	2014-03-27	Influenza A H5N1 (A/chicken/India/NIV33487/06) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11712-V08H	2010-08-13	Influenza A H5N1 (A/chicken/India/NIV33487/06) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11712-V08H1	2010-08-13	Influenza A H5N1 (A/chicken/India/NIV33487/06) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
11713-V08B	2014-12-18	Influenza A H5N1 (A/Hong kong/213/2003) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
11713-V08H	2010-10-08	Influenza A H5N1 (A/Hong kong/213/2003) Hemagglutinin / HA Protein (28 Ser/Trp, His Tag)	H5N1	HA
11713-V08H1	2010-08-13	Influenza A H5N1 (A/Hong kong/213/2003) Hemagglutinin Protein (HA1 Subunit) (28 Ser/Trp, His Tag)	H5N1	HA
11714-V08H	2010-08-13	Influenza A H4N6 (A/mallard/Ohio/657/2002) Hemagglutinin / HA Protein (His Tag)	H4N6	HA
11714-V08H1	2010-08-13	Influenza A H4N6 (A/mallard/Ohio/657/2002) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H4N6	HA
11715-V08B	2014-11-21	Influenza A H3N2 (A/Wyoming/03/2003) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
11715-V08H	2010-08-13	Influenza A H3N2 (A/Wyoming/03/2003) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
11715-V08H1	2010-08-13	Influenza A H3N2 (A/Wyoming/03/2003) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N2	HA
11716-V08B	2014-11-21	Influenza B (B/Malaysia/2506/2004) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
11716-V08H	2010-09-27	Influenza B (B/Malaysia/2506/2004) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
11716-V08H1	2010-08-13	Influenza B (B/Malaysia/2506/2004) Hemagglutinin Protein (HA1 Subunit) (His Tag)	Influenza B	HA
11717-V08H	2010-08-13	Influenza A H5N8 (A/duck/NY/191255-59/2002) Hemagglutinin / HA Protein (His Tag)	H5N8	HA
11717-V08H1	2010-08-13	Influenza A H5N8 (A/duck/NY/191255-59/2002) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N8	HA
11718-V08H	2010-08-13	Influenza A H12N5 (A/green-winged teal/ALB/199/1991) Hemagglutinin / HA Protein (His Tag)	H12N5	HA
11718-V08H1	2010-08-13	Influenza A H12N5 (A/green-winged teal/ALB/199/1991) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H12N5	HA
11719-V08B	2014-10-10	Influenza A H9N2 (A/Guinea fowl/Hong Kong/WF10/99) Hemagglutinin / HA Protein (His Tag)	H9N2	HA
11719-V08H	2010-08-13	Influenza A H9N2 (A/Guinea fowl/Hong Kong/WF10/99) Hemagglutinin / HA Protein (His Tag)	H9N2	HA
11719-V08H1	2010-09-27	Influenza A H9N2 (A/Guinea fowl/Hong Kong/WF10/99) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H9N2	HA
11720-V08H	2010-08-13	Influenza A H15N8 (A/duck/AUS/341/1983) Hemagglutinin / HA Protein (His Tag)	H15N8	HA
11720-V08H1	2010-09-27	Influenza A H15N8 (A/duck/AUS/341/1983) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H15N8	HA
11721-V08B	2014-07-25	Influenza A H13N8 (A/black-headed gull/Netherlands/1/00) Hemagglutinin / HA Protein (His Tag)	H13N8	HA
11721-V08H	2010-08-13	Influenza A H13N8 (A/black-headed gull/Netherlands/1/00) Hemagglutinin / HA Protein (His Tag)	H13N8	HA
11721-V08H1	2010-09-27	Influenza A H13N8 (A/black-headed gull/Netherlands/1/00) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H13N8	HA
11722-V08B	2014-07-25	Influenza A H8N4 (A/pintail duck/Alberta/114/1979) Hemagglutinin / HA Protein (His Tag)	H8N4	HA
11722-V08H	2010-08-13	Influenza A H8N4 (A/pintail duck/Alberta/114/1979) Hemagglutinin / HA Protein (His Tag)	H8N4	HA
11722-V08H1	2010-09-27	Influenza A H8N4 (A/pintail duck/Alberta/114/1979) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H8N4	HA
11723-V08H	2010-08-13	Influenza A H6N1 (A/northern shoveler/California/HKWF115/2007) Hemagglutinin / HA Protein (His Tag)	H6N1	HA
11723-V08H1	2010-09-27	Influenza A H6N1 (A/northern shoveler/California/HKWF115/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H6N1	HA
11972-V08B	2014-07-25	Influenza A H3N2 (A/Wisconsin/67/2005) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
11972-V08H	2010-09-27	Influenza A H3N2 (A/Wisconsin/67/2005) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
11972-V08H1	2010-09-27	Influenza A H3N2 (A/Wisconsin/67/2005) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N2	HA
40001-V08H	2011-01-19	Influenza A H5N1 (A/Duck/Hong Kong/p46/97) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40001-V08H1	2011-01-19	Influenza A H5N1 (A/Duck/Hong Kong/p46/97) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40003-V08B	2014-08-28	Influenza A H9N2 (A/duck/Hong Kong/448/78) Hemagglutinin / HA Protein (His Tag)	H9N2	HA
40003-V08H1	2014-07-25	Influenza A H9N2 (A/duck/Hong Kong/448/78) Hemagglutinin Protein (His Tag)	H9N2	HA
40004-V08H	2011-01-19	Influenza A H5N1 (A/Xinjiang/1/2006) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40004-V08H1	2011-01-19	Influenza A H5N1 (A/Xinjiang/1/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40005-V08B	2014-11-21	Influenza A H1N1 (A/England/195/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40005-V08H	2011-03-01	Influenza A H1N1 (A/England/195/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40005-V08H1	2011-03-01	Influenza A H1N1 (A/England/195/2009) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
40006-V08H	2011-03-01	Influenza A H1N1 (A/Texas/05/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40006-V08H1	2011-03-01	Influenza A H1N1 (A/Texas/05/2009) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
40007-V08H	2011-03-01	Influenza A H1N1 (A/Ohio/07/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40007-V08H1	2013-08-28	Influenza A H1N1 (A/Ohio/07/2009) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
40008-V08B	2014-07-25	Influenza A H4N4 (A/mallard duck/Alberta/299/1977) Hemagglutinin / HA Protein (His Tag)	H4N4	HA
40008-V08H	2011-12-28	Influenza A H4N4 (A/mallard duck/Alberta/299/1977) Hemagglutinin / HA Protein (His Tag)	H4N4	HA
40008-V08H1	2011-12-28	Influenza A H4N4 (A/mallard duck/Alberta/299/1977) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H4N4	HA
40009-V08B	2014-03-27	Influenza A H1N1 (A/New York/18/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40009-V08H	2011-03-01	Influenza A H1N1 (A/New York/18/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40009-V08H1	2011-03-01	Influenza A H1N1 (A/New York/18/2009) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
40010-V07E	2011-07-07	Influenza A H1N1 (A/Puerto Rico/8/34/Mount Sinai) Matrix protein 1 / M1 Protein (His Tag)	H1N1	M1
40011-V07E	2011-06-03	Influenza A H1N1 (A/Puerto Rico/8/34/Mount Sinai) Non-structural / NS1 Protein (His Tag)	H1N1	NS1
40012-VNAE	2011-07-07	Influenza A H1N1 (A/Puerto Rico/8/34/Mount Sinai) Non-structural Protein 2 / NS2	H1N1	NS2
40014-V08H1	2011-06-07	Influenza A H5N2 (A/ostrich/South Africa/AI1091/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N2	HA
40015-V08B	2014-07-25	Influenza A H5N1 (A/hubei/1/2010) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40015-V08H	2011-07-19	Influenza A H5N1 (A/Hubei/1/2010) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40016-V08B	2015-03-24	Influenza B (B/Brisbane/60/2008) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA

40016-V08H	2011-10-13	Influenza B (B/Brisbane/60/2008) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40016-V08H1	2011-08-05	Influenza B (B/Brisbane/60/2008) Hemagglutinin Protein (HA1 Subunit) (His Tag)	Influenza B	HA
40016-VNAB	2017-08-01	Influenza B (B/Brisbane/60/2008) Hemagglutinin / HA Protein	Influenza B	HA
40017-V07H	2011-08-05	Influenza A H3N2 (A/Babol/36/2005) Neuraminidase / NA (His Tag)	H3N2	NA
40017-VNAHC	2011-09-23	Influenza A H3N2 Neuraminidase / NA (Active)	H3N2	NA
40017-VNAHC1	2011-08-05	Influenza A H3N2 Neuraminidase / NA (E119V mutation) (Active)	H3N2	NA
40017-VNAHC2	2011-08-05	Influenza A H3N2 Neuraminidase / NA (N294S mutation) (Active)	H3N2	NA
40017-VNAHC3	2011-08-05	Influenza A H3N2 Neuraminidase / NA (R292K mutation) (Active)	H3N2	NA
40017-VNAHC4	2011-09-23	Influenza A H3N2 Neuraminidase / NA (H274Y mutation) (Active)	H3N2	NA
40018-V07H	2011-09-23	Influenza A H5N1 (A/Hubei/1/2010) Neuraminidase / NA (His Tag)	H5N1	NA
40022-V08H	2017-08-01	Influenza A H5N1 (A/Vietnam/UT31413II/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40022-V08H1	2013-05-30	Influenza A H5N1 (A/Vietnam/UT31413II/2008) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40024-V08B	2014-08-28	Influenza A H5N1 (A/goose/Guangdong/1/1996) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40024-V08H1	2014-07-25	Influenza A H5N1 (A/goose/Guangdong/1/1996) Hemagglutinin Protein (His Tag)	H5N1	HA
40025-V08H	2012-03-02	Influenza A H4N8 (A/chicken/Alabama/1/1975) Hemagglutinin / HA Protein (His Tag)	H4N8	HA
40025-V08H1	2011-12-28	Influenza A H4N8 (A/chicken/Alabama/1/1975) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H4N8	HA
40026-V08H	2012-07-24	Influenza A H5N1 (A/Cambodia/S1211394/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40026-V08H1	2011-12-28	Influenza A H5N1 (A/Cambodia/S1211394/2008) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40027-V08B	2014-08-13	Influenza A H6N4 (A/chicken/Hong Kong/17/1977) Hemagglutinin / HA Protein (His Tag)	H6N4	HA
40027-V08H	2012-03-02	Influenza A H6N4 (A/chicken/Hong Kong/17/1977) Hemagglutinin / HA Protein (His Tag)	H6N4	HA
40027-V08H1	2011-12-28	Influenza A H6N4 (A/chicken/Hong Kong/17/1977) Hemagglutinin / HA Protein (His Tag)	H6N4	HA
40028-V08B	2014-07-25	Influenza A H10N9 (A/duck/Hong Kong/562/1979) Hemagglutinin / HA Protein (His Tag)	H10N9	HA
40028-V08H	2012-06-11	Influenza A H10N9 (A/duck/Hong Kong/562/1979) Hemagglutinin / HA Protein (His Tag)	H10N9	HA
40028-V08H1	2012-01-12	Influenza A H10N9 (A/duck/Hong Kong/562/1979) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H10N9	HA
40029-V08B	2014-07-25	Influenza A H12N1 (A/mallard duck/Alberta/342/1983) Hemagglutinin / HA Protein (His Tag)	H12N1	HA
40029-V08H	2012-03-23	Influenza A H12N1 (A/mallard duck/Alberta/342/1983) Hemagglutinin / HA Protein (His Tag)	H12N1	HA
40029-V08H1	2011-12-28	Influenza A H12N1 (A/mallard duck/Alberta/342/1983) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H12N1	HA
40033-V08B	2011-12-20	Influenza A H2N2 Nucleoprotein / NP Protein (His Tag)	H2N2	NP
40034-V07H	2013-07-19	Influenza A H9N2 (A/chicken/Hong Kong/G9/1997) Neuraminidase / NA (His Tag)	H9N2	NA
40034-VNAHC	2011-10-20	Influenza A H9N2 Neuraminidase / NA (Active)	H9N2	NA
40035-V08H	2011-12-28	Influenza A H1N1 (A/Beijing/22808/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40035-V08H1	2011-10-13	Influenza A H1N1 (A/Beijing/22808/2009) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
40036-V08H	2012-07-05	Influenza A H9N2 (A/chicken/Hong Kong/G9/1997) Hemagglutinin / HA Protein (His Tag)	H9N2	HA
40036-V08H1	2012-01-12	Influenza A H9N2 (A/chicken/Hong Kong/G9/1997) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H9N2	HA
40040-V07H	2013-08-28	Influenza A H9N2 (A/Hong Kong/1073/99) Neuraminidase / NA (His Tag)	H9N2	NA
40043-V08B1	2015-04-30	Influenza A H3N2 (A/Perth/16/2009) Hemagglutinin / HA-specific B cell probe (His Tag)	H3N2	HA
40043-V08H	2011-12-14	Influenza A H3N2 (A/Perth/16/2009) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40043-V08H1	2011-12-14	Influenza A H3N2 (A/Perth/16/2009) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N2	HA
40043-VNAB	2014-12-18	Influenza A H3N2 (A/Perth/16/2009) Hemagglutinin / HA0 Protein	H3N2	HA
40044-V08B	2014-12-18	Influenza A H5N1 (A/common magpie/Hong Kong/5052/2007) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40044-V08H	2013-12-16	Influenza A H5N1 (A/common magpie/Hong Kong/5052/2007) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40044-V08H1	2013-08-28	Influenza A H5N1 (A/common magpie/Hong Kong/5052/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40045-VNAHC	2014-08-13	Influenza A H5N1 (A/Egypt/2321-NAMRU3/2007) Neuraminidase / NA (Active)	H5N1	NA
40049-V08H1	2013-07-19	Influenza A H5N1 (A/Egypt/3300-NAMRU3/2008) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40058-V08B	2014-07-25	Influenza A H3N2 (A/Victoria/210/2009) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40058-V08H1	2013-06-06	Influenza A H3N2 (A/reassortant/IVR-155(Victoria/210/2009 x Puerto Rico/8/1934)) Hemagglutinin Protein (HA1 Sul	H3N2	HA
40059-V08B	2014-11-21	Influenza A H3N2 (A/X-31) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40059-V08H	2013-12-16	Influenza A H3N2 (A/X-31) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40060-V08H1	2014-03-18	Influenza A H5N1 (A/Hubei/1/2010) Hemagglutinin / HA1 Protein (His Tag)	H5N1	HA
40064-V07H	2013-07-19	Influenza A H5N1 (A/Thailand/1(KAN-1)/2004) Neuraminidase / NA (His Tag)	H5N1	NA
40064-V07H-B	2014-08-28	Influenza A H5N1 (A/Thailand/1(KAN-1)/2004) Neuraminidase / NA Protein (His Tag), Biotinylated	H5N1	NA
40065-V08H1	2014-07-25	Influenza A H5N1 (A/Thailand/1(KAN-1)/2004) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40088-V08H	2015-04-30	Influenza A H5N1 (A/chicken/Yamaguchi/7/2004) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40088-V08H1	2013-08-28	Influenza A H5N1 (A/chicken/Yamaguchi/7/2004) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40090-V08B	2014-01-29	Influenza A H1N1 (A/New York/1/1918) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40090-V08H1	2014-01-29	Influenza A H1N1 (A/New York/1/1918) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
40101-V08H1	2014-03-18	Influenza A H3N2 (A/Memphis/1/1968) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40103-V08B	2013-04-28	Influenza A H7N9 (A/Anhui/1/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40103-V08H	2013-04-18	Influenza A H7N9 (A/Anhui/1/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40103-V08H1	2013-04-26	Influenza A H7N9 (A/Anhui/1/2013) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N9	HA
40103-V08H4	2013-05-27	Influenza A H7N9 (A/Anhui/1/2013) Hemagglutinin / HA Protein (HA1+HA2, cleavage) (His Tag)	H7N9	HA
40104-V08B	2013-04-28	Influenza A H7N9 (A/Shanghai/1/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40104-V08B1	2013-05-28	Influenza A H7N9 (A/Shanghai/1/2013) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N9	HA
40104-V08H	2013-04-18	Influenza A H7N9 (A/Shanghai/1/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40104-V08H1	2013-04-26	Influenza A H7N9 (A/Shanghai/1/2013) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N9	HA
40104-V08H4	2013-05-27	Influenza A H7N9 (A/Shanghai/1/2013) Hemagglutinin / HA Protein (HA1+HA2, cleavage) (His Tag)	H7N9	HA
40105-V08B	2013-05-14	Influenza A H7N9 (A/Hangzhou/1/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40105-V08H	2013-04-26	Influenza A H7N9 (A/Hangzhou/1/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40105-V08H1	2013-04-26	Influenza A H7N9 (A/Hangzhou/1/2013) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N9	HA
40106-V08B	2013-05-14	Influenza A H7N9 (A/Pigeon/Shanghai/S1069/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40106-V08B1	2013-05-28	Influenza A H7N9 (A/Pigeon/Shanghai/S1069/2013) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N9	HA
40106-V08H	2013-04-26	Influenza A H7N9 (A/Pigeon/Shanghai/S1069/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40106-V08H1	2013-04-26	Influenza A H7N9 (A/Pigeon/Shanghai/S1069/2013) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N9	HA
40107-V08E	2013-04-24	Influenza A H7N9 (A/Anhui/1/2013) Matrix protein 1 / M1 Protein (His Tag)	H7N9	M1
40108-V07H	2013-04-25	Influenza A H7N9 (A/Anhui/1/2013) Neuraminidase / NA (His Tag)	H7N9	NA
40108-V07H-B	2020-06-23	Influenza A H7N9 (A/Anhui/1/2013) Neuraminidase / NA (His Tag), Biotinylated	H7N9	NA
40108-VNAHC	2013-04-22	Influenza A H7N9 (A/Anhui/1/2013) Neuraminidase / NA (Active)	H7N9	NA
40109-V07H	2013-04-25	Influenza A H7N9 (A/Shanghai/1/2013) Neuraminidase / NA (His Tag)	H7N9	NA
40109-VNAHC	2013-04-22	Influenza A H7N9 (A/Shanghai/1/2013) Neuraminidase / NA (Active)	H7N9	NA
40110-V08B	2013-05-30	Influenza A H7N9 (A/Anhui/1-BALF_RG6/2013) Nucleocapsid / NP Protein (His Tag)	H7N9	NP
40111-V08B	2013-05-21	Influenza A H7N9 (A/Shanghai/2/2013) Nucleocapsid / NP Protein (His Tag)	H7N9	NP
40116-V08B	2013-10-31	Influenza A H3N2 (A/Hong Kong/1/1968) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40116-V08H1	2014-03-18	Influenza A H3N2 (A/Hong Kong/1/1968) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40117-V08B	2014-01-29	Influenza A H5N1 (A/bar-headed goose/Qinghai/1A/2005) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40117-V08H1	2013-10-22	Influenza A H5N1 (A/bar-headed goose/Qinghai/1A/2005) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40118-V08B	2013-11-20	Influenza A H3N2 (A/California/07/2004) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40118-V08H1	2014-08-28	Influenza A H3N2 (A/California/07/2004) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40119-V08B	2013-10-31	Influenza A H2N2 (A/Guiyang/1/1957) Hemagglutinin / HA Protein (His Tag)	H2N2	HA
40119-V08H1	2013-10-22	Influenza A H2N2 (A/Guiyang/1/1957) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H2N2	HA
40120-V08B	2014-01-29	Influenza A H3N2 (A/Fujian/411/2002) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40123-V08B	2013-07-19	Influenza A H7N9 (A/Hangzhou/3/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40125-V08B	2013-07-19	Influenza A H7N9 (A/Zhejiang/1/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40126-V08B	2013-08-28	Influenza A H7N9 (A/Shanghai/4664T/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA

40128-V08B	2013-11-20	Influenza A H7N3 (A/turkey/Italy/214845/2002) Hemagglutinin / HA Protein (His Tag)	H7N3	HA
40128-V08H1	2013-12-16	Influenza A H7N3 (A/turkey/Italy/214845/2002) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N3	HA
40129-V08H1	2014-08-13	Influenza A H7N3 (A/chicken/SK/HR-00011/2007) Hemagglutinin / HA1 Protein (His Tag)	H7N3	HA
40131-V08B	2014-07-25	Influenza A H1N1 (A/Taiwan/01/1986) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40132-V08B	2014-12-05	Influenza A H1N1 (A/Texas/36/1991) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40132-V08H1	2014-07-25	Influenza A H1N1 (A/Texas/36/1991) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
40133-V08B	2014-07-25	Influenza A H1N1 (A/Beijing/262/1995) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40133-V08H1	2014-12-18	Influenza A H1N1 (A/Beijing/262/1995) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40134-V08B	2013-10-22	Influenza A H1N1 (A/USSR/90/1977) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40134-V08H1	2014-07-25	Influenza A H1N1 (A/USSR/90/1977) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H1N1	HA
40135-V08H1	2014-07-25	Influenza A H1N8 (A/Egyptian goose/South Africa/AI1448/2007) Hemagglutinin / HA1 Protein (His Tag)	H1N8	HA
40136-V08B	2014-07-25	Influenza A H1N9 (A/mallard/Ohio/265/1987) Hemagglutinin / HA Protein (His Tag)	H1N9	HA
40136-V08H1	2014-07-25	Influenza A H1N9 (A/mallard/Ohio/265/1987) Hemagglutinin / HA1 Protein (His Tag)	H1N9	HA
40140-V08B	2014-07-25	Influenza A H3N1 (A/swine/Korea/PZ72-1/2006) Hemagglutinin / HA Protein (His Tag)	H3N1	HA
40140-V08H1	2014-07-25	Influenza A H3N1 (A/swine/Korea/PZ72-1/2006) Hemagglutinin / HA1 Protein (His Tag)	H3N1	HA
40144-V08H1	2015-01-26	Influenza A H3N2 (A/Wisconsin/15/2009) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40145-V08B	2014-10-10	Influenza A H3N2 (A/Victoria/361/2011) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40145-V08H1	2014-07-25	Influenza A H3N2 (A/Victoria/361/2011) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N2	HA
40146-V08B	2014-07-25	Influenza A H3N2 (A/Hong Kong/CUHK31987/2011) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40146-V08H1	2014-12-18	Influenza A H3N2 (A/Hong Kong/CUHK31987/2011) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40149-V08B	2014-07-25	Influenza A H3N2 (A/Sydney/5/1997) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40149-V08H1	2014-12-18	Influenza A H3N2 (A/Sydney/5/1997) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40151-V08B	2014-07-25	Influenza A H3N2 (A/Victoria/208/2009) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40151-V08H1	2014-12-05	Influenza A H3N2 (A/Victoria/208/2009) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40152-V08B	2014-07-25	Influenza A H3N2 (A/Guangdong-Luohu/1256/2009) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40152-V08B1	2017-12-28	Influenza A H3N2 (A/Guangdong-Luohu/1256/2009) Hemagglutinin / HA	H3N2	HA
40152-V08H1	2015-04-30	Influenza A H3N2 (A/Guangdong-Luohu/1256/2009) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40153-V08B	2014-07-25	Influenza A H3N2 (A/Babol/36/2005) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40153-VNAB	2014-12-18	Influenza A H3N2 (A/Babol/36/2005) Hemagglutinin / HA0 Protein	H3N2	HA
40154-V08B	2014-07-25	Influenza A H3N2 (A/Moscow/10/1999) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40154-V08H1	2015-01-26	Influenza A H3N2 (A/Moscow/10/1999) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40155-V08B	2014-01-24	Influenza A H3N8 (A/equine/Gansu/7/2008) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N8	HA
40155-V08H1	2014-01-24	Influenza A H3N8 (A/equine/Gansu/7/2008) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N8	HA
40157-V08B	2014-12-05	Influenza B (B/Yamagata/16/1988) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40157-V08H1	2014-07-25	Influenza B (B/Yamagata/16/1988) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40158-V08B	2013-10-22	Influenza A H5N1 (A/chicken/VietNam/NCVD-016/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40158-V08B2	2013-10-22	Influenza A H5N1 (A/chicken/VietNam/NCVD-016/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40158-V08H1	2014-01-24	Influenza A H5N1 (A/chicken/VietNam/NCVD-016/2008) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40160-V08B	2013-12-11	Influenza A H5N1 (A/barnswallow/HongKong/D10-1161/2010) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40160-V08B1	2013-08-15	Influenza A H5N1 (A/barnswallow/HongKong/D10-1161/2010) Hemagglutinin Protein (HA1+HA2) (His Tag)	H5N1	HA
40160-V08H1	2013-12-16	Influenza A H5N1 (A/barn swallow/Hong Kong/D10-1161/2010) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40163-V08B	2020-07-16	Influenza B (B/Victoria/02/1987) Hemagglutinin Protein (HA1 Subunit) (His Tag)	Influenza B	HA
40163-V08H	2014-10-10	Influenza B (B/Victoria/02/1987) Hemagglutinin Protein (HA1 Subunit) (His Tag)	Influenza B	HA
40164-V08B2	2014-01-29	Influenza A H5N8 (A/turkey/Ireland/1378/1983) Hemagglutinin / HA Protein (His Tag)	H5N8	HA
40164-V08H1	2014-01-24	Influenza A H5N8 (A/turkey/Ireland/1378/1983) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N8	HA
40165-V08B	2013-10-08	Influenza A H5N9 (A/chicken/Italy/22A/1998) Hemagglutinin / HA Protein (His Tag)	H5N9	HA
40165-V08H1	2013-11-20	Influenza A H5N9 (A/chicken/Italy/22A/1998) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N9	HA
40166-V08B	2015-01-26	Influenza A H6N2 (A/duck/Shantou/83/2000) Hemagglutinin / HA Protein (His Tag)	H6N2	HA
40166-V08H1	2014-08-13	Influenza A H6N2 (A/duck/Shantou/83/2000) Hemagglutinin / HA1 Protein (His Tag)	H6N2	HA
40167-V08H1	2014-08-13	Influenza A H6N5 (A/shearwater/Australia/1/1973) Hemagglutinin / HA1 Protein (His Tag)	H6N5	HA
40168-V08B	2013-12-16	Influenza A H6N8 (A/mallard/Ohio/217/1998) Hemagglutinin / HA Protein (His Tag)	H6N8	HA
40168-V08H1	2013-12-16	Influenza A H6N8 (A/mallard/Ohio/217/1998) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H6N8	HA
40169-V08H1	2014-08-13	Influenza A H7N1 (A/turkey/Italy/4602/99) Hemagglutinin / HA1 Protein (His Tag)	H7N1	HA
40170-V08B	2013-10-22	Influenza A H7N2 (A/ruddy turnstone/New Jersey/563/2006) Hemagglutinin / HA Protein (His Tag)	H7N2	HA
40170-V08H1	2014-01-29	Influenza A H7N2 (A/ruddy turnstone/New Jersey/563/2006) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H7N2	HA
40171-V08B	2013-11-20	Influenza A H7N7 (A/equine/Kentucky/1a/1975) Hemagglutinin / HA Protein (His Tag)	H7N7	HA
40172-V08B	2013-10-08	Influenza A H7N8 (A/mallard/Netherlands/33/2006) Hemagglutinin / HA Protein (His Tag)	H7N8	HA
40172-V08H1	2014-08-13	Influenza A H7N8 (A/mallard/Netherlands/33/2006) Hemagglutinin / HA1 Protein (His Tag)	H7N8	HA
40174-V08B	2013-08-15	Influenza A H9N2 (A/Hong Kong/35820/2009) Hemagglutinin / HA Protein (His Tag)	H9N2	HA
40174-V08H1	2014-07-25	Influenza A H9N2 (A/Hong Kong/35820/2009) Hemagglutinin / HA1 Protein (His Tag)	H9N2	HA
40178-V08B	2015-03-24	Influenza A H9N2 (A/Hong Kong/3239/2008) Hemagglutinin / HA Protein (His Tag)	H9N2	HA
40178-V08H	2017-08-01	Influenza A H9N2 (A/Hong Kong/3239/2008) Hemagglutinin / HA1 Protein (His Tag)	H9N2	HA
40179-V08B	2015-08-25	Influenza A H9N1 (A/duck/NZL/76/1984) Hemagglutinin / HA Protein (His Tag)	H9N1	HA
40179-V08H1	2015-06-25	Influenza A H9N1 (A/duck/NZL/76/1984) Hemagglutinin / HA1 Protein (His Tag)	H9N1	HA
40181-V08B	2014-08-28	Influenza A H9N5 (A/shorebird/DE/261/2003) Hemagglutinin / HA Protein (His Tag)	H9N5	HA
40181-V08H1	2014-07-25	Influenza A H9N5 (A/shorebird/DE/261/2003) Hemagglutinin /HA1 Protein (His Tag)	H9N5	HA
40183-V08B	2014-11-21	Influenza A H9N8 (A/chicken/Korea/164/04) Hemagglutinin / HA Protein (His Tag)	H9N8	HA
40184-V08B	2013-10-08	Influenza A H10N3 (A/mallard/Minnesota/Sg-00194/2007) Hemagglutinin / HA Protein (His Tag)	H10N3	HA
40184-V08H1	2013-12-16	Influenza A H10N3 (A/mallard/Minnesota/Sg-00194/2007) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H10N3	HA
40187-V08B	2015-01-26	Influenza A H11N2 (A/thick-billed murre/Newfoundland/031/2007) Hemagglutinin / HA Protein (His Tag)	H11N2	HA
40187-V08H1	2014-10-10	Influenza A H11N2 (A/thick-billed murre/Newfoundland/031/2007) Hemagglutinin / HA1 Protein (His Tag)	H11N2	HA
40188-V08H1	2014-07-25	Influenza A H11N6 (A/duck/England/1/1956) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H11N6	HA
40189-V08H1	2014-07-25	Influenza A H12N3 (A/bar headed goose/Mongolia/143/2005) Hemagglutinin / HA1 Protein (His Tag)	H12N3	HA
40190-V08B	2014-10-10	Influenza A H13N6 (A/black-headed gull/Sweden/1/1999) Hemagglutinin / HA Protein (His Tag)	H13N6	HA
40190-V08H	2016-02-24	Influenza A H13N6 (A/black-headed gull/Sweden/1/1999) Hemagglutinin / HA1 Protein (His Tag)	H13N6	HA
40191-V08B	2014-12-18	Influenza B (B/Massachusetts/03/2010) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40191-V08H1	2014-07-25	Influenza B (B/Massachusetts/03/2010) Hemagglutinin Protein (HA1 Subunit) (His Tag)	Influenza B	HA
40191-VNAB	2014-12-18	Influenza B (B/Massachusetts/03/2010) Hemagglutinin / HA0 Protein	Influenza B	HA
40192-V08B	2015-06-30	Influenza A H14N5 (A/mallard/Astrakhan/263/1982) Hemagglutinin / HA Protein (His Tag)	H14N5	HA
40192-V08H1	2013-11-29	Influenza A H14N5 (A/mallard/Astrakhan/263/1982) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H14N5	HA
40193-V08B	2013-11-29	Influenza A H15N2 (A/Australian shelduck/Western Australia/1756/1983) Hemagglutinin / HA Protein (His Tag)	H15N2	HA
40193-V08H1	2013-12-16	Influenza A H15N2 (A/Australian shelduck/Western Australia/1756/1983) Hemagglutinin Protein (HA1 Subunit) (His	H15N2	HA
40196-VNAHC	2014-08-13	Influenza A H1N1 (A/Puerto Rico/8/1934) Neuraminidase / NA (Active)	H1N1	NA
40197-V07H	2013-08-28	Influenza A H1N1 (A/USSR/90/1977) Neuraminidase / NA (His Tag)	H1N1	NA
40197-VNAHC	2016-02-22	Influenza A H1N1 (A/USSR/90/1977) Neuraminidase / NA (Active)	H1N1	NA
40199-V07H	2013-08-28	Influenza A H3N2 (A/Aichi/2/1968) Neuraminidase / NA (His Tag)	H3N2	NA
40199-VNAHC	2016-02-22	Influenza A H3N2 (A/Aichi/2/1968) Neuraminidase / NA (Active)	H3N2	NA
40202-V07H	2014-08-13	Influenza A H7N7 (A/Netherlands/219/2003) Neuraminidase / NA Protein (His Tag)	H7N7	NA
40202-VNAHC	2013-08-02	Influenza A H7N7 (A/Netherlands/219/2003) Neuraminidase / NA (Active)	H7N7	NA
40203-VNAHC	2016-02-22	Influenza B (B/Brisbane/60/2008) Neuraminidase / NA (Active)	Influenza B	NA
40204-V08B	2013-11-20	Influenza A H1N1 (A/Brevig Mission/1/1918) Nucleoprotein / NP Protein (His Tag)	H1N1	NP
40205-V08B	2013-10-18	Influenza A H1N1 (A/California/07/2009) Nucleoprotein / NP Protein (His Tag)	H1N1	NP
40207-V08B	2013-08-15	Influenza A H3N2 (A/Aichi/2/1968) Nucleoprotein / NP Protein (His Tag)	H3N2	NP

40208-V08B	2013-08-28	Influenza A H3N2 (A/Hong Kong/1/1968) Nucleoprotein / NP Protein (His Tag)	H3N2	NP
40211-V07E	2013-07-19	Influenza A H1N1 (A/Brevig Mission/1/1918) Matrix protein 1 / M1 Protein (His Tag)	H1N1	M1
40215-V07E	2013-07-19	Influenza A H3N2 (A/Aichi/2/1968) Matrix protein 1 / M1 Protein (His Tag)	H3N2	M1
40235-V07B	2014-07-25	Influenza A H4N6 (A/mallard/Ohio/657/2002) Neuraminidase / NA Protein (His Tag)	H4N6	NA
40235-VNAHC	2015-05-15	Influenza A H4N6 (A/mallard/Ohio/657/2002) Neuraminidase / NA (Active)	H4N6	NA
40237-VNAHC	2016-02-22	Influenza A H12N5 (A/green-winged teal/ALB/199/1991) Neuraminidase / NA (Active)	H12N5	NA
40239-V08B	2013-06-20	Influenza A H7N9 (A/Shanghai/2/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40239-V08H	2013-06-20	Influenza A H7N9 (A/Shanghai/2/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40323-V08B	2015-06-25	Influenza A H17N10 (A/little yellow-shouldered bat/Guatemala/164/2009) Hemagglutinin / HA Protein (His Tag)	H17N10	HA
40323-V08H1	2014-07-25	Influenza A H17N10 (A/little yellow-shouldered bat/Guatemala/164/2009) Hemagglutinin Protein (His Tag)	H17N10	HA
40324-V08B	2014-07-25	Influenza A H18N11 (A/flat-faced bat/Peru/033/2010) Hemagglutinin / HA Protein (His Tag)	H18N11	HA
40324-V08H1	2014-07-25	Influenza A H18N11 (A/flat-faced bat/Peru/033/2010) Hemagglutinin / HA1 Protein (His Tag)	H18N11	HA
40325-V08B	2014-01-24	Influenza A H7N9 (A/Zhejiang/DTID-ZJU10/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40325-V08H	2013-12-16	Influenza A H7N9 (A/Zhejiang/DTID-ZJU10/2013) Hemagglutinin / HA Protein (His Tag)	H7N9	HA
40350-V08B	2014-11-21	Influenza A H1N1 (A/California/06/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40350-V08H1	2014-08-13	Influenza A H1N1 (A/California/06/2009) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40351-V08H1	2014-07-25	Influenza A H10N8 (A/duck/Guangdong/E1/2012) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H10N8	HA
40352-V07B	2014-07-25	Influenza A H10N8 (A/duck/Guangdong/E1/2012) Neuraminidase / NA Protein (His Tag)	H10N8	NA
40354-V08B	2014-08-28	Influenza A H3N2 (A/Texas/50/2012) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40354-V08H1	2014-07-25	Influenza A H3N2 (A/Texas/50/2012) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H3N2	HA
40359-V08B	2014-04-14	Influenza A H10N8 (A/Jiangxi-Donghu/346/2013) Hemagglutinin / HA Protein (His Tag)	H10N8	HA
40359-V08H1	2015-01-26	Influenza A H10N8 (A/Jiangxi-Donghu/346/2013) Hemagglutinin / HA1 Protein (His Tag)	H10N8	HA
40359-VNAB	2014-08-13	Influenza A H10N8 (A/Jiangxi-Donghu/346/2013) Hemagglutinin / HA0 Protein (full length)	H10N8	HA
40360-V08H1	2014-07-25	Influenza A H10N3 (A/duck/Hunan/S11205/2012) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H10N3	HA
40372-V08B	2014-07-25	Influenza A H5N1 (A/chicken/Jilin/9/2004) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40372-V08B4	2014-07-25	Influenza A H5N1 (A/chicken/Jilin/9/2004) Hemagglutinin Protein (His Tag)	H5N1	HA
40372-V08H1	2014-07-25	Influenza A H5N1 (A/chicken/Jilin/9/2004) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H5N1	HA
40383-V08B	2015-10-09	Influenza A H5N8 (A/breeder duck/Korea/Gochang1/2014) Hemagglutinin / HA Protein (His Tag)	H5N8	HA
40383-V08H1	2015-03-24	Influenza A H5N8 (A/breeder duck/Korea/Gochang1/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40383-V08H2	2015-04-30	Influenza A H5N8 (A/breeder duck/Korea/Gochang1/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40384-V08B	2016-06-17	Influenza A H5N8 (A/broiler duck/Korea/Buan2/2014) Hemagglutinin / HA Protein (His Tag)	H5N8	HA
40384-V08H1	2015-03-24	Influenza A H5N8 (A/broiler duck/Korea/Buan2/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40384-V08H2	2015-04-30	Influenza A H5N8 (A/broiler duck/Korea/Buan2/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40385-V08H1	2015-04-30	Influenza A H5N8 (A/duck/Jiangsu/k1203/2010) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40387-V08H1	2015-03-24	Influenza A H5N8 (A/duck/Zhejiang/W24/2013) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40388-V08H1	2015-03-24	Influenza A H5N8 (A/duck/Zhejiang/6D18/2013) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40390-V08B	2016-04-20	Influenza A H4N2 (A/duck/Hunan/8-19/2009) Hemagglutinin / HA Protein (His Tag)	H4N2	HA
40390-V08H1	2015-04-30	Influenza A H4N2 (A/duck/Hunan/8-19/2009) Hemagglutinin / HA1 Protein (His Tag)	H4N2	HA
40391-V08H	2017-11-17	Influenza B (B/Victoria/504/2000) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40392-V08B	2014-12-18	Influenza A H1N1 (A/NewJersey/8/1976) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40392-V08H1	2014-10-10	Influenza A H1N1 (A/NewJersey/8/1976) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40393-V08B	2014-12-18	Influenza A H1N1 (A/swine/Belgium/1/1998) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40393-V08H1	2014-12-18	Influenza A H1N1 (A/swine/Belgium/1/1998) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40394-V08H1	2014-12-05	Influenza A H1N1 (A/Swine/Wisconsin/136/1997) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40395-V08H1	2014-10-10	Influenza A H3N2 (A/Indiana/07/2012) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40396-V08H1	2015-01-26	Influenza A H3N2 (A/Victoria/3/1975) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40397-V08H	2017-11-17	Influenza A H6N1 (A/quail/Hong Kong/1721-30/99) Hemagglutinin Protein (HA1 Subunit) (His Tag)	H6N1	HA
40398-V08B	2014-12-18	Influenza A H6N2 (A/chicken/Guangdong/C273/2011) Hemagglutinin / HA Protein (His Tag)	H6N2	HA
40398-V08H1	2014-10-10	Influenza A H6N2 (A/chicken/Guangdong/C273/2011) Hemagglutinin / HA1 Protein (His Tag)	H6N2	HA
40399-V08H1	2014-10-10	Influenza A H6N6 (A/duck/Eastern China/11/2009) Hemagglutinin / HA1 Protein (His Tag)	H6N6	HA
40431-V08H1	2015-04-30	Influenza B (B/Brisbane/3/2007) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40432-V08H1	2015-03-24	Influenza B (B/Florida/07/2004) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40433-V08B	2016-03-15	Influenza A H10N7 (A/blue-winged teal/Louisiana/Sg-00073/2007) Hemagglutinin / HA Protein (His Tag)	H10N7	HA
40433-V08H1	2015-04-30	Influenza A H10N7 (A/blue-winged teal/Louisiana/Sg-00073/2007) Hemagglutinin / HA1 Protein (His Tag)	H10N7	HA
40435-V08H1	2015-03-24	Influenza A H3N2 (A/Chiang Rai/277/2011) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40436-V08H1	2015-04-30	Influenza A H3N2 (A/New York/55/2004) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40438-V08B	2015-08-05	Influenza B (B/Florida/4/2006) Nucleoprotein / NP Protein (His Tag)	Influenza B	NP
40460-V08H1	2015-04-30	Influenza B (B/Ohio/01/2005) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40461-V08H1	2015-04-30	Influenza B (B/Hong Kong/05/1972) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40462-V08H1	2015-04-30	Influenza B (B/Wisconsin/01/2012) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40463-V08B	2015-06-30	Influenza B (B/Utah/02/2012) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40463-V08H1	2015-03-24	Influenza B (B/Utah/02/2012) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40464-V08B	2016-04-07	Influenza A H1N1 (A/Albany/12/1951) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40464-V08H1	2015-03-24	Influenza A H1N1 (A/Albany/12/1951) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40465-V08B	2015-06-30	Influenza A H5N6 (A/duck/Guangdong/GD01/2014) Hemagglutinin / HA Protein (His Tag)	H5N6	HA
40465-V08H1	2015-06-25	Influenza A H5N6 (A/duck/Guangdong/GD01/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N6	HA
40466-V08B	2016-05-10	Influenza A H5N6 (A/duck/Jiangxi/95/2014) Hemagglutinin / HA Protein (His Tag)	H5N6	HA
40466-V08H1	2015-04-30	Influenza A H5N6 (A/duck/Jiangxi/95/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N6	HA
40475-V08B	2015-12-21	Influenza A H3N2 (A/Wuhan/359/1995) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40476-V08B	2016-02-04	Influenza A H3N2 (A/Johannesburg/33/1994) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40476-V08H	2015-10-09	Influenza A H3N2 (A/Johannesburg/33/1994) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40477-V08H1	2015-04-30	Influenza A H3N2 (A/Texas/1/1977) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40478-V08H1	2015-03-24	Influenza A H3N2 (A/Christchurch/4/1985) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40479-V08H1	2015-03-24	Influenza A H3N2 (A/England/42/1972) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40479-V08H2	2015-04-30	Influenza A H3N2 (A/England/42/1972) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40480-V08H1	2015-12-21	Influenza A H3N2 (A/Guizhou/54/1989) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40483-V08B	2017-07-11	Influenza A H3N2 (A/Beijing/32/1992) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40483-V08H	2015-10-09	Influenza A H3N2 (A/Beijing/32/1992) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40485-V08B	2015-04-30	Influenza A H3N2 (A/Nanchang/933/1995) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40485-V08H1	2015-04-30	Influenza A H3N2 (A/Nanchang/933/1995) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40486-V08B	2015-08-05	Influenza A H3N2 (A/Netherlands/178/1995) (RG145K) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40486-V08H1	2015-04-30	Influenza A H3N2 (A/Netherlands/178/1995(RG145K)) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40487-V08B	2016-09-01	Influenza A H3N2 (A/Philippines/472/2002) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40487-V08H1	2015-06-30	Influenza A H3N2 (A/Philippines/472/2002) (MDCK) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40488-V08B	2015-08-05	Influenza A H3N2 (A/Fujian/411/2002) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40488-V08H1	2015-05-26	Influenza A H3N2 (A/Fujian/411/2002) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40489-V08B	2015-06-30	Influenza A H3N2 (A/Hanoi/EL134/2008) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40489-V08H1	2015-05-26	Influenza A H3N2 (A/Hanoi/EL134/2008) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40490-V08B	2015-08-05	Influenza A H3N2 (A/Hanoi/EL201/2009) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40490-V08H1	2015-04-30	Influenza A H3N2 (A/Hanoi/EL201/2009) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40494-V08B	2015-06-25	Influenza A H3N2 (A/Missouri/09/2014) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40494-V08H1	2015-06-30	Influenza A H3N2 (A/Missouri/09/2014) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40495-V08B	2015-06-25	Influenza A H5N6 (A/Sichuan/26221/2014) Hemagglutinin / HA Protein (His Tag)	H5N6	HA

40495-V08H1	2015-06-25	Influenza A H5N6 (A/Sichuan/26221/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N6	HA
40497-V08B	2015-12-21	Influenza A H3N2 (A/Switzerland/9715293/2013) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40497-V08H1	2015-06-25	Influenza A H3N2 (A/Switzerland/9715293/2013) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40497-VNAB	2015-06-25	Influenza A H3N2 (A/Switzerland/9715293/2013) Hemagglutinin / HA0 Protein (full length)	H3N2	HA
40498-V08B	2015-06-30	Influenza B (B/PHUKET/3073/2013) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40498-V08H1	2015-03-24	Influenza B (B/PHUKET/3073/2013) Hemagglutinin / HA1 Protein (His Tag)	Influenza B	HA
40498-VNAB	2015-08-25	Influenza B (B/PHUKET/3073/2013) Hemagglutinin / HA0 Protein (full length)	Influenza B	HA
40499-V08B	2015-06-30	Influenza A H3N2 (A/Switzerland/9715293/2013) Nucleoprotein / NP Protein (His Tag)	H3N2	NP
40502-V07B	2016-04-07	Influenza B (B/PHUKET/3073/2013) Neuraminidase / NA Protein (His Tag)	Influenza B	NA
40506-V08B	2016-01-07	Influenza A H1N1 (A/Bel/1942) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40506-V08H	2016-04-06	Influenza A H1N1 (A/Bel/1942) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40507-V08B	2015-12-21	Influenza A H1N1 (A/Fort Monmouth/1/1947) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40507-V08H	2016-02-04	Influenza A H1N1 (A/Fort Monmouth/1/1947) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40508-V08H	2016-04-06	Influenza A H1N1 (A/Hawaii/19/2007) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40509-V08B	2015-12-21	Influenza A H1N1 (A/Memphis/1/1987) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40509-V08H	2016-02-04	Influenza A H1N1 (A/Memphis/1/1987) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40510-V08B	2016-02-04	Influenza A H1N1 (A/Mexico/InDRE4114/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40510-V08H	2016-02-04	Influenza A H1N1 (A/Mexico/InDRE4114/2009) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40511-V08B	2015-06-25	Influenza A H5N8 (A/Ch/Netherlands/14015526/2014) Hemagglutinin / HA Protein (His Tag)	H5N8	HA
40511-V08H1	2015-04-30	Influenza A H5N8 (A/Ch/Netherlands/14015526/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40512-V08B	2016-02-04	Influenza A H5N8 (A/turkey/Germany-MV/R2472/2014) Hemagglutinin / HA Protein (His Tag)	H5N8	HA
40512-V08H1	2015-04-30	Influenza A H5N8 (A/turkey/Germany-MV/R2472/2014) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40518-V08B	2015-10-09	Influenza A H5N2 (A/chicken/Iowa/04-20/2015) Hemagglutinin / HA Protein (His Tag)	H5N2	HA
40518-V08H1	2015-08-25	Influenza A H5N2 (A/chicken/Iowa/04-20/2015) Hemagglutinin / HA1 Protein (His Tag)	H5N2	HA
40519-V08H1	2015-10-09	Influenza A H5N8 (A/turkey/California/K1500169-1.2/2015) Hemagglutinin / HA1 Protein (His Tag)	H5N8	HA
40555-V08B	2020-07-16	Influenza A H3N2 (A/Hong Kong/4801/2014) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40555-V08H	2017-01-22	Influenza A H3N2 (A/Hong Kong/4801/2014) Hemagglutinin / HA1 Protein (His Tag)	H3N2	HA
40557-V08B	2017-08-01	Influenza A H5N6 (A/yunnan/0127/2015) Hemagglutinin / HA Protein (His Tag)	H5N6	HA
40567-H08H	2018-06-06	Influenza A H1N1 (A/Michigan/45/2015) Hemagglutinin / HA1 Protein (His Tag)	H1N1	HA
40567-V08H1	2019-08-05	Influenza A H1N1 (A/Michigan/45/2015) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40568-V07H	2018-04-03	Influenza A H1N1 (A/Michigan/45/2015) Neuraminidase / NA (His Tag)	H1N1	NA
40568-V08B	2019-01-09	Influenza A H1N1 (A/Michigan/45/2015) Neuraminidase / NA (His Tag)	H1N1	NA
40569-V07H	2018-04-03	Influenza A H3N2 (A/Hong Kong/4801/2014) Neuraminidase / NA (His Tag)	H3N2	NA
40569-V08B	2019-03-28	Influenza A H3N2 (A/Hong Kong/4801/2014) Neuraminidase / NA (His Tag)	H3N2	NA
40580-V08H	2020-07-16	Influenza A H3N2 (A/Singapore/INFIMH-16-0019/2016) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40581-V08H	2020-07-16	Influenza B (B/Colorado/06/2017) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40645-V08B	2020-08-13	Influenza A H1N1 (A/swine/Hebei/0116/2017) Hemagglutinin / HA Protein (ECD, His Tag)	H1N1	HA
40648-V08H	2020-07-17	Influenza A H1N1 (A/swine/Henan/SN13/2018) Hemagglutinin / HA Protein (ECD, His Tag)	H1N1	HA
40649-V08B	2020-08-13	Influenza A H1N1 (A/swine/Jiangsu/J004/2018) Hemagglutinin / HA Protein (ECD, His Tag)	H1N1	HA
40649-V08H	2020-07-30	Influenza A H1N1 (A/swine/Jiangsu/J004/2018) Hemagglutinin / HA Protein (ECD, His Tag)	H1N1	HA
40651-V08B	2020-08-13	Influenza A H1N1 (A/swine/Shandong/1207/2016) Hemagglutinin / HA Protein (ECD, His Tag)	H1N1	HA
40651-V08H	2020-07-22	Influenza A H1N1 (A/swine/Shandong/1207/2016) Hemagglutinin / HA Protein (ECD, His Tag)	H1N1	HA
40653-V08H	2020-07-23	Influenza A H1N1 (A/New York/1/1918) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40654-V08H	2020-07-23	Influenza A H1N1 (A/swine/Ohio/23/1935) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40655-V08H	2020-07-23	Influenza A H1N1 (A/swine/Cambridge/1939) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40656-V08H	2020-07-23	Influenza A H1N1 (A/AA/Huston/1945) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40657-V08H	2020-07-23	Influenza A H1N1 (A/Melbourne/1/1946) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40658-V08H	2020-07-23	Influenza A H1N1 (A/Denver/1957) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40659-V08H	2020-07-23	Influenza A H1N1 (A/NewJersey/8/1976) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40660-V08H	2020-07-23	Influenza A H1N1 (A/swine/OMS/2112/1995) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40661-V08H	2020-07-23	Influenza A H1N1 (A/swine/Eire/89/1996) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40662-V08H	2020-07-23	Influenza A H1N1 (A/Taiwan/4845/1999) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40663-V08H	2020-07-23	Influenza A H1N1 (A/Swine/Minnesota/55551/2000) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40664-V08H	2020-07-23	Influenza A H1N1 (A/swine/Saitama/21/2004) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40665-V08H	2020-07-23	Influenza A H1N1 (A/swine/Kansas/00246/2004) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40666-V08H	2020-07-23	Influenza A H1N1 (A/swine/Denmark/12813-1/2004) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40667-V08H	2020-07-23	Influenza A H1N1 (A/Iowa/CEID23/2005) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40668-V08H	2020-07-23	Influenza A H1N1 (A/Thailand/271/2005) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40669-V08H	2020-07-23	Influenza A H1N2 (A/swine/Tainan/46-4/2005) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40670-V08H	2020-07-23	Influenza A H1N1 (A/swine/England/383/2005) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40671-V08H	2020-07-23	Influenza A H1N1 (A/swine/Canada/01093/2006) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40672-V08H	2020-07-23	Influenza A H1N2 (A/swine/Miyazaki/1/2006) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40673-V08H	2020-07-23	Influenza A H1N1 (A/swine/Korea/VDS3/2009) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40674-V08H	2020-07-29	Influenza A H1N2 (A/swine/Iowa/A01049060/2010) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40675-V08H	2020-07-29	Influenza A H1N1 (A/Wisconsin/28/2011) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40676-V08H	2020-07-29	Influenza A H1N2 (A/swine/Hong Kong/4083/2011) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40677-V08H	2020-07-29	Influenza A H1N2 (A/Minnesota/14/2012) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40678-V08H	2020-07-29	Influenza A H1N2 (A/swine/Belgium/Oostkamp-26/2012) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40679-V08H	2020-07-29	Influenza A H1N2 (A/swine/England/7856/2012) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40680-V08H	2020-07-29	Influenza A H1N2 (A/swine/England/038712/2012) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40681-V08H	2020-07-29	Influenza A H1N1 (A/swine/Mexico/AVX47/2013) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40682-V08H	2020-07-29	Influenza A H1N1 (A/Pavia/65/2016) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40683-V08H	2020-07-29	Influenza A H1N1 (A/Florida/04/2017) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40684-V08H	2020-07-29	Influenza A H3N1 (A/swine/England/704563/1995) Hemagglutinin / HA Protein (His Tag)	H3N1	HA
40685-V08H	2020-07-29	Influenza A H3N2 (A/swine/England/90591/1997) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40686-V08H	2020-07-29	Influenza A H3N2 (A/swine/Spain/33601/2001) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40687-V08H	2020-07-29	Influenza A H3N1 (A/swine/Taiwan/0408/2004) Hemagglutinin / HA Protein (His Tag)	H3N1	HA
40688-V08H	2020-07-29	Influenza A H3N2 (A/swine/Denmark/101501-1/2010) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40689-V08H	2020-07-29	Influenza A H3N2 (A/swine/Colorado/A01203748/2012) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40690-V08H	2020-07-29	Influenza A H3N2 (A/swine/Thailand/CU-P53/2012) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40691-V08H	2020-07-29	Influenza A H3N2 (A/swine/Mexico/AVX13/2012) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40692-V08H	2020-07-29	Influenza A H3N2 (A/swine/Miyazaki/2/2013) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40693-V08H	2020-07-29	Influenza A H3N2 (A/Indiana/11/2018) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40694-V08H	2020-07-29	Influenza A H5N1 (A/Hong Kong/378.1/2001) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40695-V08H	2020-07-29	Influenza A H5N1 (A/China/2006) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40696-V08H	2020-07-29	Influenza A H5N1 (A/Egypt/1394-NAMRU3/2007) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40697-V08H	2020-07-29	Influenza A H5N1 (A/Bangladesh/207095/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40698-V08H	2020-07-29	Influenza A H5N1 (A/Cambodia/X0123311/2013) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40699-V08H	2020-07-29	Influenza A H5N1 (A/Egypt/N0001/2015) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40700-V08H	2020-07-29	Influenza A H1N1 (A/swine/Saskatchewan/SD0056/2014) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40701-V08H	2020-07-29	Influenza A H1N2 (A/swine/North Carolina/01169/2006) Hemagglutinin / HA Protein (His Tag)	H1N2	HA
40702-V08H	2020-07-29	Influenza A H1N1 (A/swine/England/267/2007) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40703-V08H	2020-07-29	Influenza A H3N2 (A/Mexico/InDRE2250/2005) Hemagglutinin / HA Protein (His Tag)	H3N2	HA

40704-V08H	2020-07-29	Influenza A H3N2 (A/Ohio/14/2008) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40705-V08H	2020-07-29	Influenza B (B/Maryland/1959) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40706-V08H	2020-07-29	Influenza B (B/Ann Arbor/1/1986) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40707-V08H	2020-07-29	Influenza B (B/Oita/15/1992) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40708-V08H	2020-07-29	Influenza B (B/Sydney/3/2002) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40709-V08H	2020-07-29	Influenza B (B/Hong Kong/CUHK50947/2004) Hemagglutinin / HA Protein (His Tag)	Influenza B	HA
40710-V08H	2020-07-29	Influenza A H1N1 (A/WSN/1933) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40711-V08H	2020-07-29	Influenza A H1N1 (A/USSR/90/1977) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40712-V08H	2020-07-29	Influenza A H1N1 (A/Tawain/01/1986) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40713-V08H	2020-07-29	Influenza A H1N1 (A/Texas/36/1991) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40714-V08H	2020-07-29	Influenza A H1N1 (A/Beijing/262/1995) Hemagglutinin / HA Protein (His Tag)	H1N1	HA
40715-V08H	2020-07-29	Influenza A H3N2 (A/Hong Kong/1/1968) Hemagglutinin / HA Protein (His Tag)	H3N2	HA
40716-V08H	2020-07-29	Influenza A H5N1 (A/chicken/VietNam/NCVD-016/2008) Hemagglutinin / HA Protein (His Tag)	H5N1	HA
40725-V07H	2020-07-29	Influenza A H1N1 (A/swine/Iowa/15/1930) Neuraminidase / NA (His Tag)	H1N1	NA
40726-V07H	2020-07-29	Influenza A H1N1 (A/Henry/1936) Neuraminidase / NA (His Tag)	H1N1	NA
40727-V07H	2020-07-29	Influenza A H1N1 (A/AA/Marton/1943) Neuraminidase / NA (His Tag)	H1N1	NA
40728-V07H	2020-07-29	Influenza A H1N1 (A/Baylor/11515/1982) Neuraminidase / NA (His Tag)	H1N1	NA
40729-V07H	2020-07-29	Influenza A H1N1 (A/swine/Denmark/19216B/1993) Neuraminidase / NA (His Tag)	H1N1	NA
40730-V07H	2020-07-29	Influenza A H1N1 (A/Beijing/262/1995) Neuraminidase / NA (His Tag)	H1N1	NA
40731-V07H	2020-07-29	Influenza A H1N1 (A/Auckland/6/1996) Neuraminidase / NA (His Tag)	H1N1	NA
40732-V07H	2020-07-29	Influenza A H1N1 (A/Auckland/606/2001) Neuraminidase / NA (His Tag)	H1N1	NA
40733-V07H	2020-07-29	Influenza A H1N1 (A/swine/Canada/01093/2006) Neuraminidase / NA (His Tag)	H1N1	NA
40734-V07H	2020-07-29	Influenza A H1N1 (A/Arizona/13/2008) Neuraminidase / NA (His Tag)	H1N1	NA
40735-V07H	2020-07-29	Influenza A H1N1 (A/swine/Guangxi/NS2176/2012) Neuraminidase / NA (His Tag)	H1N1	NA
40736-V07H	2020-07-29	Influenza A H1N1 (A/swine/Alberta/SD0154/2016) Neuraminidase / NA (His Tag)	H1N1	NA
40737-V07H	2020-07-29	Influenza A H1N1 (A/Idaho/01/2017) Neuraminidase / NA (His Tag)	H1N1	NA
40738-V07H	2020-07-29	Influenza A H1N1 (A/Sw/Bulnes/VN1401-P6SP/2018) Neuraminidase / NA (His Tag)	H1N1	NA
40739-V07H	2020-07-29	Influenza A H3N2 (A/Albany/18/1968) Neuraminidase / NA (His Tag)	H3N2	NA
40740-V07H	2020-07-29	Influenza A H3N2 (A/Hong Kong/107/1971) Neuraminidase / NA (His Tag)	H3N2	NA
40741-V07H	2020-07-29	Influenza A H3N2 (A/swine/Italy/526/1985) Neuraminidase / NA (His Tag)	H3N2	NA
40742-V07H	2020-07-29	Influenza A H3N2 (A/Amsterdam/4112/1992) Neuraminidase / NA (His Tag)	H3N2	NA
40743-V07H	2020-07-29	Influenza A H3N2 (A/Hong Kong/CUHK19579/1998) Neuraminidase / NA (His Tag)	H3N2	NA
40744-V07H	2020-07-29	Influenza A H1N2 (A/Swine/Indiana/P12439/00) Neuraminidase / NA (His Tag)	H1N2	NA
40745-V07H	2020-07-29	Influenza A H3N2 (A/Australia/NHRC0001/2005) Neuraminidase / NA (His Tag)	H3N2	NA
40746-V07H	2020-07-29	Influenza A H1N2 (A/Swine/Spain/SF12091/2007) Neuraminidase / NA (His Tag)	H1N2	NA
40747-V07H	2020-07-29	Influenza A H1N2 (A/swine/Italy/191985/2009) Neuraminidase / NA (His Tag)	H1N2	NA
40748-V07H	2020-07-29	Influenza A H1N2 (A/swine/Papenburg/IDT12653/2010) Neuraminidase / NA (His Tag)	H1N2	NA
40749-V07H	2020-07-29	Influenza A H1N2 (A/swine/North Carolina/A01668056/2016) Neuraminidase / NA (His Tag)	H1N2	NA
40750-V07H	2020-07-29	Influenza A H1N2 (A/swine/Alberta/SD0217/2017) Neuraminidase / NA (His Tag)	H1N2	NA
40751-V07H	2020-07-29	Influenza A H3N2 (A/swine/China/JG20/2019) Neuraminidase / NA (His Tag)	H3N2	NA
40752-V07H	2020-07-29	Influenza B (B/Lee/1940) Neuraminidase / NA (His Tag)	Influenza B	NA

FY20 Round - April 1, 2020 until September 30, 2020.

RANK	Publication Title (Link to full text)	Contact PI	PI Affiliation	Journal	Write-Up	Commentary (Link)	NIAID News Release (Link)	Topic	Pathogen	Impact Statement	Outcome	Support	Contact PO
	Different genetic barriers for resistance to HA stem antibodies in influenza H3 and H1 viruses	Ian Wilson	TSRI	Science				Influenza broadly neutralizing antibodies	Influenza			75N93019C00051 R56AI127377 (IAW) R56AI139466 (NCW) R01AI127893 (JDB) F30AI136325 (JML)	Teresa Haugael Brooke Bozick Chelsea Lane
	Influenza A virus is transmissible via aerosolized fomites	Nicole Bouvier	Mt. Sinai	Nature Communications				Influenza transmission	Influenza				Brooke Bozick
	Origin and cross-species transmission of bat coronaviruses in China	Peter Daszak	EcoHealth Alliance	Nature Communications				SARS-CoV-2 Origin	SARS-CoV-2			R01AI110964	Erik Stemmy
	A Mouse-Adapted SARS-CoV-2 Induces Acute Lung Injury and Mortality in Standard Laboratory Mice	Ralph Baric	University of North Carolina at Chapel Hill	Cell				SARS-CoV-2 pathogenesis	SARS-CoV-2			U19AI142759, 5R01AI132178, AI110625, and AI108197 as well as an animal models contract from the NIH (HHSN272201700060 75N93020F00001)	Erik Stemmy
	Remdesivir Inhibits SARS-CoV-2 in Human Lung Cells and Chimeric SARS-CoV Expressing the SARS-CoV-2 RNA Polymerase in Mice	Timothy P Sheahan	University of North Carolina at Chapel Hill	Cell Reports				SARS-CoV-2 Therapeutics	SARS-CoV-2			U19AI142759, R01AI132178 R01AI137178-01S1, R01AI108197, T32AI007151	Erik Stemmy
	Structure-based design of prefusion-stabilized SARS-CoV-2 spikes	Jason S. McLellan	UT-Austin	Science				SARS-CoV-2 Structure/vaccines	SARS-CoV-2			R01AI127521	Erik Stemmy
	Site-specific glycan analysis of the SARS-CoV-2 spike	Max Crispin	University of Southampton	Science				SARS-CoV-2 Structure/vaccines	SARS-CoV-2			R01AI127521	Erik Stemmy

FY20 Round - April 1, 2020 until September 30, 2020.

Publication Title (Link to full text)	Contact PI	PI Affiliation	Journal	Write-Up	Commentary (Link)	NIAID News Release (Link)	Topic	Pathogen	Impact Statement	Outcome	Support	Contact PO

From: Mulach, Barbara (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: DMID GrantOps; NIAID DMID Policy
Subject: FW: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC
Date: Friday, August 21, 2020 3:47:57 PM

HI Erik,

See Matthew Fenton's note below. (b) (5) If it's easier to discuss by phone, let me know.

Thanks!
Barbara

From: Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Sent: Friday, August 21, 2020 1:31 PM
To: Bateman, Karen (NIH/NIAID) [E] (b) (6); Linde, Emily (NIH/NIAID) [E] (b) (6); Khurana, Dhana (NIH/NIAID) [E] (b) (6)
Cc: DMID GrantOps (b) (6); Powell, Maria (NIH/NIAID) [E] <maria.powell@nih.gov>
Subject: RE: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC

Karen et al. – this case has uncovered a few interesting things. First of all the 2016 incident was reported to OSP, but not to NIAID as was pointed out. Interestingly, UNC reported it under the requirement of reporting incidents under the NIH rDNA policy, which requires an incident report be filed with OSP, but is silent regarding the funding IC. (b) (5)

I am also uncertain about whether OSP regularly shares all of these incident reports with the IC (do you know if the POs are ever notified?). My understanding from the email correspondence is that in the case of the April 2020 UNC incident, Erik only knew about the report because the PI shared it with him and had told him that it had already been reported to NIH.

I wanted to raise a possible concern (b) (5)

(b) (5)

(b) (5)

, but I did want to bring it to your attention.

Best wishes,

Matthew

From: Bateman, Karen (NIH/NIAID) [E] (b) (6)
Sent: Friday, August 21, 2020 1:17 PM
To: Linde, Emily (NIH/NIAID) [E] (b) (6); Khurana, Dhana (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Cc: DMID GrantOps (b) (6)
Subject: FW: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC

Importance: High

Dear all,

We wanted to make sure that you are aware of the below inquiry and also note that (b) (5) [redacted]. Please let us know if you would like more information.

--
Thanks,
Karen
DMID GrantOps

From: Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>
Sent: Wednesday, August 19, 2020 12:25 PM
To: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: FW: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC
Importance: High

Hi GrantOps,
Wanted to loop you in on this. I'm going back through my records but thought I'd see if you had any info on this as well. I know there was an incident earlier this year he reported via the U19 (attached) but so far I'm not finding much from 2016.

Erik

From: Powell, Maria (NIH/NIAID) [E] (b) (6) [redacted]
Sent: Wednesday, August 19, 2020 12:08 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6) [redacted]
Cc: Wurster, Andrea (NIH/NIAID) [E] (b) (6) [redacted]
Subject: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC

Hello Erik-

I am reaching out to ask for your help verifying information for Dr. Fenton and the NIH Deputy Director of Extramural Research about a February 2016 lab safety incident at UNC (see attachment 1).

ACTION REQUESTED
Was this February 2016 incident reported to NIAID and, if so, for which grant was this incident report filed? Please reply to me by COB today (8/19/2020).

BACKGROUND
OER has asked DEA and OERPO to determine whether UNC followed proper procedures with respect to reporting biosafety incidents. OERPO was unable to locate incident report memos in the grants folders for these awards: U19AI109761; U19AI107810; R01AI085524; F32AI102561; R01AI110964. The first four of these awards were acknowledged in attachment 2. However, we understand that the incident memo may not have been uploaded to the grants folder or the incident may be from another award.

I know that you are incredibly busy with COVID right now. OERPO appreciates your help with this timely information request. Please let me know if you have any questions or concerns.

Regards,

Maria Powell, Ph.D., FAC-COR III
Supervisory Biodefense Health Scientist
Office of Extramural Research Policy and Operations (OERPO)
Division of Extramural Activities (DEA), NIAID
National Institutes of Health (NIH)
5601 Fishers Lane 4G22
Rockville, MD 20852
Office: (b) (6)
Work Cell: (b) (6)
(b) (6)

From: Brown, Liliana (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Mathur, Punam (NIH/NIAID) [E]
Subject: Re: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC
Date: Wednesday, August 19, 2020 3:36:57 PM

Thanks, Punam.

Sent from my iPhone

> On Aug 19, 2020, at 3:00 PM, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:
>
> Thank you Punam!
>
> **From:** Mathur, Punam (NIH/NIAID) [E] (b) (6)
> **Sent:** Wednesday, August 19, 2020 2:58 PM
> **To:** Stemmy, Erik (NIH/NIAID) [E] (b) (6); Brown, Liliana (NIH/NIAID) [E] (b) (6)
> **Subject:** RE: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC
>
> Hi Erik and Liliana,
>
> I have looked through my records and have not found anything either. I have attached the Type 5 for the reporting period: 06/01/2015 - 05/31/2016 (Year 3) of the ORFEOME Functional Genomics U19 (AI 107810).
> The second U19 mentioned (AI109761) was a CETR Cooperative Agreement/ PI: Ian Lipkin, so perhaps you might want to reach out to OBRRTR (Mike Schaefer/Maureen Beanan/Tina Parker)?
>
> Let me know if you need further help.
>
> Punam
>
> **From:** Stemmy, Erik (NIH/NIAID) [E] (b) (6)
> **Sent:** Wednesday, August 19, 2020 1:17 PM
> **To:** Brown, Liliana (NIH/NIAID) [E] (b) (6)
> **Cc:** Mathur, Punam (NIH/NIAID) [E] (b) (6)
> **Subject:** Re: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC
>
> Thank you! I've not found anything in my records.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
Email: (b) (6)

On Aug 19, 2020, at 1:16 PM, Brown, Liliana (NIH/NIAID) [E] (b) (6) wrote:

Yes, everything should be in our shared folders. I am copying Punam since she must have access and past knowledge as well. I can respond later in the day.

Sent from my iPhone

On Aug 19, 2020, at 12:35 PM, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

Hi Liliana,
I got the message below from DEA and wanted to loop you in (already sent to GrantOps). I think the U19s I think were in OGAT. Would you happen to have access to any records from 2016 about any biosafety incidents at UNC?

Erik

From: Powell, Maria (NIH/NIAID) [E]
(b) (6)
Sent: Wednesday, August 19, 2020 12:08 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Wurster, Andrea (NIH/NIAID) [E]
(b) (6)
Subject: PO Response Needed (by COB today 8/19/2020)--Biosafety at UNC

Hello Erik-

I am reaching out to ask for your help verifying information for Dr. Fenton and the NIH Deputy Director of Extramural Research about a February 2016 lab safety incident at UNC (see attachment 1).

ACTION REQUESTED
Was this February 2016 incident reported to NIAID and, if so, for which grant was this incident report filed? Please reply to me by COB today (8/19/2020).

BACKGROUND
OER has asked DEA and OERPO to determine whether UNC followed proper procedures with respect to reporting biosafety incidents. OERPO was unable to locate incident report memos in the grants folders for these awards: U19AI109761; U19AI107810; R01AI085524; F32AI102561; R01AI110964. The first four of these awards were acknowledged in attachment 2. However, we understand that the incident memo may not have been uploaded to the grants folder or the incident may be from another award.

I know that you are incredibly busy with COVID right now. OERPO appreciates your help with this timely information request. Please let me know if you have any questions or concerns.

Regards,

Maria Powell, Ph.D., FAC-COR III
Supervisory Biodefense Health Scientist
Office of Extramural Research Policy and Operations (OERPO)
Division of Extramural Activities (DEA), NIAID
National Institutes of Health (NIH)
5601 Fishers Lane 4G22
Rockville, MD 20852
Office: (b) (6)
Work Cell: (b) (6)
(b) (6)

<Near Misses at UNC Chapel Hill's High-Security Lab Illustrate Risk of Accidents With Coronaviruses — ProPublica.pdf>
<Nature Medicine UNC SARS 2015 nm.3985.pdf>

From: Lauer, Michael (NIH/OD) [E]
To: Matthew R.Torsiello
Cc: Linde, Emily (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Andrew N. Krinsky; Nels T. Lippert; Black, Jodi (NIH/OD) [E]; Erbelding, Emily (NIH/NIAID) [E]; Bulls, Michelle G. (NIH/OD) [E]; Peter Daszak; Aleksei Chmura; Lauer, Michael (NIH/OD) [E]
Subject: Re: EcoHealth Alliance re Suspension of NIH Grant No. 2R01 AI 110964-6
Date: Friday, August 14, 2020 5:17:14 AM
Attachments: image001.png
EcoHealth Alliance - Letter to NIH re Grant Suspension 8-13-2020 (with Exhibits)[2].pdf

Dear Mr. Torsiello – letter received.

Thank you, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: "Matthew R.Torsiello" (b) (6)
Date: Thursday, August 13, 2020 at 5:54 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: "Linde, Emily (NIH/NIAID) [E]" (b) (6), "Stemmy, Erik (NIH/NIAID) [E]" (b) (6), "Andrew N. Krinsky" (b) (6), "Nels T. Lippert" (b) (6), "Black, Jodi (NIH/OD) [E]" (b) (6), "Erbelding, Emily (NIH/NIAID) [E]" (b) (6), "Bulls, Michelle G. (NIH/OD) [E]" (b) (6), Peter Daszak (b) (6), Aleksei Chmura (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6)
Subject: EcoHealth Alliance re Suspension of NIH Grant No. 2R01 AI 110964-6

Dr. Lauer:

Please see the attached letter from Andrew Krinsky on behalf of EcoHealth Alliance, Inc., regarding the decision by NIH to suspend NIH Research Grant 2R01 AI 110964-6 on or about July 8, 2020.

Please confirm receipt. Thank you.


via FOIA by Judicial W
Tarter
Krinsky
&Drogin

Tarter Krinsky & Drogin LLP
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P 212.216.8000
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Andrew N. Krinsky, *Partner*
(b) (6), *Direct Dial*
(b) (6)

August 13, 2020

Via Email, Certified Mail, & FedEx
(b) (6)

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
National Institutes of Health
National Institute of Allergy and Infectious Diseases
1 Center Drive, Building 1, Room 144
Bethesda, Maryland 20892

Re: Suspension of NIH Grant 2R01 AI 110964-6

Dear Dr. Lauer:

This firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance"), in connection with the post-award decision by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institute of Health ("NIH"), under the Department of Health and Human Services ("HHS"), on July 8, 2020, to suspend grant 2R01 AI 110964-6 (the "Suspension:"), which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project").

This letter constitutes EcoHealth Alliance's initial response to the Suspension, which was due to purported concerns regarding the safety of unspecified research being conducted at the Wuhan Institute of Virology ("WIV") and for EcoHealth Alliance's alleged failure to report certain subawards in connection with grant 2R01 AI 110964-6 (the "Grant").[1] As set forth in more detail below, the Suspension is unjustified as WIV has no connection to the Project or EcoHealth Alliance's current research and EcoHealth Alliance had not issued any subawards in connection with the Grant at the time of the Suspension. Moreover, NIAID is not authorized under 45 CFR §§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates.[2] Accordingly, EcoHealth Alliance hereby demands that the Suspension be withdrawn and all funding in the HHS Payment Management System be released immediately.

BACKGROUND

A. EcoHealth Alliance

EcoHealth Alliance is a prolific New York-based nonprofit institution dedicated to protecting the health of people, animals, and the environment from emerging zoonotic diseases. For more than a decade, EcoHealth Alliance has been conducting cutting edge scientific research

[1] A copy of my prior letter, dated May 22, 2020, regarding NIH's termination of the Grant, is attached hereto as Exhibit 1.
[2] Notwithstanding NIH's lack of authority to impose extraneous conditions on the Grant and Project, EcoHealth Alliance has made a good faith effort to respond to NIH's questions regarding WIV.

to identify hundreds of new coronaviruses ("CoVs") in bats and to study the capacity of these viruses to infect human cells. The purpose of this research is to identify high risk populations so international actors can leverage their resources to address potential pandemics. In cooperation with a global network of over seventy partners, including academic institutions, intergovernmental and governmental agencies, infectious disease surveillance laboratories, and other international and national organizations in over thirty countries, EcoHealth Alliance's work has led to numerous scientific papers published in high impact journals. These publications have been critical in raising awareness of the threat that CoVs pose to global health, the global economy, and U.S. National Security.

EcoHealth Alliance has a long history of successful cooperation with NIH including multiple Research Project Grant R01 awards. In particular, Peter Daszak, EcoHealth Alliance's President and Chief Scientist, has been the Principal Investigator on more than five multidisciplinary R01s. As demonstrated by Dr. Daszak's research, which produced the first ever global emerging disease "hotspots" map that identified locations in the world where viruses with pandemic potential are most likely to emerge, EcoHealth Alliance is uniquely qualified to assist in both identifying the origins of severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2") and developing and implementing strategies to combat coronavirus disease 2019 ("COVID-19").

Significantly, at this time, EcoHealth Alliance is working with several countries including, *inter alia*, Bangladesh, Côte d'Ivoire, Indonesia, Liberia, Malaysia, Republic of Congo, and Thailand to distribute PPE and provide critical reagents to test for and contain COVID-19. Notably, this effort is being supported by both the United States Department of State and the United States Agency for International Development. EcoHealth Alliance is also assisting the U.S. Geological Survey, the U.S. Fish & Wildlife Service, the International Union for Conservation of Nature, the World Health Organization, the World Organization for Animal Health, and the World Bank Group to place the COVID-19 pandemic in historical context, assess the risk of COVID-19 resurgence and spillover impacts, and determine best practices and cost-effective solutions to combat the virus. In sum, EcoHealth Alliance's research agenda is more consequential than ever.

B. NIH Issues EcoHealth Alliance A Five-Year Research Grant To Continue The Project

NIH issued EcoHealth Alliance an initial five-year research award for the Project in 2014. In 2019, EcoHealth Alliance submitted a renewal application to NIH through NIAID that contained a revised scope of work, research goals, and proposed collaborators and sought to extend the Project for an additional five years. Upon filing of its renewal application, the Project was ranked as an "extremely high priority" (in the top 3%) by NIAID during its external review process. In light of its success, the absence of any allegation that EcoHealth Alliance had violated the terms and conditions of its prior awards, and the importance of EcoHealth Alliance's continued research, on July 24, 2019, NIH reauthorized grant R01 AI 110964 and issued EcoHealth Alliance a notice of award in the amount of $733,750.00 funded under grant 2R01 AI 110964-6.[3]

[3] A copy of the notice of award, dated July 24, 2019, is attached hereto as Exhibit 1-A.

C. EcoHealth Alliance Informs HHS That WIV Is Not A Subrecipient Of Grant Funds And Agrees Not To Collaborate With WIV In Connection With The Project

On April 19, 2020, Michael S. Lauer, MD, NIH Deputy Director for Extramural Research, sent a letter to EcoHealth Alliance on behalf of NIH regarding WIV. The letter stated that, given allegations that COVID-19 "was precipitated by the release from WIV of the coronavirus responsible for COVID-19", NIH was pursuing suspension of WIV from participating in Federal programs. However, Dr. Lauer assured EcoHealth Alliance that "[t]his suspension of the sub-recipient does not affect the remainder of [EcoHealth Alliance's] grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension." [4]

On April 21, 2020, Dr. Daszak of EcoHealth Alliance responded by email to Dr. Lauer stating that he could "categorically state that no funds from [sic] 2R01 AI 110964-6 have been sent to Wuhan Institute of Virology, nor has any contract been signed." Dr. Daszak further represented that EcoHealth Alliance would comply with all NIAID requirements. Dr. Lauer acknowledged (1) that no monies from grant 2R01 AI 110964-6 had gone to WIV and no contract between EcoHealth Alliance and WIV had been signed and (2) EcoHealth Alliance's agreement that it would not provide any funds to WIV until and unless directed otherwise by NIH.[5]

D. NIH Unlawfully Terminates The Grant "For Convenience"

Notwithstanding NIH's representation that suspension of WIV would not affect EcoHealth Alliance's ongoing research, the Grant, or the Project, on April 24, 2020, NIH notified EcoHealth Alliance by letter that, effective immediately, the Grant and Project had been terminated (the "Termination"). The purported grounds for the Termination were: (1) convenience; (2) NIH's discretion not to award a grant, or to award a grant at a particular funding level; and (3) NIH's belief that the Project outcomes did not align with the program goals and agency priorities.[6] As a result of the Termination, EcoHealth Alliance was notified by HHS that it was required to submit a Final Research Performance Progress Report for the Project.

E. EcoHealth Alliance Files A First-Level Appeal Of The Termination

On May 22, 2020, by letter, EcoHealth Alliance filed a first-level appeal of the Termination on NIH, pursuant to NIH Grants Policy Statement Section 8.7 and 42 CFR 50, Subpart D (the "Appeal"). (Ex. 1). In its Appeal, EcoHealth Alliance argued, *inter alia*, that: (1) NIH research grants are not subject to termination for convenience; (2) NIH's discretion to award a grant at a particular funding level did not authorize NIH to issue a post-award decision to terminate a duly awarded grant during the budget period; (3) the research goals of the Project and the NIAID are substantially identical; and (4) there was no rational basis to terminate the Grant for cause.

---

[4] A copy of the NIAID's letter regarding WIV, dated April 19, 2020, is attached hereto as Exhibit 1-B.
[5] A copy of the email correspondence between NIH and EcoHealth Alliance is attached hereto as Exhibit 1-C.
[6] A copy of the NIAID's letter regarding the Termination, dated April 24, 2020, is attached hereto as Exhibit 1-D.

F. NIAID Withdraws The Termination But Suspends The Grant Due To Alleged Safety Concerns At WIV And For EcoHealth's Purported Failure To Report Subawards

Lacking a rational basis for its decision to terminate the Grant, on July 8, 2020, Dr. Lauer notified EcoHealth Alliance by letter that NIAID had withdrawn its termination of the Grant supporting the Project.[7] However, citing "bio-safety concerns" at WIV and EcoHealth Alliance's purported failure to report unspecified subawards, NIAID proceeded to immediately suspend the Grant and the Project, pursuant to 45 CFR § 75.371 and NIH Grants Policy Statement Section 8.5.2, leaving the status of the Project effectively unchanged. In addition, the Suspension seeks to impose on EcoHealth Alliance the outrageous obligation to provide NIH with information and materials in the custody and control of WIV and to somehow facilitate access by an USFG "inspection team" to WIV, as a condition for lifting the Suspension.[8]

ARGUMENT

In the Suspension, NIAID identifies two and only two grounds for its decision to suspend the Grant and the Project: (1) purported safety concerns regarding WIV; and (2) EcoHealth Alliance's purported failure to report unspecified subawards. As set forth in detail herein, EcoHealth Alliance is not conducting any research or otherwise collaborating with WIV in connection with the Project. Moreover, EcoHealth Alliance had not issued any subawards in connection with the Grant at the time of the Suspension. Accordingly, the Suspension should be withdrawn immediately.[9]

A. NIH's Purported Concern That WIV Poses A Threat To Public Health And Welfare Is Not A Basis To Suspend The Grant Or The Project As WIV Is Not A Current Subrecipient Of Grant Funds And Has No Connection To The Project

Under 45 CFR §§ 75.207, 75.205, and 75.371 and NIH Grants Policy Statement Section 8.5.2, NIAID may take one or more enforcement actions where a grant recipient has failed to materially comply with the terms and conditions of the award. Under 45 CFR 75.374, the HHS awarding agency must provide the non-Federal entity an opportunity to object and provide information challenging any suspension or termination action. Given the exclusion of WIV from the Project, and NIH's failure to identify any other safety concerns, there is no basis for NIAID to suspend the Grant or to impose additional conditions.

At all relevant times, EcoHealth Alliance has duly monitored the activities of its subrecipients as necessary to ensure that any subawards were used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward. Moreover, EcoHealth Alliance is not aware of any allegation that any subrecipient of grant 1R01 AI 110964 funds has ever used such funds for unauthorized purposes, or in violation of any Federal

[7] Please confirm that, due to the withdrawal of the Termination, EcoHealth Alliance is not required to submit a final Project report at this time.
[8] A copy of the NIAID's letter regarding the Suspension, dated July 8, 2020, is attached hereto as Exhibit 2.
[9] EcoHealth Alliance notes that the Suspension did not state any specific deadline for EcoHealth Alliance to respond to the Suspension or proposed additional conditions. Accordingly, this response is timely.

statutes, regulations, or the terms and conditions of the subject subaward. Furthermore, NIH has never accused EcoHealth Alliance of any act that posed a risk to public welfare and safety.

Significantly, WIV is the only organization identified in the Suspension as posing a risk to public welfare and safety. As stated in my prior letter on May 22, 2020, regarding the now admittedly unlawful termination of the Grant, at NIH's express request, no Grant funds have been distributed to WIV and no contract has been signed between EcoHealth Alliance and WIV in connection with the Project. Thus, the allegation that WIV's independent research at its facility poses unspecified bio-safety concerns should have no bearing on the Project, which was in strict compliance with NIH Grants Policy Statement §§ 4 and 4.1.24, and the terms and conditions of the Notice of Award (Ex. 1-A), at the time of the Suspension.

To reiterate, WIV is not a subrecipient of any Grant funds and will not be involved in the Project in any capacity. (*see* Ex. 1-C-7). Significantly, NIAID explicitly told EcoHealth Alliance that it could exclude WIV and continue the Project without jeopardizing the Grant so long as "no grant funds [were] provided to WIV." (Ex. 1-B).

B. EcoHealth Alliance Has Duly Reported All Issued Subawards And Was In Compliance With The Transparency Act At The Time Of The Suspension

Contrary to NIAID's assertion that EcoHealth Alliance failed to report unspecified subawards, EcoHealth Alliance did not issue or sign any subawards in connection with the 2019 Grant or before July 8, 2020. Accordingly, the reporting requirements of the Federal Funding Accountability and Transparency Act (the "FFATA") did not apply at the time of the Suspension.

Regarding the Project period between 2014 and 2019, EcoHealth Alliance duly complied with all NIAID-system-only financial reporting requirements. While EcoHealth Alliance had not entered the FFATA reporting information in the Federal Subaward Reporting System ("the FSRS"), all subawards issued in connection with the 2014 Project and the 2019 Project are now fully reported in the FSRS. Notably, no one at NIAID or NIH ever contacted or otherwise notified EcoHealth Alliance that it was not in compliance. As EcoHealth Alliance has taken appropriate corrective action that fully resolves its alleged non-compliance with the FFATA, pursuant to NIH Grants Policy Statement Section 8.5.2, the Suspension should be withdrawn.

C. HHS Has No Authority To Impose New Conditions That Are Wholly Unrelated To The Project And EcoHealth Alliance's Ongoing Research

Under 45 CFR § 75.207, NIAID may impose additional specific award conditions under the following circumstances: when the applicant or recipient has a history of failure to comply with the general or specific terms and conditions of a Federal award; when an applicant or recipients fails to meet expected performance goals; and when an applicant or recipient is not otherwise responsible. Allowed conditions include: (1) requiring payments as reimbursements rather than advance payments; (2) withholding authority to proceed to the next phase until receipt of evidence of acceptable performance within a given period of performance; (3) requiring additional, more detailed financial reports; (4) requiring additional project monitoring (5) requiring the non-Federal entity to obtain technical or management assistance; or (6) establishing additional

prior approvals. (45 CFR § 75.207[b]). The purpose of these additional conditions are to encourage the award recipients to comply with the original terms and conditions of the award, applicable statutes, and regulations.

There is no statute or NIH Grants Policy Statement provision that authorizes NIAID to impose additional conditions that consist of demands for information and materials regarding entities that are neither current subrecipients of grant funds nor connected to the research project funded by the subject grant. This makes sense, given that the purpose of imposing additional conditions is to ensure that research funded under a particular grant is conducted safely and in compliance with applicable laws.

Here, NIH's First, Second, Third, Fourth, Fifth, and Sixth proposed conditions, which require that EcoHealth Alliance, *inter alia*, provide information and materials regarding WIV, are wholly unrelated to the safety and efficacy of Project and EcoHealth Alliance's ongoing research as WIV is not a subrecipient of Grant funds (*see* Ex. 1-C-6, 7 and 8). Moreover, certain conditions, including the Sixth condition that "EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019" seek to impose impossible obligations. EcoHealth Alliance has no authority to grant NIAID access to the WIV lab facilities and is not conducting any research with WIV in connection with the Project. Whether or not EcoHealth Alliance is able to provide responses to the proposed conditions regarding WIV will not affect the safety of EcoHealth Alliance's current research, which will not involve WIV.

Without waiving any objections, in the interest of cooperation, EcoHealth Alliance has made a good faith effort to provide responses to the additional conditions (the "Requests") based on information now known to Peter Daszak, EcoHealth Alliance's President and Chief Scientist.[10]

CONCLUSION

Every single outbreak of a novel virus has been accompanied by the allegation that the subject virus was created in a lab, including, *inter alia*, HIV, Ebola, and now SARS-CoV-2. There is no credible evidence to support these theories. By comparison, we know that seventy-five percent of new emerging diseases originate in wildlife. Every species of wildlife carry these viruses, an estimated 1.7 million of which are still unknown. While many of these viruses are benign, occasionally a lethal virus will emerge that can directly infect humans. EcoHealth Alliance is a valuable resource. The instant request to resume the Project funded by the Grant presents HHS with the opportunity to support proven research regarding the threat of zoonotic disease emergence and to support scientists who are working to determine whether certain vaccines and drugs can kill the SARS-CoV-2 virus to save our lives.

At this time, EcoHealth Alliance is in compliance with all of the terms and conditions of the award including the FFATA, there is no public health concern posed by EcoHealth Alliance's

[10] A copy of EcoHealth Alliance's Objections and Responses to the Requests is attached hereto as Exhibit 3.

resumption of the Project, which will not involve WIV in any capacity (*see* NIH Grants Policy Sections 4 and 4.1.24), and EcoHealth Alliance has hereby provided, to the best of its ability, the information and materials requested by NIH in the Suspension. Accordingly, the Suspension should be withdrawn and all funding in the HHS Payment Management System should be released immediately.

Please note that this letter is not intended to provide an exhaustive list of all possible grounds for vacating the Suspension and may not reflect all arguments and claims that EcoHealth Alliance will assert in the event that it is required to file a first-level appeal or other action or proceeding concerning any future adverse determination by NIAID affecting the Grant or the Project. All of EcoHealth Alliance's rights and remedies to seek review of any adverse determination are expressly reserved.

Should you wish to present evidence in an effort to refute any of the factual assertions made in this letter, and/or to engage in good faith negotiations regarding appropriate terms and conditions for the resumption of funding for grant 2R01 AI 110964-6, we are prepared to review such evidence and to participate in such negotiations.

We await your response to this letter.

Very truly yours,

(b) (6)

Andrew N. Krinsky

cc: (*by email*)

Dr. Erik Stemmy (b) (6)
Ms. Emily Linde (b) (6)

Exhibit 1

Tarter Krinsky & Drogin LLP
1350 Broadway
New York, NY 10018
P 212.216.8000
F 212.216.8001
www.tarterkrinsky.com

Andrew N. Krinsky, *Partner*
212-216-8080, *Direct Dial*
akrinsky@tarterkrinsky.com

May 22, 2020

Via Email, Certified Mail, & FedEx
(b) (6)

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
National Institutes of Health
National Institute of Allergy and Infectious Diseases
1 Center Drive, Building 1, Room 144
Bethesda, Maryland 20892

Re: Termination of NIH Grant 2R01 AI 110964-6

Dear Dr. Lauer:

This firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance") with regard to the post-award decision by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institute of Health ("NIH"), under the Department of Health and Human Services ("HHS"), to terminate the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964, on April 24, 2020 (the "Termination").

This letter, pursuant to NIH Grants Policy Statement Section 8.7 and 42 CFR 50, Subpart D, constitutes EcoHealth Alliance's first-level appeal of the Termination, which was "for convenience." As set forth in more detail below, the Termination is not authorized under the NIH Grants Policy Statement, arbitrary and capricious and an indefensible attack on public health and welfare given that it undermines a pivotal 10-year research project involving the origins, spread and threat of emerging bat coronaviruses during the peak of an unprecedented worldwide coronavirus pandemic. Accordingly, EcoHealth Alliance hereby demands that grant 2R01 AI 110964-6 be reinstated immediately.

BACKGROUND

A. EcoHealth Alliance

EcoHealth Alliance is a prominent New York-based nonprofit institution dedicated to protecting the health of people, animals, and the environment from emerging zoonotic diseases. For more than a decade, EcoHealth Alliance has been conducting cutting edge scientific research to identify hundreds of new coronaviruses ("CoVs") in bats and to study the capacity of these viruses to infect human cells. The purpose of this research is to identify high risk populations so international actors can leverage their resources to address potential pandemics. In cooperation with a global network of over seventy partners, including academic institutions, intergovernmental

and governmental agencies, infectious disease surveillance laboratories, and other international and national organizations in over thirty countries, EcoHealth Alliance's work has led to numerous scientific papers published in high impact journals. These publications have been critical in raising awareness of the threat that CoVs pose to global health, the global economy, and U.S. National Security.

EcoHealth Alliance has a long history of successful cooperation with NIH including multiple Research Project Grant R01 awards. In particular, Peter Daszak, EcoHealth Alliance's President and Chief Scientist, has been the Principal Investigator on five multidisciplinary R01s. All of these projects used modeling, epidemiology, laboratory, and field science to test hypotheses on the emergence of wildlife-origin viral zoonoses, including SARS-CoV, the Nipah and Hendra viruses, Avian influenza, and other bat-origin viruses. EcoHealth Alliance, a 501(c)(3) organization, is unique in that it goes one step further by leveraging its research goals to create an alliance of international collaborators that can advocate for real-world changes to protect high risk populations.

Notably, in collaboration with virologists in China, EcoHealth Alliance isolated and characterized SARSr-CoVs from bats that use the same human host cell receptor (ACE2) as SARS-CoV. This work provided critical reagents and resources that have advanced scientific understanding of virus-host binding and contributed to vaccine development. For example, the genetic sequences of the bat viruses that EcoHealth Alliance discovered under its NIH research funding, which were published online (Genbank & GISAID), have been used to test the effectiveness of the drug Remdesivir against not only SARS-CoV, but also MERS, and other potentially zoonotic or pre-pandemic bat CoVs. Significantly, this type of testing can be performed without the need for viral cultures or shipping viruses internationally.

B. NIH Awards And Extends EcoHealth Alliance Research Grant R01 AI 110964

In 2014, NIH issued EcoHealth Alliance a five-year research award for the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964 (the "Project"). EcoHealth Alliance received additional awards for the Project each year between 2015 and 2018. Between 2015 and 2019, the Project resulted in the publication of more than twenty papers.

In 2019, EcoHealth Alliance submitted a renewal application to NIH through NIAID to extend the Project period for an additional five years. Upon filing of its renewal application, the Project was ranked as an "extremely high priority" (in the top 3%) by NIAID during its external review process. In light of its success and the importance of EcoHealth Alliance's work, on July 24, 2019, NIH reauthorized grant R01 AI 110964 and increased EcoHealth Alliance's funding. EcoHealth Alliance was issued a notice of award in the amount of $733,750.00 (the "2019 Award"). The notice of award also extended the Project period for an additional five years to 2024. A copy of the notice of award is attached hereto as Exhibit A.

C. EcoHealth Alliance Agrees Not To Fund The Wuhan Institute Of Virology

During the pendency of the Project, in December of 2019, China reported a cluster of cases of pneumonia in Wuhan, Hubei Province. It was later determined that the cause of this pneumonia

was a novel CoV, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causing coronavirus disease (COVID-19). Thereafter, SARS-CoV-2 spread to nearly every country throughout the world. In response, EcoHealth Alliance has prioritized its efforts in conducting research that will be integral to developing an effective strategy to combat SARS-CoV-2.

On April 19, 2020, Michael S. Lauer, MD, NIH Deputy Director for Extramural Research, sent a letter to EcoHealth Alliance on behalf of NIH regarding a laboratory in China, the Wuhan Institute of Virology ("WIV"). WIV was a prior sub-recipient of a small portion of the R01 AI 110964 grant funds. The letter stated that, given allegations that COVID-19 "was precipitated by the release from WIV of the coronavirus responsible for COVID-19", NIH was pursuing suspension of WIV from participating in Federal programs. However, Mr. Lauer assured EcoHealth Alliance that "[t]his suspension of the sub-recipient does not affect the remainder of [EcoHealth Alliance's] grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension." A copy of the letter is attached hereto as Exhibit B.

On April 21, 2020, Dr. Daszak of EcoHealth Alliance responded by email to Dr. Lauer stating that he could "categorically state that no funds from [sic] 2R01 AI 110964-6 have been sent to Wuhan Institute of Virology, nor has any contract been signed." Dr. Daszak further represented that EcoHealth Alliance would comply with all NIAID requirements. Dr. Lauer acknowledged (1) that no monies from grant 2R01 AI 110964-6 had gone to WIV and no contract between EcoHealth Alliance and WIV had been signed and (2) EcoHealth Alliance's agreement that it would not provide any funds to WIV until and unless directed otherwise by NIH. A copy of the email correspondence between NIH and EcoHealth Alliance is attached hereto as Exhibit C.

D. NIH Abruptly Terminates Research Grant 2R01 AI 110964-6 "For Convenience"

Notwithstanding NIH's representation that suspension of WIV would not affect the remainder of EcoHealth Alliance's 2019 Award, on April 24, 2020, NIH notified EcoHealth Alliance by letter that, effective immediately, the 2019 Award had been terminated by NIAID. The stated grounds for the Termination were: (1) convenience; (2) NIH's discretion not to award a grant, or to award a grant at a particular funding level; and (3) NIH's belief that the Project outcomes did not align with the program goals and agency priorities. A copy of the Termination is attached hereto as Exhibit D.

ARGUMENT

A. NIH Research Grants Are Not Subject To Termination For Convenience

"Termination for convenience" refers to the exercise of the government's right to bring to an end the performance of all or part of the work provided for under a contract prior to the expiration of the contract "when it is in the Government's interest" to do so. Federal agencies typically incorporate clauses in their procurement contracts which give them the right to terminate for convenience. Here, there is no clause in the terms and conditions applicable to the 2019 Award, or in the NIH Grants Policy Statement, that permits NIAID or NIH to issue a post-award decision to terminate a NIH research grant award "for convenience."

Moreover, the unprecedented assertion by NIH that active research grants can be terminated "for convenience" during the subject budget period renders Section 8.5.2 of the NIH Grants Policy Statement meaningless. *See, e.g., Li v. Eddy*, 324 F.3d 1109, 1110 (9th Cir. 2003) (rejecting suggested statutory interpretation on the grounds that the interpretation ran squarely against the canon of construction that courts interpret statutes so as not to render any section meaningless). Section 8.5.2 of the NIH Grants Policy Statement governs, *inter alia*, modification or termination of an award for misconduct. If NIH grants were terminable for convenience, NIH could always choose to terminate for convenience to avoid (1) the "for cause" restriction on grant terminations and (2) the labor intensive task of enforcing compliance through disallowing costs, withholding further awards, or wholly suspending the grant, pending corrective action.

B. NIH's Discretion Not To Award A Grant, Or To Award a Grant At A Particular Funding Level, Does Not Authorize A Post-Award Decision To Terminate

NIH's discretion regarding the "decision not to award a grant, or to award a grant at a particular funding level" does not give NIH the authority to issue a post-award decision terminating a duly awarded grant during the budget period. This purported discretion, which is based on language in the last paragraph of NIH Grants Policy Statement Section 2.4.4, entitled *Disposition of Applications*, concerns NIH's authority to reject incomplete or otherwise undesirable grant applications in the first instance only. The provisions of Section 2, generally, have no bearing on post-award decisions affecting duly approved grants for which specified funds have already been allocated. As the 2019 Grant in the amount of $733,750.00 was awarded to EcoHealth Alliance on July 24, 2019, NIH's authority to deny initial grant applications does not allow NIH to terminate the 2019 Grant.

C. The Research Goals Of EcoHealth Alliance And NIAID Are Virtually Identical

NIH's contention that the Project's outcomes do not align with the agency's priorities is demonstrably false. First, the Project was ranked as "extremely high priority" on external review by NIAID less than nine months ago, before the discovery of SARS-CoV-2. Since this discovery, NIH has promulgated new grants seeking applicants to conduct research on the same issues covered by the Project and the 2019 Award.

In addition, there is substantial overlap between the four strategic research priorities on page 1 of NIAID's Strategic Plan for COVID-19 Research, published April 22, 2020, and the three Specific Aims of the Project. Both NIAID and EcoHealth Alliance seek to: (1) improve fundamental knowledge of SARS-Cov-2; (2) develop methods to assess the rate of infection and disease incidence; (3) contribute to the development of an effective vaccine; and (4) increase public health preparedness. Copies of the Project's Specific Aims and the NIAID Strategic Plan's four strategic research priorities for COVID-19 research are attached hereto as Exhibit E.

D. There Is No Rational Basis To Terminate The 2019 Award For Cause

The grounds and procedures for suspension and termination of awards are specified in NIH Grants Policy Statement Section 8.5.2 and 45 CFR Parts 75.371 through 75.373. Notably, Section

8.5.2 provides, *inter alia*, that NIH will generally suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. Through this lens, 45 CFR 75.372 provides that NIH may terminate a Federal award, in whole or in part, if: (1) the non-Federal entity fails to comply with the terms and conditions of the award; (2) for cause; (3) by the HHS awarding agency or pass-through entity with the consent of the non-Federal entity; or (4) by the non-Federal entity upon written notice to the HHS awarding agency setting forth the reasons for such termination, and other information. None of the foregoing predicate conditions exist here.

As of the date of the Termination, EcoHealth Alliance had not received any notice from NIH, NIAID, or HHS that it either failed to comply with any of the terms or conditions of the 2019 Award, or committed any misconduct in connection with the award. To the contrary, in email correspondence following EcoHealth Alliance's representation that it had not and would not give any funds from the 2019 Award to WIV, Aleksei Chmura, EcoHealth Alliance's Chief of Staff, memorialized the mutual agreement between NIH and EcoHealth Alliance that EcoHealth Alliance was in compliance with all requests. (Ex. C, p. 1). To be clear, EcoHealth Alliance clearly and unequivocally stated that it had not and will not distribute any funds from the 2019 Award to WIV.

In sum, there is no statutory, regulatory, or contractual basis for NIAID's termination of the Project, *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01 AI 110964-6. However, please note that this letter is not intended to provide an exhaustive list of all possible grounds for reversal of the Termination and may not reflect all arguments and claims that EcoHealth Alliance will assert in the event that a formal second-level appeal of the Termination is required.

Should you wish to present evidence in an effort to refute any of the factual assertions made in this letter and/or to engage in good faith negotiations regarding appropriate terms and conditions for the resumption of funding for grant 2R01 AI 110964-6, we are prepared to review such evidence and to participate in such negotiations.

We await your response to this letter.

Very truly yours,

(b) (6)

Andrew W. Krinsky

cc: (*by email*)

Dr. Erik Stemmy (b) (6)
Ms. Emily Linde (b) (6)

Exhibit A

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 07/24/2019

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 2R01AI110964-06
FAIN: R01AI110964

Principal Investigator(s):
PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Dr. Daszak, Peter
PD/PI
460 West 34th Street
Suite 1701
New York, NY 100012320

Award e-mailed to: (b) (6)

Period Of Performance:
Budget Period: 07/24/2019 – 06/30/2020
Project Period: 06/01/2014 – 06/30/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $733,750 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tseday G Girma
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I – AWARD DATA – 2R01AI110964-06

[redacted]

[redacted]

Approved Budget	$733,750
Total Amount of Federal Funds Obligated (Federal Share)	$733,750
TOTAL FEDERAL AWARD AMOUNT	$733,750
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$733,750

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
6	$733,750	$733,750
7	$709,750	$709,750
8	$709,750	$709,750
9	$709,750	$709,750
10	$709,750	$709,750

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1311726494A1
Document Number:	RAI110964B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019	2020	2021	2022	2023
AI	8472364	$733,750	$709,750	$709,750	$709,750	$709,750

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M51C B / **OC**: 414B / **Released**: (b) (6) 07/18/2019
Award Processed: 07/24/2019 12:03:26 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2R01AI110964-06

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 2R01AI110964-06

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

SECTION IV – AI Special Terms and Conditions – 2R01AI110964-06

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

[redacted]

****

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

[redacted]

****

This award reflects current Federal policies regarding Facilities & Administrative (F&A) Costs for foreign grantees including foreign sub-awardees, and domestic awards with foreign sub-awardees. Please see: Chapter 16 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components, Section 16.6 "Allowable and Unallowable Cost" of the NIH Grants Policy.

****

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

****

The budget period anniversary start date for future year(s) will be **July** 1.

****

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the page(s) **203** of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

****

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

****

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

****

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

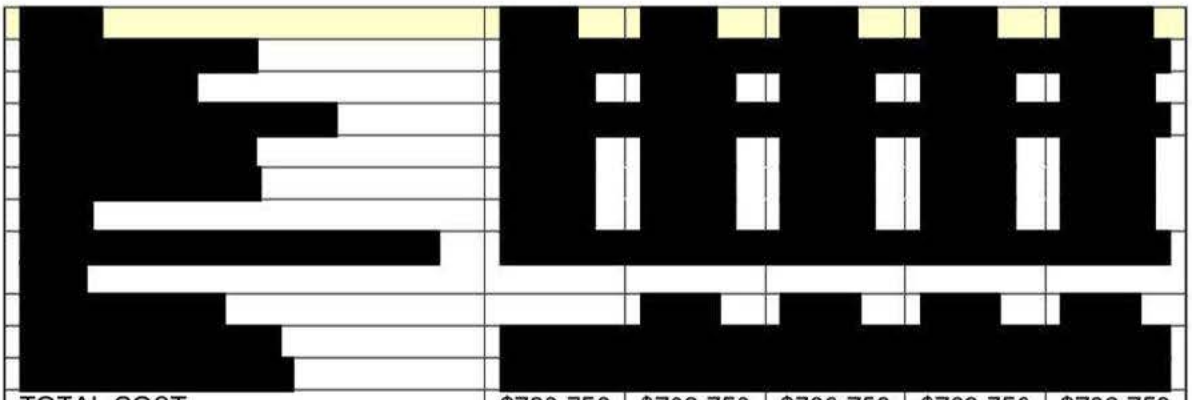
The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Tseday G Girma
Email: (b) (6) **Phone**: (b) (6) **Fax**: 301-493-0597

Program Official: Erik J. Stemmy
Email: (b) (6) **Phone**: (b) (6)

SPREADSHEET SUMMARY
GRANT NUMBER: 2R01AI110964-06

INSTITUTION: ECOHEALTH ALLIANCE, INC.



TOTAL COST	$733,750	$709,750	$709,750	$709,750	$709,750

Facilities and Administrative Costs	Year 6	Year 7	Year 8	Year 9	Year 10
F&A Cost Rate 1	32%	32%	32%	32%	32%
F&A Cost Base 1	$438,711	$363,711	$363,711	$363,711	$363,711
F&A Costs 1	$140,388	$116,388	$116,388	$116,388	$116,388

Exhibit B

Date: April 19, 2020

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.19 10:47:40 -04'00'

To: Kevin Olival, PhD
Vice-President for Research
EcoHealth Alliance
(b) (6)

Naomi Schrag, JD
Vice-President for Research Compliance, Training, and Policy
Columbia University
(b) (6)

Subject: Project Number 2R01AI110964-06

Dear Dr. Olival and Ms. Schrag:

EcoHealth Alliance, Inc. is the recipient, as grantee, of an NIH grant entitled "Understanding the Risk of Bat Coronavirus Emergence." It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ("WIV"). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs.

While we review these allegations during the period of suspension, you are instructed to cease providing any funds from the above noted grant to the WIV. This temporary action is authorized by 45 C.F.R. § 75.371(d) ("Initiate suspension or debarment proceedings as authorized under 2 C.F.R. part 180"). The incorporated OMB provision provides that the funding agency may, through suspension, immediately and temporarily exclude from Federal programs persons who are not presently responsible where "immediate action is necessary to protect the public interest." 2 C.F.R. § 180.700(c). It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.

Exhibit C

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Sunday, April 19, 2020 11:00 AM
To: (b) (6); Naomi Schrag (b) (6)
Cc: Black, Jodi (NIH/OD) [E] (b) (6)
Subject: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Importance: High

Dear Dr. Olival and Ms. Schrag

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Kevin Olival [redacted]
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 20, 2020 at 4:12:28 PM EDT
To: "Lauer, Michael (NIH/OD) [E]" [redacted]
Cc: Naomi Schrag [redacted] "Black, Jodi (NIH/OD) [E]" [redacted]

Dear Mike,

I received the attached letter, however please note:

1. I am not the PI on this award. You should contact Dr. Peter Daszak [redacted] who is the PI and leading this project for EcoHealth Alliance.
2. Columbia University is not involved in this NIH project, and it is not clear to me why Naomi and Columbia University were included.

Thank you,
Kevin

Kevin J. Olival, PhD
Vice President for Research

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

[redacted] (direct)
[redacted] (mobile)
1.212.380.4465 (fax)
www.ecohealthalliance.org

Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Lauer, Michael (NIH/OD) [E] (b) (6)

Mon 4/20/2020 4:31 PM

To: Kevin Olival (b) (6) Peter Daszak (b) (6)

Cc: Naomi Schrag (b) (6); Black, Jodi (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6);

Importance: High

2 attachments

Screen Shot 2020-04-20 at 4.23.38 PM.png; EcoHealth Alliance re AI grant 4 19 20.pdf;

Thank you Kevin

- We need to work with a senior responsible business official – usually PI's and senior business officials are different people.
- When I looked you up on the web, I see the Columbia logo (see attached screenshot). Specifically, it appears to be Columbia University > Ecology, Evolution, and Environmental Biology > EcoHealth Alliance (labeled as an "Affiliation/Department"). Thus the web profile makes it look to me as if EcoHealth Alliance is linked to Columbia University.
- In any case, I'm looping in Dr. Daszak.
- We need to know all sites in China that have been in any way linked to this award (Type 1 and Type 2). We have data in NIH, but we want to make absolutely sure that we're of the same understanding.

We greatly appreciate your prompt attention to this matter.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

4 Michael Lauer email on 20 April 2020

Lauer, Michael (NIH/OD) [E] (b) (6)

Mon 4/20/2020 6:34 PM

To:Naomi Schrag (b) (6); Kevin Olival (b) (6); Peter Daszak (b) (6);

Cc:Black, Jodi (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6);

1 attachment

Screen Shot 2020-04-20 at 4.23.38 PM.png;

Thanks Naomi – not the impression an observer would get looking at the website (see screen shot), but we understand about the grant.

If they "are entirely separate entities" then why does Columbia identify EcoHealth Alliance as an "Affiliation/Department" on its website.

Maybe with the label "Affiliation/Department" you would have a clearly visible disclaimer that says, "EcoHealth Alliance is not affiliated with nor a department of Columbia"? – although even that is internally contradictory.

Best, Mike

From: Naomi Schrag (b) (6)
Date: Monday, April 20, 2020 at 5:19 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6), Kevin Olival (b) (6), (b) (6)
Cc: Naomi Schrag (b) (6), "Black, Jodi (NIH/OD) [E]" (b) (6)
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Dear Dr. Lauer,
Columbia and EcoHealth Alliance are entirely separate entities. Some individuals affiliated with EcoHealth Alliance do have adjunct appointments in Columbia's Ecology, Evolution, and Environmental Biology ("E3B") department, but we are not aware of any Columbia involvement with the referenced grant, and have found no agreement or record in our grants system to the contrary.

We would be happy to answer any additional questions. Thank you.
Sincerely,
Naomi Schrag

Naomi J. Schrag

Vice President for Research Compliance, Training and Policy
Office of Research Compliance and Training
475 Riverside Drive, Suite 840
New York, New York 10115
(b) (6)
www.researchcompliance.columbia.edu

RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

5 Peter Daszak email on 21 April 2020

Peter Daszak

Tue 4/21/2020 1:32 AM

To: Lauer, Michael (NIH/OD) [E] (b) (6); Naomi Schrag (b) (6); Kevin Olival (b) (6)

Cc: Black, Jodi (NIH/OD) [E] (b) (6);

Dear Michael Lauer & Jodi Black – I now have your email and will deal with it directly with you and your staff. Naomi is correct that there is no involvement of Columbia University in this grant. I'm sure NIH has records to confirm that.

From this moment on, I will not cc any staff at Columbia as part of this discussion, and I hope you will also honor that. Respecfully, the discussion of whether or not EHA is an affiliate of CU is entirely irrelevant to the request that you contacted us about, and should remain a private matter between EcoHealth Alliance and Columbia University.

I'll look over your email and respond tomorrow.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

6 Peter Daszak email on 21 April 2020

Peter Daszak

Tue 4/21/2020 7:03 PM

To:Lauer, Michael (NIH/OD) [E] (b) (6);

Cc:Black, Jodi (NIH/OD) [E] (b) (6); Aleksei Chmura (b) (6);
Stemmy, Erik (NIH/NIAID) [E] (b) (6); (b) (6);

Importance: High

1 attachment

EcoHealth Alliance re AI grant 4 19 20.pdf;

Dear Michael – Confirming receipt of your email. I'm also cc'ing the following people so they're aware of this request:

1. Our AOR – Dr. Aleksei Chmura, who has access to all our records
2. My Program Officer for this award, Dr. Erik Stemmy & the Division Director (DMID), Dr. Emily Erberding, so they are informed and aware of the request and our response.

That said we need some time to go through the request for information and will provide this as quickly as we can.

However, **I can categorically state that no funds form 2R01AI110964-06 have been sent to Wuhan Institute of Virology, nor has any contract been signed.** Furthermore, we will comply with NIAID requirements, of course.
Concerning the request for information on all of the sites linked to this award in China, you should be aware that these are documented in our progress reports over the course of the grant. As you can understand we are under enormous pressure to generate data related to the current pandemic, and we do not want to divert staff to this effort. We are hoping the previously filed reports will satisfy this request.

We are well aware of the political concerns over the origins of this outbreak. Our collaboration with Wuhan Institute of Virology has been scientific and we have been consistently impressed with the scientific capabilities of that laboratory and its research staff. Our joint work has led to a series of critical papers published in high impact journals that served to raise awareness of the future threat coronaviruses pose for global health and therefore US national security. Scientific insights with epidemiological significance have been jointly published and our relationship has always been open and transparent and with one concern only, scientific validity. We are concerned that current actions may jeopardize 15 years of fruitful collaboration with colleagues in Wuhan, who are working at the leading edge to design vaccines and drugs that could help us fight this new threat in future years. It is quite remarkable that of the 5 vaccine candidates listed by WHO that are already in human trials, 3 have been developed in China. That said, we of course will

do all we can to make sure any further questions from NIH or any Federal agency are addressed to our fullest knowledge.

Yours sincerely,

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: **Lauer, Michael (NIH/OD) [E]** (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 21, 2020 at 19:28
To: Peter Daszak (b) (6)
Cc: Black, Jodi (NIH/OD) [E] (b) (6), Aleksei Chmura (b) (6), Stemmy, Erik (NIH/NIAID) [E] (b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6)

ML

Many thanks Peter for your response.

We note that:

- No monies have gone to WIV on the Type 2 award and no contract has been signed.
- You agree that you will not provide any funds to WIV until and unless directed otherwise by NIH.
- All foreign sites for the Type 1 and Type 2 awards have been documented in the progress reports submitted to NIH.

We appreciate your working with us.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

8 Aleksei Chmura email on 21 April 2020

From: **Aleksei Chmura** (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 23, 2020 at 13:50
To: Lauer, Michael (NIH/OD) [E] (b) (6)
Cc: Peter Daszak (b) (6), Black, Jodi (NIH/OD) [E] (b) (6), Erik Stemmy (b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6)

(b) (6)

Dear Mike,

I read that we are in agreement and in compliance with all requests. Please let us know if anything further is required. We will continue in our usual close communication with our Program Officer Erik Stemmy.

Sincerely,

-Aleksei

Aleksei Chmura
Chief of Staff &
Authorized Organizational Representative

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

(b) (6) (office)
(b) (6) (mobile)
www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

From: **Lauer, Michael (NIH/OD) [E]** (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 23, 2020 at 13:59
To: Aleksei Chmura (b) (6)
Cc: Peter Daszak (b) (6), Black, Jodi (NIH/OD) [E] (b) (6), Stemmy, Erik (NIH/NIAID) [E] (b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6), Compliance Review (b) (6)

ML

Many thanks Aleksei.

9 Michael Lauer email on 21 April 2020

Best, Mike

From: **Lauer, Michael (NIH/OD) [E]** (b) (6)
Subject: PLEASE READ -- Re: Please read and acknowledge receipt - Actions needed regarding 2R01AI110964-06

Date: April 24, 2020 at 16:47
To: Aleksei Chmura (b) (6), Peter Daszak (b) (6)
Cc: Black, Jodi (NIH/OD) [E] (b) (6), Stemmy, Erik (NIH/NIAID) [E] (b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6), Linde, Emily (NIH/NIAID) [E] lindee@mail.nih.gov, Lauer, Michael (NIH/OD) [E] michael.lauer@nih.gov, Bulls, Michelle G. (NIH/OD) [E] michelle.bulls@nih.gov

ML

Dear Dr. Chmura and Dr. Daszak

Please see attached.

10 Michael Lauer email on 24 April 2020

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: (b) (6)

From: **Aleksei Chmura** (b) (6)
Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 27, 2020 at 23:57
To: Lauer, Michael (NIH/OD) [E] (b) (6)
Cc: Peter Daszak (b) (6), Black, Jodi (NIH/OD) [E] (b) (6), Erik Stemmy (b) (6), Emily Erbelding (b) (6), Linde, Emily (NIH/NIAID) [E] (b) (6), Bulls, Michelle G. (NIH/OD) [E] (b) (6), Alison Andre (b) (6)

(b) (6)

Dear Michael,

Could Peter and I have a quick chat with you sometime tomorrow (Tuesday) about your email, below?

Sincerely,

11 Aleksei Chmura email on 27 April 2020

-Aleksei

Aleksei Chmura, PhD
Chief of Staff

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

Exhibit D

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

24 April 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: Termination of NIH Grant R01 AI 110964

Dear Drs. Chmura and Daszak:

I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS) has elected to terminate the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964, for convenience. This grant project was issued under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284). This grant was funded as a discretionary grant as outlined in the NIH Grants Policy Statement, which states that the decision not to award a grant, or to award a grant at a particular funding level, is at the discretion of the agency, in accordance with NIH's dual review system.

At this time, NIH does not believe that the current project outcomes align with the program goals and agency priorities. NIAID has determined there are no animal and human ethical considerations, as this project is not a clinical trial, but rather an observational study.

As a result of this termination, a total of $369,819.56 will be remitted to NIAID and additional drawdowns will not be supported. The remaining funds have been restricted in the HHS Payment Management System, effective immediately.

Please let me know if you have any questions concerning the information in this letter.

Sincerely,

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.04.24 16:41:16 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

Exhibit E

SPECIFIC AIMS

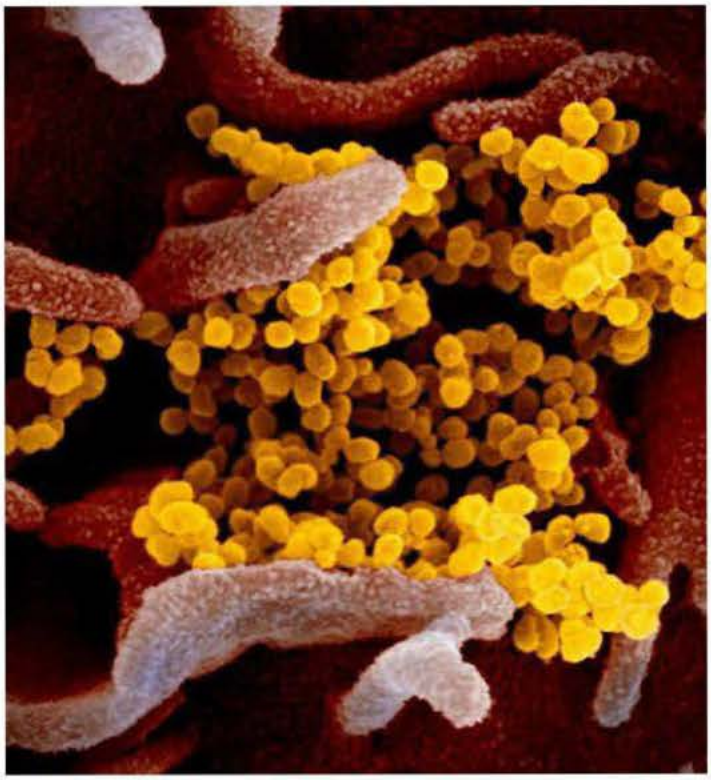
Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) in 2002, and the continuing spread of Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then we have sequenced dozens of novel SARS-related CoV (SARSr-CoV) strains. Our previous R01 work demonstrates that bats in southern China harbor an extraordinary diversity of SARSr-CoVs, some of which are able to use human ACE2 to enter into human cells, can infect humanized mouse models to cause SARS-like illness, and evade available therapies or vaccines. We found that the bat hosts of SARSr-CoVs appear to no longer be traded in wildlife markets, and that people living close to bat habitats are the primary risk groups for spillover. At one of these sites, we found diverse SARSr-CoVs containing every genetic element of the wild-type SARS-CoV genome, and serological evidence of human exposure among people living nearby. Thus, there is significant potential for future spillover of SARSr-CoVs, and of public health impacts. *Yet salient questions remain: Are there specific bat communities and sites that harbor CoV strains with higher risk for bat-to-human spillover? Which human behaviors drive risk of bat SARSr-CoV exposure that could lead to infection? Does human exposure to these viruses cause SARS-like or other illness? Can we characterize viral strain diversity, bat traits and human behaviors to assess risk of potential future CoV spillover?* **The proposed work in this renewal R01 builds on these findings** to address these issues by conducting: **1)** focused sampling of bats in southern China to **identify viral strains with high predicted risk of spillover**; **2)** community-based, and clinic-based syndromic, sampling of people to **identify spillover, and assess behavioral risk factors and evidence of illness**; and **3)** conduct *in vitro* and *in vivo* viral characterization and analyze epidemiological data **to identify hotspots of future CoV spillover risk**. This work will follow 3 specific aims:

Aim 1: Characterize the diversity and distribution of high spillover-risk SARSr-CoVs in bats in southern China. We will conduct targeted bat sampling at sites where we predict that undiscovered high risk SARSr-CoV strains exist. Bat sampling will be targeted geographically and by host species to test predictions about evolutionary diversity of SARSr-CoV. We will analyze RdRp and S protein sequences to test their capacity for spillover to people in Aim 3.

Aim 2: Community- and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences. We will conduct focused, targeted human surveys and sampling to identify key risk factors for SARSr-CoV spillover and evidence of illness. To maximize our opportunity of capturing human exposure to bat CoVs, we will conduct community-based surveillance in regions with high SARSr-CoV prevalence and diversity, and individuals having contact with bats. We will assess bat-CoV seropositive status against a small number of questions about human-wildlife contact and exposure. We will conduct clinic-based syndromic surveillance close to these sites to identify patients presenting with influenza-like illness and severe acute respiratory illness, assess their exposure to bats via a questionnaire, and test samples for PCR- and serological evidence of SARSr-CoV infection. We will conduct follow-up sampling to capture patients who had not yet seroconverted at the time of clinic visit.

Aim 3: *In vitro* and *in vivo* characterization of SARSr-CoV spillover risk, coupled with spatial and phylogenetic analyses to identify the regions and viruses of public health concern. We will characterize the propensity of novel SARSr-CoVs to infect people *in vitro* using primary human airway epithelial cells and *in vivo* using the transgenic hACE2 mouse model. We will use mAb and vaccine treatments to test our hypothesis that SARSr-CoVs with 10-25% divergence in S protein sequences from SARS-CoV are likely able to infect human cells, and to evade mAb therapeutics and vaccines. We will then map the geographic distribution of their bat hosts and other ecological risk factors to identify the key 'hotspots' of risk for future spillover.

Overall, our SARSr-CoV program serves as a model platform to integrate virologic, molecular and ecologic factors contributing to CoV emergence while informing high impact strategies to intervene and prevent future pandemics. This includes providing critical reagents, therapeutic interventions and recombinant viruses for future SARSr-CoV pandemic and public health preparedness.



This scanning electron microscope image shows SARS-CoV-2 (yellow), the virus that causes COVID-19, isolated from a patient in the United States, emerging from the surface of cells (pink) cultured in the lab. Credit: NIAID-RML

NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

FY2020 – FY2024

April 22, 2020

NIH National Institute of Allergy and Infectious Diseases

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

Table of Contents

Executive Summary

The National Institute of Allergy and Infectious Diseases (NIAID) at the United States (U.S.) National Institutes of Health (NIH) is committed to safeguarding the health of Americans and people around the world by accelerating research efforts to prevent, diagnose, and treat COVID-19 and characterize the causative agent of this disease, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This *NIAID Strategic Plan for COVID-19 Research* builds on current trans-NIAID efforts to better understand SARS-CoV-2 pathogenesis, transmission, and mechanisms of protective immunity by expanding resources and activities that support rapid development of biomedical tools to more effectively combat this disease and pandemic. Given the urgency of the public health response, studies that inform efforts to control virus spread and mitigate morbidity and mortality, including therapeutic and vaccine development, are the priority. In addition, it is essential to develop rapid, accurate, point-of-care diagnostics—a critical asset to mitigating the spread of COVID-19.

Box 1
NIAID Strategic Plan for COVID-19 Research Mission

Conduct and support research on SARS-CoV-2 and COVID-19 to accelerate the development of safe and effective medical countermeasures that decrease disease incidence, mitigate morbidity and prevent mortality.

The *NIAID Strategic Plan for COVID-19 Research* aligns with the priorities set by U.S. Government–wide task forces for the development of medical countermeasures. NIAID actively participates in COVID-19 task forces to identify opportunities, ensure open communication, encourage resource sharing, and avoid duplication of effort. The plan is structured around four strategic research priorities:

1. **Improve fundamental knowledge of SARS-CoV-2 and COVID-19,** including studies to characterize the virus and how it is transmitted and understand the natural history, epidemiology, host immunity, disease immunopathogenesis, and the genetic, immunologic, and clinical associations with more severe disease outcomes. This includes accelerating the development of small and large animal models that replicate human disease.

2. **Support the development of diagnostics and assays**, including point-of-care molecular and antigen-based diagnostics for identifying and isolating COVID-19 cases and serologic assays to better understand disease prevalence in the population. Diagnostics also will be essential for evaluating the effectiveness of candidate countermeasures.

3. **Characterize and test therapeutics**, including identifying and evaluating repurposed drugs and novel broad-spectrum antivirals, virus-targeted antibody-based therapies (including plasma-derived intravenous immunoglobulin (IVIG) and monoclonal antibodies), and host-directed strategies to combat COVID-19.

4. **Develop safe and effective vaccines against SARS-CoV-2,** including support of clinical trial testing.

To accelerate research, NIAID will leverage current resources and global collaborations, including existing research programs and clinical trials networks. NIAID's research response to COVID-19 will build on experience with diseases caused by other zoonotic coronaviruses (CoVs), including severe acute

respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). NIAID will pursue public-private partnerships to facilitate the translation of research outcomes into life-saving public health interventions. Working with pharmaceutical companies, NIAID has already initiated Phase 1 clinical trials for candidate COVID-19 vaccines and therapeutics. A concerted effort will be made to include minority populations, as well as at-risk and vulnerable populations, in all aspects of NIAID-sponsored research to address health disparities between diverse groups. Characterization of the fundamental virology of SARS-CoV-2 and the immunological response to infection will inform future studies and facilitate the development of effective medical countermeasures. With collaboration from all agencies within the U.S. government and other key U.S. and global partners, NIAID will rapidly disseminate these results so that the information can be translated into clinical practice and public health interventions to combat the pandemic. As such, NIAID has already implemented open sharing of scientific data through publicly available websites and will continue to promote the prompt disclosure of SARS-CoV-2 and COVID-19 research data by the scientific community.

Research Plan

Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Developing effective medical and public health countermeasures against a newly emergent virus like SARS-CoV-2 will require a better understanding of the complex molecular and immune mechanisms underlying infection and disease. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Early studies suggest that the clinical manifestations of COVID-19 can vary significantly, and disease severity can range from mild to critical. Thus, a detailed understanding of the clinical course of disease, as well as the clinical, virologic, immunological, and genetic predictors of disease severity, are needed. Gaps also exist in our understanding of the dynamics of disease transmission in different populations over time, including the role of pediatric and elderly populations in viral spread, and the potential seasonality of viral circulation.

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection

- **Support the development and distribution of reagents and viral isolates to researchers.** NIAID will continue to support both intramural and extramural researchers by developing reagents and assays for virus characterization and immunological analyses. NIAID will continue to accelerate SARS-CoV-2 research by sourcing viral isolates and clinical specimens for the research community and placing them in repositories to help advance research and countermeasure development. In addition, NIAID will place other critical reagents needed for assay development (e.g., pseudovirions and antigens) in publicly available repositories for distribution.

- **Characterize virus biology and immunological responses to disease.** A comprehensive understanding of the

Box 2
Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection
Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies
Objective 1.3: Develop animal models that recapitulate human disease

biological processes involved in SARS-CoV-2 infection and the pathogenesis of COVID-19 are paramount to developing new medical countermeasures to fight the spread of disease. Building on prior research related to MERS and SARS coronaviruses, early studies confirmed several critical features of SARS-CoV-2 infection, including the primary host receptor, angiotensin converting enzyme 2 (ACE-2), and the structure of the virus receptor-binding domain. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Understanding the function of essential viral proteins will be necessary for improving diagnostic and immunological assays, *in vitro* and *in vivo* models, and other resources needed to advance safe and effective medical countermeasure development. In addition, evaluating the dynamics of host-pathogen interactions at the molecular and cellular levels will be critical to advancing our understanding of viral pathogenesis and immune responses that contribute to SARS-CoV-2 infection.

- **Determine viral evolution and molecular epidemiology.** With a newly emergent virus like SARS-CoV-2, studies to characterize genetic diversity, including those that assess the potential for the virus to evolve and escape host immunity, are pivotal for understanding disease progression and transmission dynamics and may have implications for countermeasure development. Viral genomic analysis matched with patient clinical data will be important to identify biomarkers of virulence and establish paradigms of sequence diversity. In addition, evaluating viral sequence associations with disease outcomes, immune status, and viral replication will provide crucial data to accelerate the development of effective medical countermeasures.

- **Develop low-containment assays to study virus neutralization.** Studies using non-infectious pseudovirions can be conducted in labs without BSL-3 capacity, making them an important tool to enhance understanding of SARS-CoV-2 infection. This capability would enable researchers without high-containment infrastructure to study the dynamics of virus neutralization *in vitro*.

- **Research into optimal public health prevention and mitigation modalities**. Clinical trials including family members of a COVID-19 positive individual can be devised to evaluate transmission, prevention, and other mitigation measures within the household.

Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies

- **Characterize disease incidence through surveillance studies.** Clinical manifestations of COVID-19 can vary greatly, ranging from asymptomatic or mildly symptomatic to the development of pneumonia, acute respiratory distress syndrome, and even death.[1] The variation in clinical presentation of COVID-19, combined with the challenges in diagnostic capacity, have made accurate initial assessments of disease incidence a formidable challenge. However, rapid point-of-care and point-of-need molecular tests, which became available in March 2020, will enable hospitals and other healthcare facilities to make informed decisions regarding patient isolation and care. Studies that leverage existing high-throughput diagnostic capacity along with these rapid tests will advance our understanding of disease incidence across the nation and will be a critical component of strategies to implement effective medical countermeasures. Combining these studies with broad serosurveillance studies across existing surveillance networks, including blood bank studies, would

[1] Wu Z and McGoogan JM. *JAMA* 2020 Feb 24. Epub. PMID 32091533.

provide a more complete picture of the scope of disease and the dynamics of infection. Detailed knowledge of host genetics and the human responses to infection across the lifespan will not only provide insights into new approaches for diagnosis, treatment, and prevention, but also may elucidate why individuals respond to SARS-CoV-2 in different ways. Reports to date suggest that COVID-19 resolves in most cases,[2] implying that the immune system can keep the infection from progressing to severe disease in many individuals. However, additional research is needed to better understand why some people progress to severe disease, which will lend critical insights to medical countermeasure development.

- **Assess the dynamics of disease transmission.** Our current understanding of COVID-19 transmission is limited. While recent studies have suggested timeframes for virus survival in aerosols and on surfaces,[3] the contributions of different routes of transmission and the dynamics of animal-to-human and human-to-human transmission remain unclear. The diverse clinical presentations of COVID-19, including a high prevalence of asymptomatic cases, add further complexity to understanding transmission dynamics. Providing a clearer picture of the natural history of viral shedding is a priority, both in acute cases and in asymptomatic infection. Given the challenges of accurately diagnosing asymptomatic individuals because they do not present for treatment, determining the role they play in transmission would provide valuable insights. Elucidating the role of pediatric cases in the spread of SARS-CoV-2 is particularly important. Although pediatric COVID-19 cases are generally asymptomatic or have less severe clinical manifestations than those of adults, the role that children play in spreading the virus is unknown. Additionally, studies to identify potential animal reservoirs and better understand transmission from animals to humans are a research priority, as these reservoirs may lead to future virus introductions and re-emergence of disease in humans. Virus transmission depends on a complex interplay of host, viral, and environmental factors that contribute to disease incidence and spread. Identifying the factors that maintain the disease transmission cycle is critical to developing effective medical countermeasures and public health interventions that will prevent future pandemics.

- **Determine disease progression through natural history studies.** Delineating the natural history of COVID-19 will inform immunopathogenesis, viral tropisms and length of shedding, immune phenotypes, and both protective immunity and host susceptibility. Disease assessment using longitudinal cohort studies, including among high-risk populations such as healthcare workers and the elderly, are important to better understand disease pathogenesis and immune responses to infection. Biomarkers identified from these studies may provide valuable insights into predictors of disease severity.

Objective 1.3: Develop animal models that recapitulate human disease

- **Develop small and large animal models that replicate SARS-CoV-2 pathogenesis.** Developing animal models that recapitulate human disease is a vital early step toward understanding disease pathogenesis and testing the efficacy of medical countermeasures. Small animal models enable rapid, scalable analyses that are particularly valuable for screening countermeasure candidates for efficacy and addressing issues concerning vaccine-induced immune enhancement. Among the small animal models being tested, transgenic mice expressing the human ACE-2 receptor are a promising candidate. In parallel, development and characterization of large animal models, including non-human primates (NHPs) that mimic human COVID-19, are a pivotal step to advance promising

[2] ibid.

[3] van Doremalen *N et al. N Engl J Med* 2020 Mar 17. Epub. PMID 32182409.

countermeasure candidates. Previous experience with related coronavirus diseases such as MERS and SARS suggests that replicating human disease, particularly its more severe manifestations, in an animal model may be challenging. Fundamental research assessing animal models ranging from mice to NHPs is already underway. NIAID will continue to support the development of small and large animal model candidates to better understand this emerging infection and investigate optimal ways to treat and prevent COVID-19. NIAID also will ensure that validated animal models are made available to the scientific community for evaluating priority countermeasures.

Priority 2: Support the development of diagnostics and assays

Availability of rapid, accurate Food and Drug Administration (FDA)-cleared or authorized diagnostics will increase testing capacity and are critical for identifying and rapidly isolating cases, tracking spread of the virus, managing patient care, and supporting clinical trials. Molecular tests specifically designed to detect SARS-Cov-2 RNA in clinical samples are able to detect low levels of pathogen in clinical samples and offer robust specificity in differentiating SARS-CoV-2 from other related viruses. Continuing to improve the speed and accuracy of molecular and antigen-based diagnostics and making them available at point- of-care will be paramount to accelerating the ability to mitigate disease spread in the current outbreak and any future outbreaks. The development of serologic assays would further bolster surveillance efforts, including the ability to identify individuals who may have resolved prior infection with SARS-CoV-2.

Objective 2.1: Accelerate the development and evaluation of diagnostic platforms

- **Support the development, characterization and availability of reagents for diagnostic validation.** NIAID will support this effort through the development and testing of reagents for diagnostic validation that will be made available through NIAID-sponsored repositories.

Box 3 **Priority 2: Support the development of diagnostics and assays**
Objective 2.1: Accelerate the development and evaluation of diagnostic platforms *Objective 2.2: Develop assays to increase understanding of infection and disease incidence*

- **Support the development of new rapid diagnostics.** NIAID will provide funding to support the development of new rapid diagnostics, including molecular tests and novel antigen detection tests with improved sensitivity, if deemed feasible based on natural history studies.

- **Support the evaluation of promising diagnostics.** In some cases, stakeholders that develop potential diagnostic tests do not have the infrastructure needed to rigorously validate those tests against clinical samples. NIAID will support the testing of promising diagnostics and provide the capacity for evaluating them with live virus samples using our biocontainment laboratories.

Objective 2.2: Develop assays to increase understanding of infection and disease incidence

- **Develop and validate SARS-CoV-2 serological assays.** Serological tests, which detect host antibodies to infectious agents, do not detect the presence of a pathogen directly but can be used as a surrogate marker of infection. Developing more effective serologic tests would help provide information on the extent of asymptomatic infections and cumulative disease incidence, for example through serosurveillance studies. NIAID, with the Centers for Disease Control and

Prevention and the FDA, is developing tests that identify antibodies to SARS-CoV-2 proteins to determine seroprevalence rates and potentially help distinguish antibody responses in individuals receiving vaccines. NIAID will support the development and validation of additional serological assays for serosurveillance studies and as tools for testing the efficacy of promising vaccine or therapeutic candidates.

Priority 3: Characterize and test therapeutics

Currently, there are no FDA-approved or licensed therapeutics specific for coronaviruses. While traditional development pathways for therapeutics can take years, the urgency of the current outbreak underscores the need for rapid development and testing of promising therapeutics. Possible avenues for developing therapeutics include the evaluation of broad-spectrum antiviral agents (antivirals) that have shown promise for other coronaviruses and the identification of novel monoclonal antibodies (mAbs). For broad-spectrum antivirals, Phase 2/2b testing of the RNA polymerase inhibitor developed by Gilead, remdesivir, is already underway. Additional studies will be critical to identify promising therapeutic candidates and to advance them through clinical trial testing. To optimize findings during the pandemic, multiple clinical trials will be conducted in parallel among various populations, including both inpatient and outpatient studies.

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2

- **Screen protease inhibitor and nucleotide analogue class agents and other small molecules with documented activity against other coronaviruses SARS-CoV-2**. Screening drugs that are already licensed by the FDA for other indications and might be efficacious against SARS-CoV-2 infection may provide a route to identifying a therapeutic for use in the current pandemic. Broad-spectrum antivirals that are already FDA approved or in clinical development for other indications—including those previously targeting SARS-CoV-1 and MERS CoV—can be evaluated for their potential activity against SARS-CoV-2 infections. Approved therapeutics for other infectious diseases also are being evaluated as possible treatments for COVID-19. By leveraging their existing efficacy, safety, and manufacturability data, the time to development and production can be reduced. NIAID also will continue working with partners to screen compound libraries for potential activity against SARS-CoV-2. For these studies, priority will be given to compounds based on *in vitro* screening data and the existence of human safety data.

- **Identify viral targets for therapeutic development**. Advances in structural biology technology enable researchers to map key viral structures at an unprecedented level. The Structural Genomics Centers for Infectious Diseases (SGCID) apply state-of-the-art, high-throughput technologies and methodologies, including computational modeling, x-ray crystallography, nuclear magnetic resonance imaging, and cryogenic electron microscopy, to experimentally characterize the three dimensional atomic structure of proteins that play an important biological role in human pathogens and infectious diseases. NIAID will continue to support use of this powerful technology to identify viral targets of SARS-CoV-2 for therapeutics or vaccines.

Box 4
Priority 3: Characterize and test therapeutics

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2
Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates

- **Identify novel mAbs for use as therapy or prophylaxis.** Data from early studies indicate that well-characterized convalescent plasma may provide a treatment benefit in COVID-19.[4] Therefore, IVIG derived from convalescent plasma may also hold promise for treatment. Moreover, peripheral blood mononuclear cells and plasma are being used to identify novel neutralizing antibodies. Through collaborations with structural biologists, binding properties can be quickly assessed. Paired with assessment of neutralization activity, the most promising mAbs will be identified for further characterization in animal models and human trials.

Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates

- **Characterize and evaluate host-directed strategies for treatment of disease.** Experience with other coronaviruses indicates that infection of the respiratory tract is rapid and damage is primarily mediated by the host inflammatory response.[5] These conditions may make it difficult to modify COVID-19 with pathogen-directed therapeutics. Instead, host-directed strategies that target the immune response may exert a beneficial therapeutic effect. Host-directed strategies, including immune-modulating agents, will be investigated as potential therapeutic candidates.

- **Conduct clinical trials to demonstrate safety and efficacy of lead therapeutic candidates.** Many potential therapeutic candidates have been identified and are being tested in clinical trials.
  - In March 2020, NIAID launched a multicenter, adaptive, randomized controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral drug remdesivir (GS-5734) for the treatment of COVID-19 in hospitalized adults with laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement. The trial builds on recent studies by NIAID scientists showing that remdesivir can improve the disease course in rhesus macaques when administered promptly after viral challenge with the MERS CoV.[6] The trial is also adaptive, allowing for additional arms should other therapeutics warrant assessment for efficacy.
  - NIAID is finalizing the protocol for the Big Effect Trial (BET), in which putative therapeutics that have existing human data and are readily available will be tested in patients hospitalized with lower respiratory tract disease. Each potential intervention will be given to approximately 75 patients and evaluated for mitigating disease symptoms. Candidate therapeutics that meet the criteria in this initial study will be further evaluated in larger clinical trials for which the infrastructure is already in place.
  - As mentioned above, identification of novel mAbs for therapy or prophylaxis is another strategic priority. These mAbs should be safe, highly effective, amenable to fast manufacturing, and easy to administer. They will be tested in clinical trials to develop immunotherapies for the prevention and early treatment of COVID-19, potentially in high-risk populations including healthcare workers.

- **Conduct outpatient studies for mild COVID-19 cases**. In cases of mild COVID-19 that do not require hospitalization, outpatient studies could be extremely valuable for testing promising, orally administered FDA-approved drugs that have existing safety data. The antiviral activity of hydroxychloroquine and azithromycin against SARS-CoV-2 has been the focus of many early

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[4] Roback JD and Guarner J. *JAMA* 2020 Mar 27. Epub. 32219429.

[5] Newton AH et al. *Semin Immunopathol*. 2016;38(4):471-82. PMID 26965109.

[6] de Wit E et al. *Proc Natl Acad Sci USA* 2020;117(12):6771-6. PMID 32054787.

therapeutic studies.[7,8,9] Testing of these and other candidates, including protease inhibitors and other molecules, in outpatient studies may provide critical efficacy data and could identify an existing drug or drug combination that is safe and effective against COVID-19.

- **Conduct outpatient studies in high-risk populations.** High-risk populations, including health care workers, the elderly or individuals with chronic conditions, are a critical target for the development of therapeutics. Conducting studies in patients with mild cases of COVID-19 among these high-risk groups would be of interest for identifying the benefits of early treatment strategies to mitigate the impact of infection. Therapeutic candidates that have once a day dosing could also be considered for pre-exposure prophylaxis (PrEP) in some of these populations.

Priority 4: Develop safe and effective vaccines against SARS-CoV-2

Developing a safe and effective SARS-CoV-2 vaccine is a priority for preventing future outbreaks of the virus. As vaccine candidates for MERS-CoV, SARS-CoV-1 and other coronaviruses have previously been developed, NIAID investigators and the scientific community are well poised to use similar approaches in the current pandemic. NIAID will leverage its broad intramural and extramural infrastructure to advance vaccine candidates through Phase 1 safety and dosing clinical trials, with considerations for Phase 2/2b clinical trials for the most promising candidates.

Objective 4.1: Advance promising vaccine candidates through clinical trial testing

- **Conduct a Phase 1 clinical trial of (mRNA) platform candidate mRNA-1273.** Given the urgency of the response effort to develop a safe and effective vaccine, NIAID is prioritizing promising vaccine candidates that can be rapidly produced and tested. NIAID, in collaboration with the biotechnology company Moderna, is conducting a Phase 1 clinical trial of a vaccine candidate that uses a messenger RNA (mRNA) vaccine platform expressing a NIAID-designed recombinant spike protein of SARS-CoV-2. The trial is being conducted at NIAID-funded clinical research sites, with the first enrolled individual receiving the vaccine on March 16, 2020.

- **Prepare for a pivotal Phase 2/2b clinical trial of candidate mRNA-1273. Preparing for the likelihood of a seasonal recurrence of SARS-CoV-2 is imperative to the public health response.** Given the theoretical risk of vaccine-enhanced respiratory disease, large Phase 2 trials are unlikely to launch until this possibility is evaluated in animal models. Planning for those animal studies is underway, and, assuming favorable results, a Phase 2/2b study could be launched later in 2020. This represents a historically fast timeline for the development and testing of a vaccine candidate. Additionally, these studies will provide information on correlates of immunity that will help accelerate the advancement of other vaccine candidates. If the mRNA-1273 vaccine candidate shows protection against SARS-CoV-2 infection in a Phase 2/2b trial, NIAID will work with government partners to ensure that the vaccine is manufactured in sufficient quantities to allow prompt distribution to those at highest risk of acquiring disease.

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[7] Gautret P et al. *Int J Antimicrob Agents*. 2020 Mar 20:105949. Epub. PMID 32205204.

[8] Molina JM et al. 2020 Med Mal Infect. 2020 Mar 30. pii:S0399-077X(20)30085-8. Epub. PMID 32240719.

[9] Chen Z et al. medRxiv 2020:2020.03.22.20040758.
https://www.medrxiv.org/content/10.1101/2020.03.22.20040758v2

Box 5.
Priority 4: Develop safe and effective vaccines against SARS-CoV-2

Objective 4.1: Advance promising vaccine candidates through clinical trial testing
Objective 4.2: Advance vaccine development through assay and reagent development
Objective 4.3: Advance vaccine development through adjuvant characterization and development

- **Investigate additional candidates through NIAID vaccine programs.** Although promising candidates may show efficacy in preclinical studies, many do not translate into effective vaccines in clinical trials. Therefore, it is crucial to support multiple promising preclinical candidates in the research and development pipeline. To that end, NIAID is advancing multiple additional SARS-CoV-2 vaccine candidates through its Rocky Mountain Laboratories (RML), including approaches that have shown promise against coronaviruses that cause SARS and MERS. Building on previous research to develop a MERS-CoV vaccine, scientists at RML are collaborating with Oxford University investigators to develop a SARS-CoV-2 vaccine that uses a chimpanzee adenovirus vector. RML investigators also are partnering with the biopharmaceutical company CureVac on an mRNA vaccine candidate and collaborating with the University of Washington on a universal coronavirus vaccine development. By leveraging its extensive expertise and research infrastructure, NIAID will continue working with partners and collaborators to advance promising SARS-CoV-2 vaccine candidates.

- **Leverage existing vaccine approaches to target SARS-CoV-2.** NIAID is pursuing multiple strategies to develop a COVID-19 vaccine. Building on past research on emerging pathogens, especially MERS-CoV and SARS-CoV-1 (the virus that causes SARS), NIAID is using previously developed vaccine platforms to rapidly assess the potential of SARS-CoV-2 vaccine candidates. This approach has already resulted in several promising strategies that may be leveraged for SARS-CoV-2, including vaccination using recombinant spike protein, chimpanzee adenovirus vaccine vector, virus-like particles, and live attenuated virus. In addition, NIAID is funding the development of novel vaccine candidates that will be efficacious across the lifespan, including in the elderly.

Objective 4.2: Advance vaccine development through assay and reagent development

- **Develop critical reagents to support vaccine development**. Appropriate tools are needed to identify the most promising vaccine candidates and advance the development of lead candidates as rapidly as possible. To accelerate the vaccine pipeline, NIAID is generating master and working SARS-CoV-2 virus stocks and other reagents critical for developing SARS-CoV-2 immune assays, developing quantitative tests for characterizing SARS-CoV2 assay material, developing a quantitative SARS-CoV-2-specific ELISA, developing virus-specific neutralization assays, and developing quantitative assays for assessing SARS-CoV-2 viral load.

Objective 4.3: Advance vaccine development through adjuvant characterization and development

- **Provide adjuvants to support vaccine development**. Adjuvants are vaccine components that improve vaccine efficacy by inducing long-lived protective immunity. Selection of appropriate adjuvants is crucial for developing safe and effective vaccines. NIAID is working with multiple collaborators to provide adjuvants to the research community for use in SARS-CoV-2 vaccine candidates. These adjuvants are at various stages of development and include compounds that

specifically improve vaccine efficacy in elderly individuals or modulate host immunity toward protective responses while limiting or preventing harmful inflammatory responses.

Conclusion

The sudden emergence and rapid global spread of the novel coronavirus SARS-CoV-2 has created a daunting public health challenge. To address this challenge, NIAID is focusing its considerable expertise and emerging infectious disease resources to facilitate the development of medical countermeasures including diagnostics, therapeutics, and vaccines. The resulting discoveries will not only help mitigate the current pandemic, but also inform prevention, diagnosis, and treatment of future emerging infectious diseases.

A comprehensive strategy requires a coordinated effort among governmental, academic, private, and community-based organizations. The *NIAID Strategic Plan for COVID-19 Research* defines the areas of COVID-19 research within the NIAID mission and outlines the institute's research priorities and goals. This strategic plan builds on many other national efforts and represents a commitment from multiple U.S. government agencies to improve coordination of COVID-19 research and discovery efforts and the development of medical countermeasures.

Exhibit 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

Exhibit 3

ECOHEALTH ALLIANCE'S OBJECTIONS AND RESPONSES TO NIH'S ADDITIONAL CONDITIONS ON GRANT 2R01 AI 110964-6

EcoHealth Alliance, Inc. ("EcoHealth Alliance"), by and through its attorneys, Tarter Krinsky & Drogin LLP, hereby responds and objects to the additional conditions (the Requests") imposed on grant 2R01 AI 110964-6 on July 8, 2020, by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institutes of Health ("NIH"), under the Department of Health and Human Services ("HHS"), as follows:

GENERAL OBJECTIONS[1]

1. EcoHealth Alliance objects to the Requests to the extent they purport to impose obligations beyond those authorized by the NIH Grants Policy Statement and the applicable statutes and regulations.

2. EcoHealth Alliance objects to the Requests to the extent they seek information and documents that are neither relevant to the Project nor reasonably likely to affect the safety or efficacy of EcoHealth Alliance's continued research funded by grant 2R01 AI 110964-6.

3. EcoHealth Alliance objects to the Requests to the extent they seek the production of documents that are not in EcoHealth Alliance's possession, custody, or control.

4. EcoHealth Alliance objects to the Requests to the extent they are vague, ambiguous, or otherwise unclear as to the precise categories of documents and information sought.

5. EcoHealth Alliance objects to the Requests to the extent that they are overbroad, unduly burdensome, or unreasonably cumulative and duplicative.

6. EcoHealth Alliance objects to the Requests to the extent they seek documents and information concerning personal information relating to individuals not affiliated with the Project or Grant on the ground that such requests may invade the rights of privacy of such individuals.

[1] Any capitalized terms not otherwise defined herein shall have the same meaning ascribed to them in EcoHealth Alliance's letter to NIAID, dated August 12, 2020.

7. EcoHealth Alliance objects to the Requests to the extent they seek documents and information regarding transactions or occurrences that took place on or before July 1, 2019, on the ground that such requests are overbroad, and that such documents and information are not relevant to EcoHealth Alliance's continued research funded by grant 2R01 AI 110964-6.

8. EcoHealth Alliance's Responses and Objections to the Requests (including each Request therein) shall not be interpreted as implying that: (i) responsive documents or information exist, (ii) EcoHealth Alliance acknowledges the proprietary of any Request; or (iii) that any Request propounded by NIH is either factually correct or legally binding upon EcoHealth Alliance.

9. EcoHealth Alliance specifically reserves its right to amend, modify, or supplement the objections and responses provided herein.

10. These general objections ("General Objections") are hereby incorporated by reference into each and every of EcoHealth Alliance's responses to the Requests, below.

RESPONSES AND OBJECTIONS TO THE REQUESTS

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.

Response to Request No. 1:

EcoHealth Alliance objects to the Request to the extent it seeks documents and information that are not in EcoHealth Alliance's possession, custody, or control. EcoHealth Alliance further objects to the Request to the extent it seeks information that is not relevant to the Project, which was granted prior to the discovery of SARS-CoV-2. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that it has no knowledge or information regarding the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.

2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.

Response to Request No. 2:

See General Objections. EcoHealth Alliance objects to the Request to the extent it purports to seek information or documents that are not in EcoHealth Alliance's possession, custody, or control. EcoHealth Alliance further objects to the Request to the extent it seeks information that is not relevant to the Project. EcoHealth Alliance further objects to the extent the Request seeks documents and information concerning personal information relating to individuals who are not affiliated with the Project. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that it lacks knowledge or information regarding the alleged "disappearance of Huang Yanling" or the contention that her "lab web presence has been deleted."

3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.

Response to Request No. 3:

See General Objections. EcoHealth Alliance objects to the Request to the extent it purports to seek information or documents that are not in EcoHealth Alliance's possession, custody, or control. EcoHealth Alliance further objects to the Request to the extent it seeks information that is not relevant to the Project. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that, upon information and belief, it is not in possession, custody, or control of "WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns."

4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.

Response to Request No. 4:

See General Objections. EcoHealth Alliance objects to the Request in that it is vague, ambiguous, or otherwise unclear as to the precise categories of documents and information that are being sought and because the term "out-of-ordinary" is undefined. EcoHealth Alliance further objects to the Request to the extent it purports to seek documents or information that are not in EcoHealth Alliance's possession, custody, or control. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that it lacks knowledge or information regarding "diminished cell-phone traffic in October 2019" and/or "roadblocks surrounding [WIV] from October 14-19, 2019."

5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.

Response to Request No. 5:

See General Objections. EcoHealth Alliance objects to the Request to the extent it purports to seek information or documents that are not in EcoHealth Alliance's possession, custody, or control. EcoHealth Alliance further objects to the Request to the extent it seeks information that is not relevant to the Project. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that it lacks knowledge or information regarding the contention that "WIV failed to note that the RatG13 virus…was [] isolated from an abandoned mine where three men died in 2012" and why this was not followed up.

6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.

Response to Request No. 6:

See General Objections. EcoHealth Alliance objects to the Request to the extent it seeks to impose obligations on EcoHealth Alliance that are not authorized by the NIH Grants Policy Statement or any applicable statute or regulation. EcoHealth Alliance further objects to the Request to the extent it seeks to impose obligations that are wholly unrelated to the Project or EcoHealth Alliance's ongoing research funding by the Grant. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that, on April 19, 2020, Michael S. Lauer, MD, NIH Deputy Director for Extramural Research, sent a letter to EcoHealth Alliance on behalf of NIH that stated that EcoHealth Alliance was not allowed to collaborate with WIV regarding the Project and that it should not remit any Grant funds to WIV. On April 21, 2020, Peter Daszak of EcoHealth Alliance sent an email to Dr. Lauer that confirmed (i) no funds from the Grant had been sent to WIV, (ii) no contract had been signed between EcoHealth Alliance regarding research funded under the Grant, and (iii) EcoHealth Alliance would not provide any funds to WIV. As a result, at this time, EcoHealth Alliance is not collaborating with WIV, is not

in possession, custody, or control of WIV, and has no authority to grant NIAID and the U.S. National Academy of Sciences access the facility to conduct an inspection.

7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System.

Response to Request No. 7:

See General Objections. Subject to and notwithstanding the General Objections and without prejudice thereto, EcoHealth Alliance responds that, upon information and belief, as of the date of these responses, all of EcoHealth Alliance's subawards are fully reported in the Federal Subaward Reporting System.

Dated: New York, New York
August 13, 2020

TARTER KRINSKY & DROGIN LLP
Attorneys for EcoHealth Alliance

By: [redacted (b) (6)]
Andrew N. Krinsky
1350 Broadway, 11th Floor
New York, New York 10018
Tel: [redacted (b) (6)]

TO: Dr. Michael S. Lauer [redacted (b) (6)]
Dr. Erik Stemmy [redacted (b) (6)]
Ms. Emily Linde [redacted (b) (6)]

Best,

Matthew

Matthew R.Torsiello | Associate
D: (b) (6) | F: 212-216-8001
(b) (6) | Bio

Tarter Krinsky & Drogin LLP
1350 Broadway | New York | NY | 10018
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COVID-19 RESOURCE CENTER

From: Matthew R.Torsiello
To: Lauer, Michael (NIH/OD) [E]
Cc: Linde, Emily (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Andrew N. Krinsky; Nels T. Lippert; Black, Jodi (NIH/OD) [E]; Erbelding, Emily (NIH/NIAID) [E]; Bulls, Michelle G. (NIH/OD) [E]; Peter Daszak; Aleksei Chmura
Subject: EcoHealth Alliance re Termination of NIH Research Grant R01 AI 110964
Date: Friday, May 22, 2020 5:13:04 PM
Attachments: image8d11b0.PNG
EcoHealth Alliance First-Level Appeal of NIH Grant Termination, dated May 22, 2020 (R01 AI 110964) (02103179xA1AB5).PDF

Dr. Lauer:

Please see the attached letter from Andrew N. Krinsky on behalf of EcoHealth Alliance, Inc., pursuant to NIH Grants Policy Statement Section 8.7, regarding the decision by NIAID to terminate NIH Research Grant R01 AI 110964 on or about April 24, 2020.

Thank you.

Best,

Matthew R. Torsiello

Tarter Krinsky &Drogin

Matthew R.Torsiello | Associate
D: (b) (6) | F: 212-216-8001
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Andrew N. Krinsky, *Partner*
212-216-8080, *Direct Dial*
akrinsky@tarterkrinsky.com

May 22, 2020

Via Email, Certified Mail, & FedEx
(b) (6)

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
National Institutes of Health
National Institute of Allergy and Infectious Diseases
1 Center Drive, Building 1, Room 144
Bethesda, Maryland 20892

Re: Termination of NIH Grant 2R01 AI 110964-6

Dear Dr. Lauer:

This firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance") with regard to the post-award decision by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institute of Health ("NIH"), under the Department of Health and Human Services ("HHS"), to terminate the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964, on April 24, 2020 (the "Termination").

This letter, pursuant to NIH Grants Policy Statement Section 8.7 and 42 CFR 50, Subpart D, constitutes EcoHealth Alliance's first-level appeal of the Termination, which was "for convenience." As set forth in more detail below, the Termination is not authorized under the NIH Grants Policy Statement, arbitrary and capricious and an indefensible attack on public health and welfare given that it undermines a pivotal 10-year research project involving the origins, spread and threat of emerging bat coronaviruses during the peak of an unprecedented worldwide coronavirus pandemic. Accordingly, EcoHealth Alliance hereby demands that grant 2R01 AI 110964-6 be reinstated immediately.

BACKGROUND

A. EcoHealth Alliance

EcoHealth Alliance is a prominent New York-based nonprofit institution dedicated to protecting the health of people, animals, and the environment from emerging zoonotic diseases. For more than a decade, EcoHealth Alliance has been conducting cutting edge scientific research to identify hundreds of new coronaviruses ("CoVs") in bats and to study the capacity of these viruses to infect human cells. The purpose of this research is to identify high risk populations so international actors can leverage their resources to address potential pandemics. In cooperation with a global network of over seventy partners, including academic institutions, intergovernmental

and governmental agencies, infectious disease surveillance laboratories, and other international and national organizations in over thirty countries, EcoHealth Alliance's work has led to numerous scientific papers published in high impact journals. These publications have been critical in raising awareness of the threat that CoVs pose to global health, the global economy, and U.S. National Security.

EcoHealth Alliance has a long history of successful cooperation with NIH including multiple Research Project Grant R01 awards. In particular, Peter Daszak, EcoHealth Alliance's President and Chief Scientist, has been the Principal Investigator on five multidisciplinary R01s. All of these projects used modeling, epidemiology, laboratory, and field science to test hypotheses on the emergence of wildlife-origin viral zoonoses, including SARS-CoV, the Nipah and Hendra viruses, Avian influenza, and other bat-origin viruses. EcoHealth Alliance, a 501(c)(3) organization, is unique in that it goes one step further by leveraging its research goals to create an alliance of international collaborators that can advocate for real-world changes to protect high risk populations.

Notably, in collaboration with virologists in China, EcoHealth Alliance isolated and characterized SARSr-CoVs from bats that use the same human host cell receptor (ACE2) as SARS-CoV. This work provided critical reagents and resources that have advanced scientific understanding of virus-host binding and contributed to vaccine development. For example, the genetic sequences of the bat viruses that EcoHealth Alliance discovered under its NIH research funding, which were published online (Genbank & GISAID), have been used to test the effectiveness of the drug Remdesivir against not only SARS-CoV, but also MERS, and other potentially zoonotic or pre-pandemic bat CoVs. Significantly, this type of testing can be performed without the need for viral cultures or shipping viruses internationally.

B. NIH Awards And Extends EcoHealth Alliance Research Grant R01 AI 110964

In 2014, NIH issued EcoHealth Alliance a five-year research award for the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964 (the "Project"). EcoHealth Alliance received additional awards for the Project each year between 2015 and 2018. Between 2015 and 2019, the Project resulted in the publication of more than twenty papers.

In 2019, EcoHealth Alliance submitted a renewal application to NIH through NIAID to extend the Project period for an additional five years. Upon filing of its renewal application, the Project was ranked as an "extremely high priority" (in the top 3%) by NIAID during its external review process. In light of its success and the importance of EcoHealth Alliance's work, on July 24, 2019, NIH reauthorized grant R01 AI 110964 and increased EcoHealth Alliance's funding. EcoHealth Alliance was issued a notice of award in the amount of $733,750.00 (the "2019 Award"). The notice of award also extended the Project period for an additional five years to 2024. A copy of the notice of award is attached hereto as Exhibit A.

C. EcoHealth Alliance Agrees Not To Fund The Wuhan Institute Of Virology

During the pendency of the Project, in December of 2019, China reported a cluster of cases of pneumonia in Wuhan, Hubei Province. It was later determined that the cause of this pneumonia

was a novel CoV, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causing coronavirus disease (COVID-19). Thereafter, SARS-CoV-2 spread to nearly every country throughout the world. In response, EcoHealth Alliance has prioritized its efforts in conducting research that will be integral to developing an effective strategy to combat SARS-CoV-2.

On April 19, 2020, Michael S. Lauer, MD, NIH Deputy Director for Extramural Research, sent a letter to EcoHealth Alliance on behalf of NIH regarding a laboratory in China, the Wuhan Institute of Virology ("WIV"). WIV was a prior sub-recipient of a small portion of the R01 AI 110964 grant funds. The letter stated that, given allegations that COVID-19 "was precipitated by the release from WIV of the coronavirus responsible for COVID-19", NIH was pursuing suspension of WIV from participating in Federal programs. However, Mr. Lauer assured EcoHealth Alliance that "[t]his suspension of the sub-recipient does not affect the remainder of [EcoHealth Alliance's] grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension." A copy of the letter is attached hereto as Exhibit B.

On April 21, 2020, Dr. Daszak of EcoHealth Alliance responded by email to Dr. Lauer stating that he could "categorically state that no funds from [sic] 2R01 AI 110964-6 have been sent to Wuhan Institute of Virology, nor has any contract been signed." Dr. Daszak further represented that EcoHealth Alliance would comply with all NIAID requirements. Dr. Lauer acknowledged (1) that no monies from grant 2R01 AI 110964-6 had gone to WIV and no contract between EcoHealth Alliance and WIV had been signed and (2) EcoHealth Alliance's agreement that it would not provide any funds to WIV until and unless directed otherwise by NIH. A copy of the email correspondence between NIH and EcoHealth Alliance is attached hereto as Exhibit C.

D. NIH Abruptly Terminates Research Grant 2R01 AI 110964-6 "For Convenience"

Notwithstanding NIH's representation that suspension of WIV would not affect the remainder of EcoHealth Alliance's 2019 Award, on April 24, 2020, NIH notified EcoHealth Alliance by letter that, effective immediately, the 2019 Award had been terminated by NIAID. The stated grounds for the Termination were: (1) convenience; (2) NIH's discretion not to award a grant, or to award a grant at a particular funding level; and (3) NIH's belief that the Project outcomes did not align with the program goals and agency priorities. A copy of the Termination is attached hereto as Exhibit D.

ARGUMENT

A. NIH Research Grants Are Not Subject To Termination For Convenience

"Termination for convenience" refers to the exercise of the government's right to bring to an end the performance of all or part of the work provided for under a contract prior to the expiration of the contract "when it is in the Government's interest" to do so. Federal agencies typically incorporate clauses in their procurement contracts which give them the right to terminate for convenience. Here, there is no clause in the terms and conditions applicable to the 2019 Award, or in the NIH Grants Policy Statement, that permits NIAID or NIH to issue a post-award decision to terminate a NIH research grant award "for convenience."

Moreover, the unprecedented assertion by NIH that active research grants can be terminated "for convenience" during the subject budget period renders Section 8.5.2 of the NIH Grants Policy Statement meaningless. *See, e.g., Li v. Eddy*, 324 F.3d 1109, 1110 (9th Cir. 2003) (rejecting suggested statutory interpretation on the grounds that the interpretation ran squarely against the canon of construction that courts interpret statutes so as not to render any section meaningless). Section 8.5.2 of the NIH Grants Policy Statement governs, *inter alia*, modification or termination of an award for misconduct. If NIH grants were terminable for convenience, NIH could always choose to terminate for convenience to avoid (1) the "for cause" restriction on grant terminations and (2) the labor intensive task of enforcing compliance through disallowing costs, withholding further awards, or wholly suspending the grant, pending corrective action.

B. NIH's Discretion Not To Award A Grant, Or To Award a Grant At A Particular Funding Level, Does Not Authorize A Post-Award Decision To Terminate

NIH's discretion regarding the "decision not to award a grant, or to award a grant at a particular funding level" does not give NIH the authority to issue a post-award decision terminating a duly awarded grant during the budget period. This purported discretion, which is based on language in the last paragraph of NIH Grants Policy Statement Section 2.4.4, entitled *Disposition of Applications*, concerns NIH's authority to reject incomplete or otherwise undesirable grant applications in the first instance only. The provisions of Section 2, generally, have no bearing on post-award decisions affecting duly approved grants for which specified funds have already been allocated. As the 2019 Grant in the amount of $733,750.00 was awarded to EcoHealth Alliance on July 24, 2019, NIH's authority to deny initial grant applications does not allow NIH to terminate the 2019 Grant.

C. The Research Goals Of EcoHealth Alliance And NIAID Are Virtually Identical

NIH's contention that the Project's outcomes do not align with the agency's priorities is demonstrably false. First, the Project was ranked as "extremely high priority" on external review by NIAID less than nine months ago, before the discovery of SARS-CoV-2. Since this discovery, NIH has promulgated new grants seeking applicants to conduct research on the same issues covered by the Project and the 2019 Award.

In addition, there is substantial overlap between the four strategic research priorities on page 1 of NIAID's Strategic Plan for COVID-19 Research, published April 22, 2020, and the three Specific Aims of the Project. Both NIAID and EcoHealth Alliance seek to: (1) improve fundamental knowledge of SARS-Cov-2; (2) develop methods to assess the rate of infection and disease incidence; (3) contribute to the development of an effective vaccine; and (4) increase public health preparedness. Copies of the Project's Specific Aims and the NIAID Strategic Plan's four strategic research priorities for COVID-19 research are attached hereto as Exhibit E.

D. There Is No Rational Basis To Terminate The 2019 Award For Cause

The grounds and procedures for suspension and termination of awards are specified in NIH Grants Policy Statement Section 8.5.2 and 45 CFR Parts 75.371 through 75.373. Notably, Section

8.5.2 provides, *inter alia*, that NIH will generally suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. Through this lens, 45 CFR 75.372 provides that NIH may terminate a Federal award, in whole or in part, if: (1) the non-Federal entity fails to comply with the terms and conditions of the award; (2) for cause; (3) by the HHS awarding agency or pass-through entity with the consent of the non-Federal entity; or (4) by the non-Federal entity upon written notice to the HHS awarding agency setting forth the reasons for such termination, and other information. None of the foregoing predicate conditions exist here.

As of the date of the Termination, EcoHealth Alliance had not received any notice from NIH, NIAID, or HHS that it either failed to comply with any of the terms or conditions of the 2019 Award, or committed any misconduct in connection with the award. To the contrary, in email correspondence following EcoHealth Alliance's representation that it had not and would not give any funds from the 2019 Award to WIV, Aleksei Chmura, EcoHealth Alliance's Chief of Staff, memorialized the mutual agreement between NIH and EcoHealth Alliance that EcoHealth Alliance was in compliance with all requests. (Ex. C, # 8). To be clear, EcoHealth Alliance clearly and unequivocally stated that it had not and will not distribute any funds from the 2019 Award to WIV.

In sum, there is no statutory, regulatory, or contractual basis for NIAID's termination of the Project, *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01 AI 110964-6. However, please note that this letter is not intended to provide an exhaustive list of all possible grounds for reversal of the Termination and may not reflect all arguments and claims that EcoHealth Alliance will assert in the event that a formal second-level appeal of the Termination is required.

Should you wish to present evidence in an effort to refute any of the factual assertions made in this letter and/or to engage in good faith negotiations regarding appropriate terms and conditions for the resumption of funding for grant 2R01 AI 110964-6, we are prepared to review such evidence and to participate in such negotiations.

We await your response to this letter.

Very truly yours,

(b) (6)

Andrew K. Krinsky

cc: (*by email*)

Dr. Erik Stemmy (b) (6)
Ms. Emily Linde (b) (6)

Exhibit A

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 07/24/2019

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 2R01AI110964-06
FAIN: R01AI110964

Principal Investigator(s):
PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Dr. Daszak, Peter
PD/PI
460 West 34th Street
Suite 1701
New York, NY 100012320

Award e-mailed to: (b) (6)

Period Of Performance:
Budget Period: 07/24/2019 – 06/30/2020
Project Period: 06/01/2014 – 06/30/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $733,750 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tseday G Girma
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I – AWARD DATA – 2R01AI110964-06

[redacted]

[redacted]

Approved Budget	$733,750
Total Amount of Federal Funds Obligated (Federal Share)	$733,750
TOTAL FEDERAL AWARD AMOUNT	$733,750
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$733,750

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
6	$733,750	$733,750
7	$709,750	$709,750
8	$709,750	$709,750
9	$709,750	$709,750
10	$709,750	$709,750

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1311726494A1
Document Number:	RAI110964B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019	2020	2021	2022	2023
AI	8472364	$733,750	$709,750	$709,750	$709,750	$709,750

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M51C B / **OC**: 414B / **Released**: (b) (6) 07/18/2019
Award Processed: 07/24/2019 12:03:26 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2R01AI110964-06

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 2R01AI110964-06

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

SECTION IV – AI Special Terms and Conditions – 2R01AI110964-06

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

[redacted]

****

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

[redacted]

****

This award reflects current Federal policies regarding Facilities & Administrative (F&A) Costs for foreign grantees including foreign sub-awardees, and domestic awards with foreign sub-awardees. Please see: Chapter 16 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components, Section 16.6 "Allowable and Unallowable Cost" of the NIH Grants Policy.

****

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

****

The budget period anniversary start date for future year(s) will be **July** 1.

****

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the page(s) **203** of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

****

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

****

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

****

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

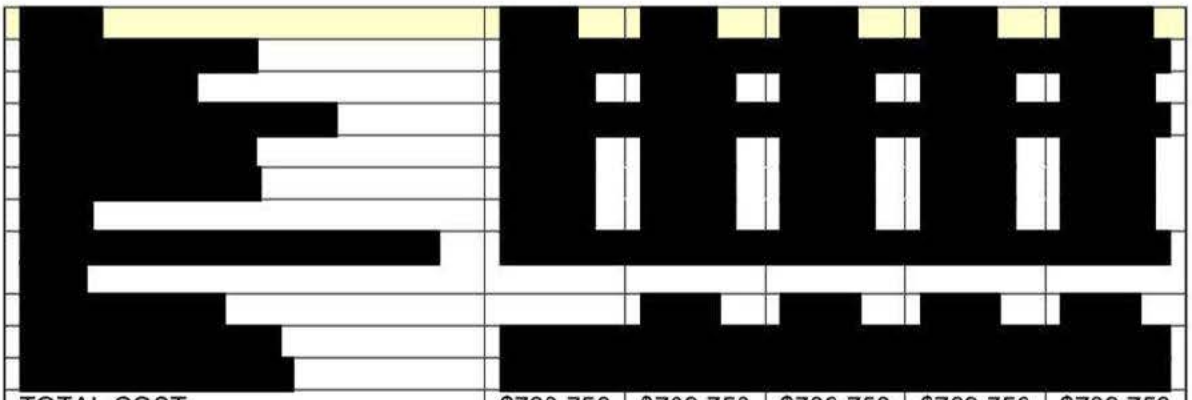
The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Tseday G Girma
Email: (b) (6) **Phone**: (b) (6) **Fax**: 301-493-0597

Program Official: Erik J. Stemmy
Email: (b) (6) **Phone**: (b) (6)

SPREADSHEET SUMMARY
GRANT NUMBER: 2R01AI110964-06

INSTITUTION: ECOHEALTH ALLIANCE, INC.



TOTAL COST	$733,750	$709,750	$709,750	$709,750	$709,750

Facilities and Administrative Costs	Year 6	Year 7	Year 8	Year 9	Year 10
F&A Cost Rate 1	32%	32%	32%	32%	32%
F&A Cost Base 1	$438,711	$363,711	$363,711	$363,711	$363,711
F&A Costs 1	$140,388	$116,388	$116,388	$116,388	$116,388

Exhibit B

Date: April 19, 2020

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.19 10:47:40 -04'00'

To: Kevin Olival, PhD
Vice-President for Research
EcoHealth Alliance
(b) (6)

Naomi Schrag, JD
Vice-President for Research Compliance, Training, and Policy
Columbia University
(b) (6)

Subject: Project Number 2R01AI110964-06

Dear Dr. Olival and Ms. Schrag:

EcoHealth Alliance, Inc. is the recipient, as grantee, of an NIH grant entitled "Understanding the Risk of Bat Coronavirus Emergence." It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ("WIV"). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs.

While we review these allegations during the period of suspension, you are instructed to cease providing any funds from the above noted grant to the WIV. This temporary action is authorized by 45 C.F.R. § 75.371(d) ("Initiate suspension or debarment proceedings as authorized under 2 C.F.R. part 180"). The incorporated OMB provision provides that the funding agency may, through suspension, immediately and temporarily exclude from Federal programs persons who are not presently responsible where "immediate action is necessary to protect the public interest." 2 C.F.R. § 180.700(c). It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.

Exhibit C

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Sunday, April 19, 2020 11:00 AM
To: (b) (6); Naomi Schrag (b) (6)
Cc: Black, Jodi (NIH/OD) [E] (b) (6)
Subject: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Importance: High

Dear Dr. Olival and Ms. Schrag

Please see attached. (Referring to Exhibit B)

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Kevin Olival [redacted]
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 20, 2020 at 4:12:28 PM EDT
To: "Lauer, Michael (NIH/OD) [E]" [redacted]
Cc: Naomi Schrag [redacted] "Black, Jodi (NIH/OD) [E]" [redacted]

Dear Mike,

I received the attached letter, however please note:

1. I am not the PI on this award. You should contact Dr. Peter Daszak [redacted] who is the PI and leading this project for EcoHealth Alliance.
2. Columbia University is not involved in this NIH project, and it is not clear to me why Naomi and Columbia University were included.

Thank you,
Kevin

Kevin J. Olival, PhD
Vice President for Research

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

[redacted] (direct)
[redacted] (mobile)
1.212.380.4465 (fax)
www.ecohealthalliance.org

Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Lauer, Michael (NIH/OD) [E] (b) (6)

Mon 4/20/2020 4:31 PM

To: Kevin Olival (b) (6); Peter Daszak (b) (6)

Cc: Naomi Schrag (b) (6); Black, Jodi (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6);

Importance: High

2 attachments

Screen Shot 2020-04-20 at 4.23.38 PM.png; EcoHealth Alliance re AI grant 4 19 20.pdf;

Thank you Kevin

- We need to work with a senior responsible business official – usually PI's and senior business officials are different people.
- When I looked you up on the web, I see the Columbia logo (see attached screenshot). Specifically, it appears to be Columbia University > Ecology, Evolution, and Environmental Biology > EcoHealth Alliance (labeled as an "Affiliation/Department"). Thus the web profile makes it look to me as if EcoHealth Alliance is linked to Columbia University.
- In any case, I'm looping in Dr. Daszak.
- We need to know all sites in China that have been in any way linked to this award (Type 1 and Type 2). We have data in NIH, but we want to make absolutely sure that we're of the same understanding.

We greatly appreciate your prompt attention to this matter.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

4 Michael Lauer email on 20 April 2020

Lauer, Michael (NIH/OD) [E] (b) (6)

Mon 4/20/2020 6:34 PM

To:Naomi Schrag (b) (6); Kevin Olival (b) (6) Peter Daszak (b) (6);

Cc:Black, Jodi (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6);

1 attachment

Screen Shot 2020-04-20 at 4.23.38 PM.png;

Thanks Naomi – not the impression an observer would get looking at the website (see screen shot), but we understand about the grant.

If they "are entirely separate entities" then why does Columbia identify EcoHealth Alliance as an "Affiliation/Department" on its website.

Maybe with the label "Affiliation/Department" you would have a clearly visible disclaimer that says, "EcoHealth Alliance is not affiliated with nor a department of Columbia"? – although even that is internally contradictory.

Best, Mike

From: Naomi Schrag (b) (6)
Date: Monday, April 20, 2020 at 5:19 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6), Kevin Olival (b) (6), (b) (6)
Cc: Naomi Schrag (b) (6), "Black, Jodi (NIH/OD) [E]" (b) (6)
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Dear Dr. Lauer,
Columbia and EcoHealth Alliance are entirely separate entities. Some individuals affiliated with EcoHealth Alliance do have adjunct appointments in Columbia's Ecology, Evolution, and Environmental Biology ("E3B") department, but we are not aware of any Columbia involvement with the referenced grant, and have found no agreement or record in our grants system to the contrary.

We would be happy to answer any additional questions. Thank you.
Sincerely,
Naomi Schrag

Naomi J. Schrag

Vice President for Research Compliance, Training and Policy
Office of Research Compliance and Training
475 Riverside Drive, Suite 840
New York, New York 10115
(b) (6)
www.researchcompliance.columbia.edu

RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

5 Peter Daszak email on 21 April 2020

Peter Daszak

Tue 4/21/2020 1:32 AM

To: Lauer, Michael (NIH/OD) [E] (b) (6); Naomi Schrag (b) (6); Kevin Olival (b) (6)

Cc: Black, Jodi (NIH/OD) [E] (b) (6);

Dear Michael Lauer & Jodi Black – I now have your email and will deal with it directly with you and your staff. Naomi is correct that there is no involvement of Columbia University in this grant. I'm sure NIH has records to confirm that.

From this moment on, I will not cc any staff at Columbia as part of this discussion, and I hope you will also honor that. Respecfully, the discussion of whether or not EHA is an affiliate of CU is entirely irrelevant to the request that you contacted us about, and should remain a private matter between EcoHealth Alliance and Columbia University.

I'll look over your email and respond tomorrow.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

6 Peter Daszak email on 21 April 2020

Peter Daszak

Tue 4/21/2020 7:03 PM

To:Lauer, Michael (NIH/OD) [E] (b) (6);

Cc:Black, Jodi (NIH/OD) [E] (b) (6); Aleksei Chmura (b) (6);
Stemmy, Erik (NIH/NIAID) [E] (b) (6); (b) (6);

Importance: High

1 attachment

EcoHealth Alliance re AI grant 4 19 20.pdf;

Dear Michael – Confirming receipt of your email. I'm also cc'ing the following people so they're aware of this request:

1. Our AOR – Dr. Aleksei Chmura, who has access to all our records
2. My Program Officer for this award, Dr. Erik Stemmy & the Division Director (DMID), Dr. Emily Erberding, so they are informed and aware of the request and our response.

That said we need some time to go through the request for information and will provide this as quickly as we can.

However, **I can categorically state that no funds form 2R01AI110964-06 have been sent to Wuhan Institute of Virology, nor has any contract been signed.** Furthermore, we will comply with NIAID requirements, of course.
Concerning the request for information on all of the sites linked to this award in China, you should be aware that these are documented in our progress reports over the course of the grant. As you can understand we are under enormous pressure to generate data related to the current pandemic, and we do not want to divert staff to this effort. We are hoping the previously filed reports will satisfy this request.

We are well aware of the political concerns over the origins of this outbreak. Our collaboration with Wuhan Institute of Virology has been scientific and we have been consistently impressed with the scientific capabilities of that laboratory and its research staff. Our joint work has led to a series of critical papers published in high impact journals that served to raise awareness of the future threat coronaviruses pose for global health and therefore US national security. Scientific insights with epidemiological significance have been jointly published and our relationship has always been open and transparent and with one concern only, scientific validity. We are concerned that current actions may jeopardize 15 years of fruitful collaboration with colleagues in Wuhan, who are working at the leading edge to design vaccines and drugs that could help us fight this new threat in future years. It is quite remarkable that of the 5 vaccine candidates listed by WHO that are already in human trials, 3 have been developed in China. That said, we of course will

do all we can to make sure any further questions from NIH or any Federal agency are addressed to our fullest knowledge.

Yours sincerely,

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

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Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: **Lauer, Michael (NIH/OD) [E]** (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 21, 2020 at 19:28
To: Peter Daszak (b) (6)
Cc: Black, Jodi (NIH/OD) [E] (b) (6), Aleksei Chmura (b) (6), Stemmy, Erik (NIH/NIAID) [E] (b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6)

ML

Many thanks Peter for your response.

We note that:

- No monies have gone to WIV on the Type 2 award and no contract has been signed.
- You agree that you will not provide any funds to WIV until and unless directed otherwise by NIH.
- All foreign sites for the Type 1 and Type 2 awards have been documented in the progress reports submitted to NIH.

We appreciate your working with us.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

8 Aleksei Chmura email on 21 April 2020

From: **Aleksei Chmura** (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 23, 2020 at 13:50
To: Lauer, Michael (NIH/OD) [E] (b) (6)
Cc: Peter Daszak (b) (6), Black, Jodi (NIH/OD) [E] (b) (6), Erik Stemmy (b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6)

(b) (6)

Dear Mike,

I read that we are in agreement and in compliance with all requests. Please let us know if anything further is required. We will continue in our usual close communication with our Program Officer Erik Stemmy.

Sincerely,

-Aleksei

Aleksei Chmura
Chief of Staff &
Authorized Organizational Representative

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

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From: **Lauer, Michael (NIH/OD) [E]** (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 23, 2020 at 13:59
To: Aleksei Chmura (b) (6)
Cc: Peter Daszak (b) (6), Black, Jodi (NIH/OD) [E] (b) (6), Stemmy, Erik (NIH/NIAID) [E] (b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6), Compliance Review

ML

Many thanks Aleksei.

9 Michael Lauer email on 21 April 2020

Best, Mike

From: **Lauer, Michael (NIH/OD) [E]** (b) (6)
Subject: PLEASE READ -- Re: Please read and acknowledge receipt - Actions needed regarding 2R01AI110964-06

Date: April 24, 2020 at 16:47
To: Aleksei Chmura (b) (6), Peter Daszak (b) (6)
Cc: Black, Jodi (NIH/OD) [E] (b) (6), Stemmy, Erik (NIH/NIAID) [E] (b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6), Linde, Emily (NIH/NIAID) [E] (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6), Bulls, Michelle G. (NIH/OD) [E] (b) (6)

10 Michael Lauer email on 24 April 2020

Dear Dr. Chmura and Dr. Daszak

Please see attached. (Referring to Exhibit D)

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: **Aleksei Chmura** (b) (6)
Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 27, 2020 at 23:57
To: Lauer, Michael (NIH/OD) [E] (b) (6)
Cc: Peter Daszak (b) (6), Black, Jodi (NIH/OD) [E] (b) (6), Erik Stemmy (b) (6), Emily Erbelding (b) (6), Linde, Emily (NIH/NIAID) [E] (b) (6), Bulls, Michelle G. (NIH/OD) [E] (b) (6), Alison Andre (b) (6)

(b) (6)

Dear Michael,

Could Peter and I have a quick chat with you sometime tomorrow (Tuesday) about your email, below?

Sincerely,

11 Aleksei Chmura email on 27 April 2020

-Aleksei

Aleksei Chmura, PhD
Chief of Staff

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

Exhibit D

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

24 April 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: Termination of NIH Grant R01 AI 110964

Dear Drs. Chmura and Daszak:

I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS) has elected to terminate the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964, for convenience. This grant project was issued under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284). This grant was funded as a discretionary grant as outlined in the NIH Grants Policy Statement, which states that the decision not to award a grant, or to award a grant at a particular funding level, is at the discretion of the agency, in accordance with NIH's dual review system.

At this time, NIH does not believe that the current project outcomes align with the program goals and agency priorities. NIAID has determined there are no animal and human ethical considerations, as this project is not a clinical trial, but rather an observational study.

As a result of this termination, a total of $369,819.56 will be remitted to NIAID and additional drawdowns will not be supported. The remaining funds have been restricted in the HHS Payment Management System, effective immediately.

Please let me know if you have any questions concerning the information in this letter.

Sincerely,

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.04.24 16:41:16 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

Exhibit E

SPECIFIC AIMS

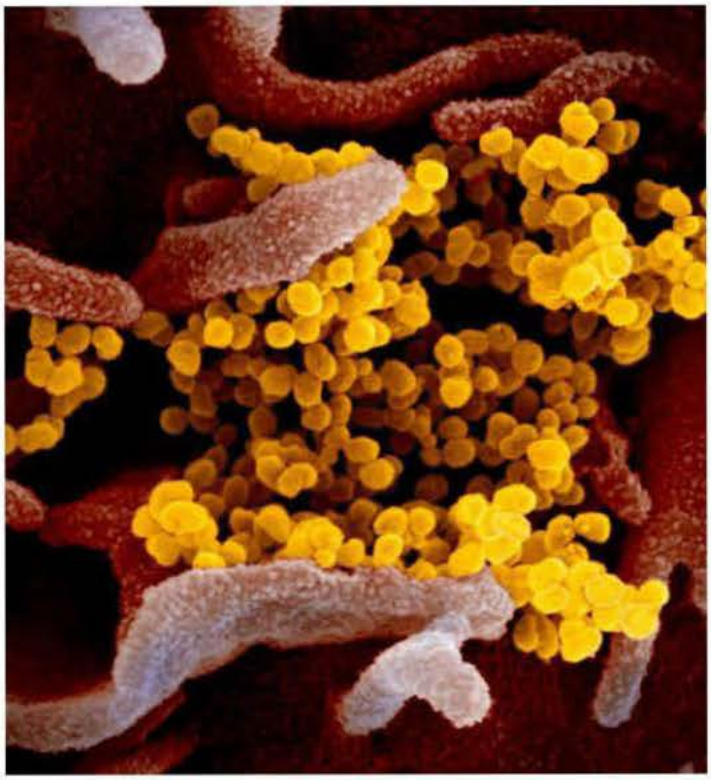
Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) in 2002, and the continuing spread of Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then we have sequenced dozens of novel SARS-related CoV (SARSr-CoV) strains. Our previous R01 work demonstrates that bats in southern China harbor an extraordinary diversity of SARSr-CoVs, some of which are able to use human ACE2 to enter into human cells, can infect humanized mouse models to cause SARS-like illness, and evade available therapies or vaccines. We found that the bat hosts of SARSr-CoVs appear to no longer be traded in wildlife markets, and that people living close to bat habitats are the primary risk groups for spillover. At one of these sites, we found diverse SARSr-CoVs containing every genetic element of the wild-type SARS-CoV genome, and serological evidence of human exposure among people living nearby. Thus, there is significant potential for future spillover of SARSr-CoVs, and of public health impacts. *Yet salient questions remain: Are there specific bat communities and sites that harbor CoV strains with higher risk for bat-to-human spillover? Which human behaviors drive risk of bat SARSr-CoV exposure that could lead to infection? Does human exposure to these viruses cause SARS-like or other illness? Can we characterize viral strain diversity, bat traits and human behaviors to assess risk of potential future CoV spillover?* **The proposed work in this renewal R01 builds on these findings** to address these issues by conducting: **1)** focused sampling of bats in southern China to **identify viral strains with high predicted risk of spillover**; **2)** community-based, and clinic-based syndromic, sampling of people to **identify spillover, and assess behavioral risk factors and evidence of illness**; and **3)** conduct *in vitro* and *in vivo* viral characterization and analyze epidemiological data **to identify hotspots of future CoV spillover risk**. This work will follow 3 specific aims:

Aim 1: Characterize the diversity and distribution of high spillover-risk SARSr-CoVs in bats in southern China. We will conduct targeted bat sampling at sites where we predict that undiscovered high risk SARSr-CoV strains exist. Bat sampling will be targeted geographically and by host species to test predictions about evolutionary diversity of SARSr-CoV. We will analyze RdRp and S protein sequences to test their capacity for spillover to people in Aim 3.

Aim 2: Community- and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences. We will conduct focused, targeted human surveys and sampling to identify key risk factors for SARSr-CoV spillover and evidence of illness. To maximize our opportunity of capturing human exposure to bat CoVs, we will conduct community-based surveillance in regions with high SARSr-CoV prevalence and diversity, and individuals having contact with bats. We will assess bat-CoV seropositive status against a small number of questions about human-wildlife contact and exposure. We will conduct clinic-based syndromic surveillance close to these sites to identify patients presenting with influenza-like illness and severe acute respiratory illness, assess their exposure to bats via a questionnaire, and test samples for PCR- and serological evidence of SARSr-CoV infection. We will conduct follow-up sampling to capture patients who had not yet seroconverted at the time of clinic visit.

Aim 3: *In vitro* and *in vivo* characterization of SARSr-CoV spillover risk, coupled with spatial and phylogenetic analyses to identify the regions and viruses of public health concern. We will characterize the propensity of novel SARSr-CoVs to infect people *in vitro* using primary human airway epithelial cells and *in vivo* using the transgenic hACE2 mouse model. We will use mAb and vaccine treatments to test our hypothesis that SARSr-CoVs with 10-25% divergence in S protein sequences from SARS-CoV are likely able to infect human cells, and to evade mAb therapeutics and vaccines. We will then map the geographic distribution of their bat hosts and other ecological risk factors to identify the key 'hotspots' of risk for future spillover.

Overall, our SARSr-CoV program serves as a model platform to integrate virologic, molecular and ecologic factors contributing to CoV emergence while informing high impact strategies to intervene and prevent future pandemics. This includes providing critical reagents, therapeutic interventions and recombinant viruses for future SARSr-CoV pandemic and public health preparedness.



This scanning electron microscope image shows SARS-CoV-2 (yellow), the virus that causes COVID-19, isolated from a patient in the United States, emerging from the surface of cells (pink) cultured in the lab. Credit: NIAID-RML

NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

FY2020 – FY2024

April 22, 2020

NIH National Institute of Allergy and Infectious Diseases

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

Table of Contents

Executive Summary

The National Institute of Allergy and Infectious Diseases (NIAID) at the United States (U.S.) National Institutes of Health (NIH) is committed to safeguarding the health of Americans and people around the world by accelerating research efforts to prevent, diagnose, and treat COVID-19 and characterize the causative agent of this disease, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This *NIAID Strategic Plan for COVID-19 Research* builds on current trans-NIAID efforts to better understand SARS-CoV-2 pathogenesis, transmission, and mechanisms of protective immunity by expanding resources and activities that support rapid development of biomedical tools to more effectively combat this disease and pandemic. Given the urgency of the public health response, studies that inform efforts to control virus spread and mitigate morbidity and mortality, including therapeutic and vaccine development, are the priority. In addition, it is essential to develop rapid, accurate, point-of-care diagnostics—a critical asset to mitigating the spread of COVID-19.

Box 1
NIAID Strategic Plan for COVID-19 Research Mission

Conduct and support research on SARS-CoV-2 and COVID-19 to accelerate the development of safe and effective medical countermeasures that decrease disease incidence, mitigate morbidity and prevent mortality.

The *NIAID Strategic Plan for COVID-19 Research* aligns with the priorities set by U.S. Government–wide task forces for the development of medical countermeasures. NIAID actively participates in COVID-19 task forces to identify opportunities, ensure open communication, encourage resource sharing, and avoid duplication of effort. The plan is structured around four strategic research priorities:

1. **Improve fundamental knowledge of SARS-CoV-2 and COVID-19,** including studies to characterize the virus and how it is transmitted and understand the natural history, epidemiology, host immunity, disease immunopathogenesis, and the genetic, immunologic, and clinical associations with more severe disease outcomes. This includes accelerating the development of small and large animal models that replicate human disease.

2. **Support the development of diagnostics and assays**, including point-of-care molecular and antigen-based diagnostics for identifying and isolating COVID-19 cases and serologic assays to better understand disease prevalence in the population. Diagnostics also will be essential for evaluating the effectiveness of candidate countermeasures.

3. **Characterize and test therapeutics**, including identifying and evaluating repurposed drugs and novel broad-spectrum antivirals, virus-targeted antibody-based therapies (including plasma-derived intravenous immunoglobulin (IVIG) and monoclonal antibodies), and host-directed strategies to combat COVID-19.

4. **Develop safe and effective vaccines against SARS-CoV-2,** including support of clinical trial testing.

To accelerate research, NIAID will leverage current resources and global collaborations, including existing research programs and clinical trials networks. NIAID's research response to COVID-19 will build on experience with diseases caused by other zoonotic coronaviruses (CoVs), including severe acute

respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). NIAID will pursue public-private partnerships to facilitate the translation of research outcomes into life-saving public health interventions. Working with pharmaceutical companies, NIAID has already initiated Phase 1 clinical trials for candidate COVID-19 vaccines and therapeutics. A concerted effort will be made to include minority populations, as well as at-risk and vulnerable populations, in all aspects of NIAID-sponsored research to address health disparities between diverse groups. Characterization of the fundamental virology of SARS-CoV-2 and the immunological response to infection will inform future studies and facilitate the development of effective medical countermeasures. With collaboration from all agencies within the U.S. government and other key U.S. and global partners, NIAID will rapidly disseminate these results so that the information can be translated into clinical practice and public health interventions to combat the pandemic. As such, NIAID has already implemented open sharing of scientific data through publicly available websites and will continue to promote the prompt disclosure of SARS-CoV-2 and COVID-19 research data by the scientific community.

Research Plan

Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Developing effective medical and public health countermeasures against a newly emergent virus like SARS-CoV-2 will require a better understanding of the complex molecular and immune mechanisms underlying infection and disease. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Early studies suggest that the clinical manifestations of COVID-19 can vary significantly, and disease severity can range from mild to critical. Thus, a detailed understanding of the clinical course of disease, as well as the clinical, virologic, immunological, and genetic predictors of disease severity, are needed. Gaps also exist in our understanding of the dynamics of disease transmission in different populations over time, including the role of pediatric and elderly populations in viral spread, and the potential seasonality of viral circulation.

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection

- **Support the development and distribution of reagents and viral isolates to researchers.** NIAID will continue to support both intramural and extramural researchers by developing reagents and assays for virus characterization and immunological analyses. NIAID will continue to accelerate SARS-CoV-2 research by sourcing viral isolates and clinical specimens for the research community and placing them in repositories to help advance research and countermeasure development. In addition, NIAID will place other critical reagents needed for assay development (e.g., pseudovirions and antigens) in publicly available repositories for distribution.

- **Characterize virus biology and immunological responses to disease.** A comprehensive understanding of the

Box 2
Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection
Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies
Objective 1.3: Develop animal models that recapitulate human disease

biological processes involved in SARS-CoV-2 infection and the pathogenesis of COVID-19 are paramount to developing new medical countermeasures to fight the spread of disease. Building on prior research related to MERS and SARS coronaviruses, early studies confirmed several critical features of SARS-CoV-2 infection, including the primary host receptor, angiotensin converting enzyme 2 (ACE-2), and the structure of the virus receptor-binding domain. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Understanding the function of essential viral proteins will be necessary for improving diagnostic and immunological assays, *in vitro* and *in vivo* models, and other resources needed to advance safe and effective medical countermeasure development. In addition, evaluating the dynamics of host-pathogen interactions at the molecular and cellular levels will be critical to advancing our understanding of viral pathogenesis and immune responses that contribute to SARS-CoV-2 infection.

- **Determine viral evolution and molecular epidemiology.** With a newly emergent virus like SARS-CoV-2, studies to characterize genetic diversity, including those that assess the potential for the virus to evolve and escape host immunity, are pivotal for understanding disease progression and transmission dynamics and may have implications for countermeasure development. Viral genomic analysis matched with patient clinical data will be important to identify biomarkers of virulence and establish paradigms of sequence diversity. In addition, evaluating viral sequence associations with disease outcomes, immune status, and viral replication will provide crucial data to accelerate the development of effective medical countermeasures.

- **Develop low-containment assays to study virus neutralization.** Studies using non-infectious pseudovirions can be conducted in labs without BSL-3 capacity, making them an important tool to enhance understanding of SARS-CoV-2 infection. This capability would enable researchers without high-containment infrastructure to study the dynamics of virus neutralization *in vitro*.

- **Research into optimal public health prevention and mitigation modalities**. Clinical trials including family members of a COVID-19 positive individual can be devised to evaluate transmission, prevention, and other mitigation measures within the household.

Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies

- **Characterize disease incidence through surveillance studies.** Clinical manifestations of COVID-19 can vary greatly, ranging from asymptomatic or mildly symptomatic to the development of pneumonia, acute respiratory distress syndrome, and even death.[1] The variation in clinical presentation of COVID-19, combined with the challenges in diagnostic capacity, have made accurate initial assessments of disease incidence a formidable challenge. However, rapid point-of-care and point-of-need molecular tests, which became available in March 2020, will enable hospitals and other healthcare facilities to make informed decisions regarding patient isolation and care. Studies that leverage existing high-throughput diagnostic capacity along with these rapid tests will advance our understanding of disease incidence across the nation and will be a critical component of strategies to implement effective medical countermeasures. Combining these studies with broad serosurveillance studies across existing surveillance networks, including blood bank studies, would

[1] Wu Z and McGoogan JM. *JAMA* 2020 Feb 24. Epub. PMID 32091533.

provide a more complete picture of the scope of disease and the dynamics of infection. Detailed knowledge of host genetics and the human responses to infection across the lifespan will not only provide insights into new approaches for diagnosis, treatment, and prevention, but also may elucidate why individuals respond to SARS-CoV-2 in different ways. Reports to date suggest that COVID-19 resolves in most cases,[2] implying that the immune system can keep the infection from progressing to severe disease in many individuals. However, additional research is needed to better understand why some people progress to severe disease, which will lend critical insights to medical countermeasure development.

- **Assess the dynamics of disease transmission.** Our current understanding of COVID-19 transmission is limited. While recent studies have suggested timeframes for virus survival in aerosols and on surfaces,[3] the contributions of different routes of transmission and the dynamics of animal-to-human and human-to-human transmission remain unclear. The diverse clinical presentations of COVID-19, including a high prevalence of asymptomatic cases, add further complexity to understanding transmission dynamics. Providing a clearer picture of the natural history of viral shedding is a priority, both in acute cases and in asymptomatic infection. Given the challenges of accurately diagnosing asymptomatic individuals because they do not present for treatment, determining the role they play in transmission would provide valuable insights. Elucidating the role of pediatric cases in the spread of SARS-CoV-2 is particularly important. Although pediatric COVID-19 cases are generally asymptomatic or have less severe clinical manifestations than those of adults, the role that children play in spreading the virus is unknown. Additionally, studies to identify potential animal reservoirs and better understand transmission from animals to humans are a research priority, as these reservoirs may lead to future virus introductions and re-emergence of disease in humans. Virus transmission depends on a complex interplay of host, viral, and environmental factors that contribute to disease incidence and spread. Identifying the factors that maintain the disease transmission cycle is critical to developing effective medical countermeasures and public health interventions that will prevent future pandemics.

- **Determine disease progression through natural history studies.** Delineating the natural history of COVID-19 will inform immunopathogenesis, viral tropisms and length of shedding, immune phenotypes, and both protective immunity and host susceptibility. Disease assessment using longitudinal cohort studies, including among high-risk populations such as healthcare workers and the elderly, are important to better understand disease pathogenesis and immune responses to infection. Biomarkers identified from these studies may provide valuable insights into predictors of disease severity.

Objective 1.3: Develop animal models that recapitulate human disease

- **Develop small and large animal models that replicate SARS-CoV-2 pathogenesis.** Developing animal models that recapitulate human disease is a vital early step toward understanding disease pathogenesis and testing the efficacy of medical countermeasures. Small animal models enable rapid, scalable analyses that are particularly valuable for screening countermeasure candidates for efficacy and addressing issues concerning vaccine-induced immune enhancement. Among the small animal models being tested, transgenic mice expressing the human ACE-2 receptor are a promising candidate. In parallel, development and characterization of large animal models, including non-human primates (NHPs) that mimic human COVID-19, are a pivotal step to advance promising

[2] ibid.

[3] van Doremalen *N et al. N Engl J Med* 2020 Mar 17. Epub. PMID 32182409.

countermeasure candidates. Previous experience with related coronavirus diseases such as MERS and SARS suggests that replicating human disease, particularly its more severe manifestations, in an animal model may be challenging. Fundamental research assessing animal models ranging from mice to NHPs is already underway. NIAID will continue to support the development of small and large animal model candidates to better understand this emerging infection and investigate optimal ways to treat and prevent COVID-19. NIAID also will ensure that validated animal models are made available to the scientific community for evaluating priority countermeasures.

Priority 2: Support the development of diagnostics and assays

Availability of rapid, accurate Food and Drug Administration (FDA)-cleared or authorized diagnostics will increase testing capacity and are critical for identifying and rapidly isolating cases, tracking spread of the virus, managing patient care, and supporting clinical trials. Molecular tests specifically designed to detect SARS-Cov-2 RNA in clinical samples are able to detect low levels of pathogen in clinical samples and offer robust specificity in differentiating SARS-CoV-2 from other related viruses. Continuing to improve the speed and accuracy of molecular and antigen-based diagnostics and making them available at point- of-care will be paramount to accelerating the ability to mitigate disease spread in the current outbreak and any future outbreaks. The development of serologic assays would further bolster surveillance efforts, including the ability to identify individuals who may have resolved prior infection with SARS-CoV-2.

Objective 2.1: Accelerate the development and evaluation of diagnostic platforms

- **Support the development, characterization and availability of reagents for diagnostic validation.** NIAID will support this effort through the development and testing of reagents for diagnostic validation that will be made available through NIAID-sponsored repositories.

Box 3 **Priority 2: Support the development of diagnostics and assays**
Objective 2.1: Accelerate the development and evaluation of diagnostic platforms *Objective 2.2: Develop assays to increase understanding of infection and disease incidence*

- **Support the development of new rapid diagnostics.** NIAID will provide funding to support the development of new rapid diagnostics, including molecular tests and novel antigen detection tests with improved sensitivity, if deemed feasible based on natural history studies.

- **Support the evaluation of promising diagnostics.** In some cases, stakeholders that develop potential diagnostic tests do not have the infrastructure needed to rigorously validate those tests against clinical samples. NIAID will support the testing of promising diagnostics and provide the capacity for evaluating them with live virus samples using our biocontainment laboratories.

Objective 2.2: Develop assays to increase understanding of infection and disease incidence

- **Develop and validate SARS-CoV-2 serological assays.** Serological tests, which detect host antibodies to infectious agents, do not detect the presence of a pathogen directly but can be used as a surrogate marker of infection. Developing more effective serologic tests would help provide information on the extent of asymptomatic infections and cumulative disease incidence, for example through serosurveillance studies. NIAID, with the Centers for Disease Control and

Prevention and the FDA, is developing tests that identify antibodies to SARS-CoV-2 proteins to determine seroprevalence rates and potentially help distinguish antibody responses in individuals receiving vaccines. NIAID will support the development and validation of additional serological assays for serosurveillance studies and as tools for testing the efficacy of promising vaccine or therapeutic candidates.

Priority 3: Characterize and test therapeutics

Currently, there are no FDA-approved or licensed therapeutics specific for coronaviruses. While traditional development pathways for therapeutics can take years, the urgency of the current outbreak underscores the need for rapid development and testing of promising therapeutics. Possible avenues for developing therapeutics include the evaluation of broad-spectrum antiviral agents (antivirals) that have shown promise for other coronaviruses and the identification of novel monoclonal antibodies (mAbs). For broad-spectrum antivirals, Phase 2/2b testing of the RNA polymerase inhibitor developed by Gilead, remdesivir, is already underway. Additional studies will be critical to identify promising therapeutic candidates and to advance them through clinical trial testing. To optimize findings during the pandemic, multiple clinical trials will be conducted in parallel among various populations, including both inpatient and outpatient studies.

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2

- **Screen protease inhibitor and nucleotide analogue class agents and other small molecules with documented activity against other coronaviruses SARS-CoV-2**. Screening drugs that are already licensed by the FDA for other indications and might be efficacious against SARS-CoV-2 infection may provide a route to identifying a therapeutic for use in the current pandemic. Broad-spectrum antivirals that are already FDA approved or in clinical development for other indications—including those previously targeting SARS-CoV-1 and MERS CoV—can be evaluated for their potential activity against SARS-CoV-2 infections. Approved therapeutics for other infectious diseases also are being evaluated as possible treatments for COVID-19. By leveraging their existing efficacy, safety, and manufacturability data, the time to development and production can be reduced. NIAID also will continue working with partners to screen compound libraries for potential activity against SARS-CoV-2. For these studies, priority will be given to compounds based on *in vitro* screening data and the existence of human safety data.

- **Identify viral targets for therapeutic development**. Advances in structural biology technology enable researchers to map key viral structures at an unprecedented level. The Structural Genomics Centers for Infectious Diseases (SGCID) apply state-of-the-art, high-throughput technologies and methodologies, including computational modeling, x-ray crystallography, nuclear magnetic resonance imaging, and cryogenic electron microscopy, to experimentally characterize the three dimensional atomic structure of proteins that play an important biological role in human pathogens and infectious diseases. NIAID will continue to support use of this powerful technology to identify viral targets of SARS-CoV-2 for therapeutics or vaccines.

Box 4
Priority 3: Characterize and test therapeutics

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2
Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates

- **Identify novel mAbs for use as therapy or prophylaxis.** Data from early studies indicate that well-characterized convalescent plasma may provide a treatment benefit in COVID-19.[4] Therefore, IVIG derived from convalescent plasma may also hold promise for treatment. Moreover, peripheral blood mononuclear cells and plasma are being used to identify novel neutralizing antibodies. Through collaborations with structural biologists, binding properties can be quickly assessed. Paired with assessment of neutralization activity, the most promising mAbs will be identified for further characterization in animal models and human trials.

Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates

- **Characterize and evaluate host-directed strategies for treatment of disease.** Experience with other coronaviruses indicates that infection of the respiratory tract is rapid and damage is primarily mediated by the host inflammatory response.[5] These conditions may make it difficult to modify COVID-19 with pathogen-directed therapeutics. Instead, host-directed strategies that target the immune response may exert a beneficial therapeutic effect. Host-directed strategies, including immune-modulating agents, will be investigated as potential therapeutic candidates.

- **Conduct clinical trials to demonstrate safety and efficacy of lead therapeutic candidates.** Many potential therapeutic candidates have been identified and are being tested in clinical trials.
  - In March 2020, NIAID launched a multicenter, adaptive, randomized controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral drug remdesivir (GS-5734) for the treatment of COVID-19 in hospitalized adults with laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement. The trial builds on recent studies by NIAID scientists showing that remdesivir can improve the disease course in rhesus macaques when administered promptly after viral challenge with the MERS CoV.[6] The trial is also adaptive, allowing for additional arms should other therapeutics warrant assessment for efficacy.
  - NIAID is finalizing the protocol for the Big Effect Trial (BET), in which putative therapeutics that have existing human data and are readily available will be tested in patients hospitalized with lower respiratory tract disease. Each potential intervention will be given to approximately 75 patients and evaluated for mitigating disease symptoms. Candidate therapeutics that meet the criteria in this initial study will be further evaluated in larger clinical trials for which the infrastructure is already in place.
  - As mentioned above, identification of novel mAbs for therapy or prophylaxis is another strategic priority. These mAbs should be safe, highly effective, amenable to fast manufacturing, and easy to administer. They will be tested in clinical trials to develop immunotherapies for the prevention and early treatment of COVID-19, potentially in high-risk populations including healthcare workers.

- **Conduct outpatient studies for mild COVID-19 cases**. In cases of mild COVID-19 that do not require hospitalization, outpatient studies could be extremely valuable for testing promising, orally administered FDA-approved drugs that have existing safety data. The antiviral activity of hydroxychloroquine and azithromycin against SARS-CoV-2 has been the focus of many early

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[4] Roback JD and Guarner J. *JAMA* 2020 Mar 27. Epub. 32219429.

[5] Newton AH et al. *Semin Immunopathol*. 2016;38(4):471-82. PMID 26965109.

[6] de Wit E et al. *Proc Natl Acad Sci USA* 2020;117(12):6771-6. PMID 32054787.

therapeutic studies.[7,8,9] Testing of these and other candidates, including protease inhibitors and other molecules, in outpatient studies may provide critical efficacy data and could identify an existing drug or drug combination that is safe and effective against COVID-19.

- **Conduct outpatient studies in high-risk populations.** High-risk populations, including health care workers, the elderly or individuals with chronic conditions, are a critical target for the development of therapeutics. Conducting studies in patients with mild cases of COVID-19 among these high-risk groups would be of interest for identifying the benefits of early treatment strategies to mitigate the impact of infection. Therapeutic candidates that have once a day dosing could also be considered for pre-exposure prophylaxis (PrEP) in some of these populations.

Priority 4: Develop safe and effective vaccines against SARS-CoV-2

Developing a safe and effective SARS-CoV-2 vaccine is a priority for preventing future outbreaks of the virus. As vaccine candidates for MERS-CoV, SARS-CoV-1 and other coronaviruses have previously been developed, NIAID investigators and the scientific community are well poised to use similar approaches in the current pandemic. NIAID will leverage its broad intramural and extramural infrastructure to advance vaccine candidates through Phase 1 safety and dosing clinical trials, with considerations for Phase 2/2b clinical trials for the most promising candidates.

Objective 4.1: Advance promising vaccine candidates through clinical trial testing

- **Conduct a Phase 1 clinical trial of (mRNA) platform candidate mRNA-1273.** Given the urgency of the response effort to develop a safe and effective vaccine, NIAID is prioritizing promising vaccine candidates that can be rapidly produced and tested. NIAID, in collaboration with the biotechnology company Moderna, is conducting a Phase 1 clinical trial of a vaccine candidate that uses a messenger RNA (mRNA) vaccine platform expressing a NIAID-designed recombinant spike protein of SARS-CoV-2. The trial is being conducted at NIAID-funded clinical research sites, with the first enrolled individual receiving the vaccine on March 16, 2020.

- **Prepare for a pivotal Phase 2/2b clinical trial of candidate mRNA-1273. Preparing for the likelihood of a seasonal recurrence of SARS-CoV-2 is imperative to the public health response.** Given the theoretical risk of vaccine-enhanced respiratory disease, large Phase 2 trials are unlikely to launch until this possibility is evaluated in animal models. Planning for those animal studies is underway, and, assuming favorable results, a Phase 2/2b study could be launched later in 2020. This represents a historically fast timeline for the development and testing of a vaccine candidate. Additionally, these studies will provide information on correlates of immunity that will help accelerate the advancement of other vaccine candidates. If the mRNA-1273 vaccine candidate shows protection against SARS-CoV-2 infection in a Phase 2/2b trial, NIAID will work with government partners to ensure that the vaccine is manufactured in sufficient quantities to allow prompt distribution to those at highest risk of acquiring disease.

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[7] Gautret P et al. *Int J Antimicrob Agents*. 2020 Mar 20:105949. Epub. PMID 32205204.

[8] Molina JM et al. 2020 Med Mal Infect. 2020 Mar 30. pii:S0399-077X(20)30085-8. Epub. PMID 32240719.

[9] Chen Z et al. medRxiv 2020:2020.03.22.20040758.
https://www.medrxiv.org/content/10.1101/2020.03.22.20040758v2

Box 5.
Priority 4: Develop safe and effective vaccines against SARS-CoV-2

Objective 4.1: Advance promising vaccine candidates through clinical trial testing
Objective 4.2: Advance vaccine development through assay and reagent development
Objective 4.3: Advance vaccine development through adjuvant characterization and development

- **Investigate additional candidates through NIAID vaccine programs.** Although promising candidates may show efficacy in preclinical studies, many do not translate into effective vaccines in clinical trials. Therefore, it is crucial to support multiple promising preclinical candidates in the research and development pipeline. To that end, NIAID is advancing multiple additional SARS-CoV-2 vaccine candidates through its Rocky Mountain Laboratories (RML), including approaches that have shown promise against coronaviruses that cause SARS and MERS. Building on previous research to develop a MERS-CoV vaccine, scientists at RML are collaborating with Oxford University investigators to develop a SARS-CoV-2 vaccine that uses a chimpanzee adenovirus vector. RML investigators also are partnering with the biopharmaceutical company CureVac on an mRNA vaccine candidate and collaborating with the University of Washington on a universal coronavirus vaccine development. By leveraging its extensive expertise and research infrastructure, NIAID will continue working with partners and collaborators to advance promising SARS-CoV-2 vaccine candidates.

- **Leverage existing vaccine approaches to target SARS-CoV-2.** NIAID is pursuing multiple strategies to develop a COVID-19 vaccine. Building on past research on emerging pathogens, especially MERS-CoV and SARS-CoV-1 (the virus that causes SARS), NIAID is using previously developed vaccine platforms to rapidly assess the potential of SARS-CoV-2 vaccine candidates. This approach has already resulted in several promising strategies that may be leveraged for SARS-CoV-2, including vaccination using recombinant spike protein, chimpanzee adenovirus vaccine vector, virus-like particles, and live attenuated virus. In addition, NIAID is funding the development of novel vaccine candidates that will be efficacious across the lifespan, including in the elderly.

Objective 4.2: Advance vaccine development through assay and reagent development

- **Develop critical reagents to support vaccine development**. Appropriate tools are needed to identify the most promising vaccine candidates and advance the development of lead candidates as rapidly as possible. To accelerate the vaccine pipeline, NIAID is generating master and working SARS-CoV-2 virus stocks and other reagents critical for developing SARS-CoV-2 immune assays, developing quantitative tests for characterizing SARS-CoV2 assay material, developing a quantitative SARS-CoV-2-specific ELISA, developing virus-specific neutralization assays, and developing quantitative assays for assessing SARS-CoV-2 viral load.

Objective 4.3: Advance vaccine development through adjuvant characterization and development

- **Provide adjuvants to support vaccine development**. Adjuvants are vaccine components that improve vaccine efficacy by inducing long-lived protective immunity. Selection of appropriate adjuvants is crucial for developing safe and effective vaccines. NIAID is working with multiple collaborators to provide adjuvants to the research community for use in SARS-CoV-2 vaccine candidates. These adjuvants are at various stages of development and include compounds that

specifically improve vaccine efficacy in elderly individuals or modulate host immunity toward protective responses while limiting or preventing harmful inflammatory responses.

Conclusion

The sudden emergence and rapid global spread of the novel coronavirus SARS-CoV-2 has created a daunting public health challenge. To address this challenge, NIAID is focusing its considerable expertise and emerging infectious disease resources to facilitate the development of medical countermeasures including diagnostics, therapeutics, and vaccines. The resulting discoveries will not only help mitigate the current pandemic, but also inform prevention, diagnosis, and treatment of future emerging infectious diseases.

A comprehensive strategy requires a coordinated effort among governmental, academic, private, and community-based organizations. The *NIAID Strategic Plan for COVID-19 Research* defines the areas of COVID-19 research within the NIAID mission and outlines the institute's research priorities and goals. This strategic plan builds on many other national efforts and represents a commitment from multiple U.S. government agencies to improve coordination of COVID-19 research and discovery efforts and the development of medical countermeasures.

From: Sanders, Ashley (NIH/OD) [E]
To: Miller, David A. (NK) (FBI)
Cc: Stemmy, Erik (NIH/NIAID) [E]; Shannon, Mike (NIH/OD) [E]
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Friday, May 22, 2020 3:18:05 PM
Attachments: SF 424 AI110964.docx

Hi David,

In preparation for our call on Tuesday, Erik (cc'd) has provided responses to your initial questions below (also attached).

Hope you have a great holiday weekend!

Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: (b) (6)
Cell: (b) (6)
(b) (6)ov

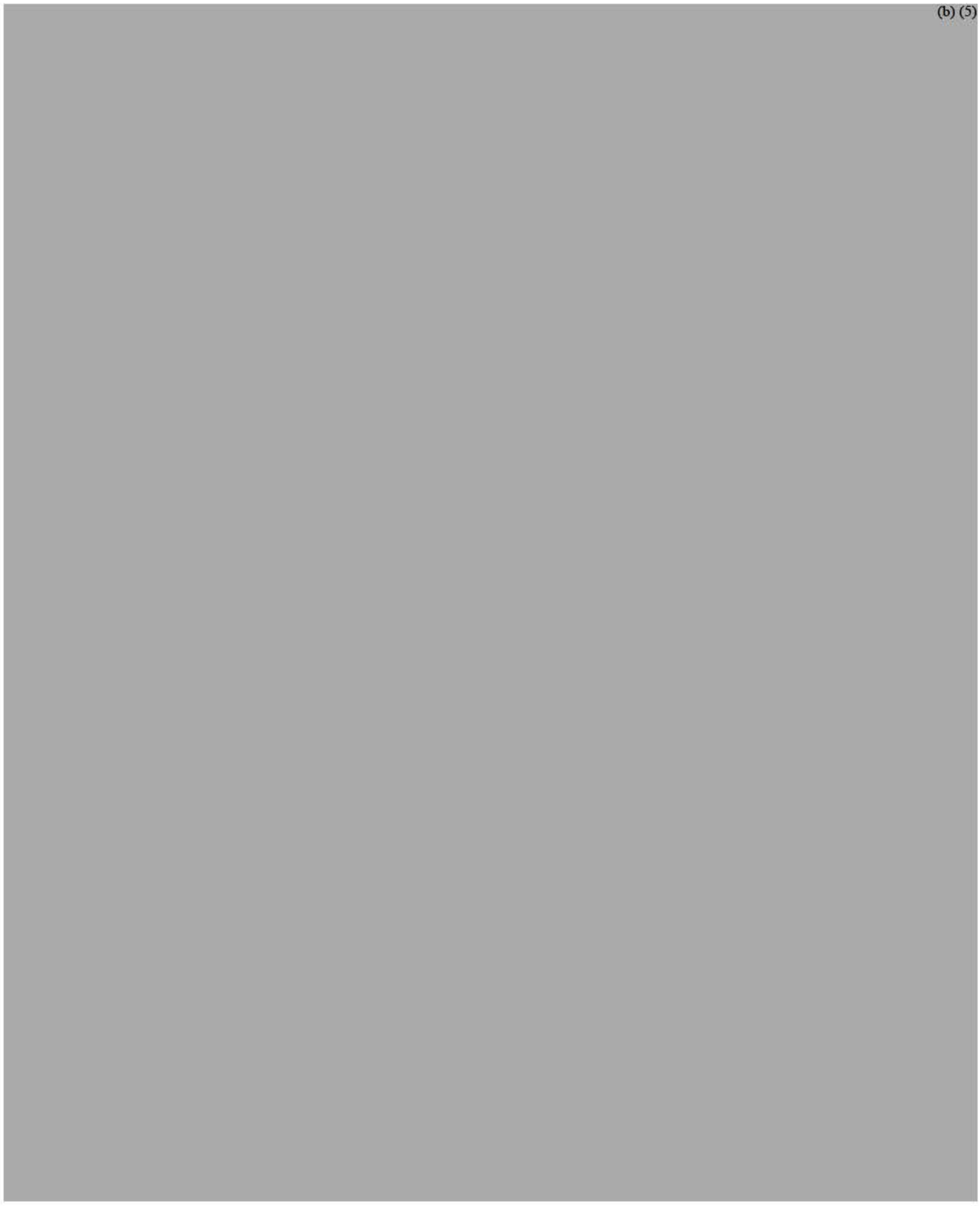
SF 424 AI110964-06 (received date 11/05/2018)

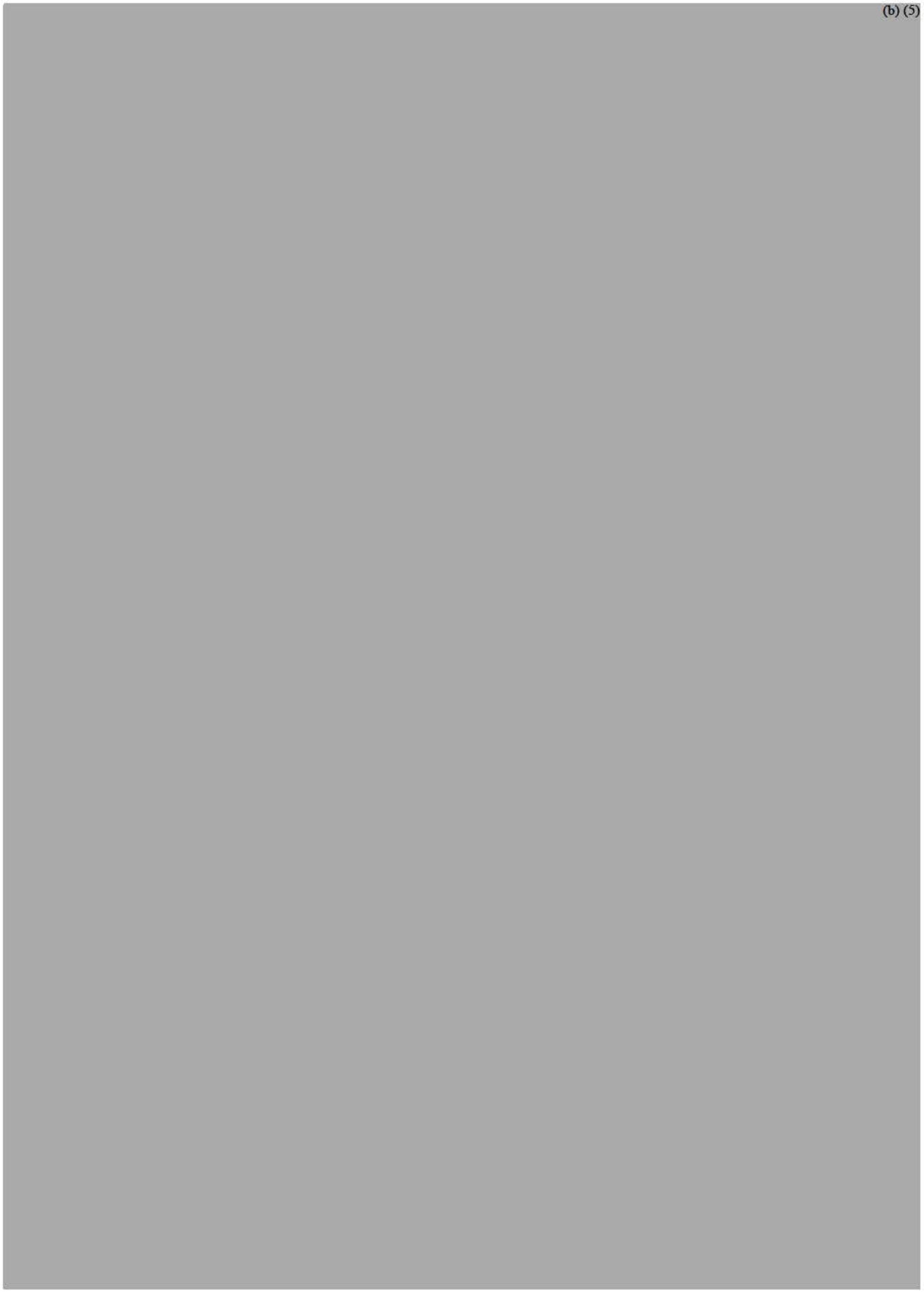
(b) (5)

SF 424 AI110964-06 (received date 11/05/2018)

(b) (5)

[redacted]





From: Miers, Sarah (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]
Cc: Abbey, Lillian (NIH/NIAID) [E]
Subject: FW: Round II Clearance: 390335 McSally (Wuhan Institute of Virology)
Date: Thursday, May 21, 2020 8:49:06 AM
Attachments: 390335 McSally #3 corr.pdf
390335-II McSally #3 cleardoc.pdf
390335 McSally NIAID Comments FINAL.docx

Hi Emily and Erik – the OER response to Senator McSally and Representative Gaetz about Wuhan has been edited and has come through for a second round of clearance. All NIAID comments were incorporated. Can you please let us know by 1:45 PM today if you are okay with it? It looks fine to me.
Thank you very much.
Sarah

From: "Harris, Kara (NIH/NIAID) [E]" (b) (6)
Date: Thursday, May 21, 2020 at 8:42 AM
To: NIAID DEA DART (b) (6) NIAID BUGS (b) (6) "Erbelding, Emily (NIH/NIAID) [E]" (b) (6)
Cc: NIAID OCGR Correspondence (b) (6) NIAID OCGR Leg (b) (6), "Eisinger, Robert (NIH/NIAID) [E]" (b) (6), "Marston, Hilary (NIH/NIAID) [E]" (b) (6), "Lerner, Andrea (NIH/NIAID) [E]" (b) (6), "McGowan, John J. (NIH/NIAID) [E]" (b) (6), "Harper, Jill (NIH/NIAID) [E]" (b) (6), "Billet, Courtney (NIH/NIAID) [E]" (b) (6), "Auchincloss, Hugh (NIH/NIAID) [E]" (b) (6)
Subject: Round II Clearance: 390335 McSally (Wuhan Institute of Virology)
Good morning –
Clearance due to NIAID OCGR Correspondence by **2:00 p.m. today, Thursday, May 21**.
Background: Attached for a second round of clearance is the draft response to Senator McSally and Rep. Gaetz. As you may recall, the members of Congress had written with concerns about NIH's relationship with the Wuhan Institute of Virology.
The response was drafted by OER. We had cleared the previous version of the response with comments earlier this month. Those comments have been incorporated.
The first attachment contains the incoming correspondence.
The second attachment contains the revised response.
The last attachment contains our comments on the previous version of the response. These are attached for your reference only.
Action: Please provide your clearance on the revised draft response and submit it to NIAID OCGR Correspondence by **2:00 p.m. today**. OSP is also clearing.
Thank you,
Kara

Congress of the United States
Washington, DC 20515

April 21, 2020

The Honorable Francis Collins, M.D.
Director, U.S. National Institutes of Health
600 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

Thank you for your leadership in confronting the coronavirus pandemic. We are writing to express our deep concerns regarding the National Institutes of Health's (NIH) past and current relationship with China's controversial bio-agent laboratory the Wuhan Institute of Virology (WIV) and to ensure no additional U.S. tax dollars are directed to this notorious institution.

On Friday evening, President Donald Trump announced his intention to cut NIH funding for WIV following reports that the agency has been supporting secretive and treacherous laboratory research at the WIV for many years.[1,2] According to the NIH's website, the WIV is currently authorized to receive taxpayer funding for animal research (Assurance ID# F16-00279).[3]

Taxpayers' money should not be sent to a dangerous Chinese state-run bio-agent laboratory that lacks any meaningful oversight from U.S. authorities and is run by adversaries with a history of lab leaks, including SARS, and deception about the causes and extent of deadly disease outbreaks, including COVID-19.

We respectfully request that all active grants, sub-grants and contracts awarded to WIV be canceled immediately and that WIV be stripped of its eligibility to receive taxpayer funds from the NIH in the future.

Additionally, please provide the following details about the NIH's relationship with the WIV:

- When did WIV first start receiving funding from the NIH?
- How much total taxpayer funding, by year, has WIV received from the NIH?
- List all active *and* inactive NIH grants, sub-grants or contracts that have in any way supported research at WIV. For each grant, please include:
    - Project title
    - Project number
    - Grantee institution

---

[1] Taxpayer-funded Animal Experiments Tied To Chinese 'Wet Markets' and Wuhan Laboratory, Carlin Becker - https://www.washingtonexaminer.com/news/taxpayer-funded-animal-experiments-tied-to-chinese-wet-markets-and-wuhan-laboratory

[2] Trump Says He'll End Obama-Era Funding To Chinese Lab That May Have Spawned The Coronavirus. David Krayden - https://dailycaller.com/2020/04/18/donald-trump-end-funding-china-lab-coronavrus-covid-19/

[3] NIH website, Institutions with a PHS Approved Animal Welfare Assurance - https://olaw.nih.gov/assured/app/index.html#FOREIGN

- Start and end dates
- Fiscal Year 2019 funding
- Total funding since grant's inception
- Details about WIV's involvement in the project

Thank you for your efforts and assistance in this matter. We look forward to working with you to ensure no future NIH funds are directed to the WIV. If you have any questions regarding this letter, please contact and Ed Kim with Sen. Martha McSally (edward_kim@mcsally.senate.gov) or Devin Murphy with Rep. Matt Gaetz (devin.murphy@mail.house.gov).

Sincerely,

Martha McSally
U.S. Senator

Matt Gaetz
Member of Congress

Cc: The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

(b) (5)

[redacted]

(b) (5)

390335 McSally
May 5, 2020

To: National Institutes of Health
Executive Secretariat

From: National Institute of Allergy and Infectious Diseases (NIAID)
Office of Communications and Government Relations

Subject: Clearance – Response Letter to Senator McSally and Rep. Gaetz

NIAID clears the response letter with the following comments:

1. (b) (5) [redacted]
2. [redacted]
3. [redacted]

From: Abbey, Lillian (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]
Cc: NIAID BUGS
Subject: FW: Clearance: 390335 McSally (Wuhan Institute of Virology)
Date: Monday, May 4, 2020 1:42:02 PM
Attachments: 390335 McSally #2 corr.pdf
390335 McSally #3 cleardoc.pdf

Hi Erik – wanted to loop you in...this response came back for our review by COB today. Must change edits only will be considered. Let us know if you have any concerns.
Thank you,
Lillian

From: Harris, Kara (NIH/NIAID) [E] (b) (6)
Sent: Monday, May 4, 2020 11:16 AM
To: NIAID BUGS (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); NIAID DEA DART (b) (6)
Cc: NIAID OCGR Correspondence (b) (6); NIAID OCGR Leg (b) (6); Eisinger, Robert (NIH/NIAID) [E] (b) (6); Marston, Hilary (NIH/NIAID) [E] (b) (6); Lerner, Andrea (NIH/NIAID) [E] (b) (6); McGowan, John J. (NIH/NIAID) [E] (b) (6); Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6)
Subject: RE: Clearance: 390335 McSally (Wuhan Institute of Virology)
Looping in DEA for this clearance too. Also, we are seeking must changes only.
Thanks!

From: Harris, Kara (NIH/NIAID) [E]
Sent: Monday, May 4, 2020 11:13 AM
To: NIAID BUGS (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Correspondence (b) (6); NIAID OCGR Leg (b) (6); Eisinger, Robert (NIH/NIAID) [E] (b) (6); Marston, Hilary (NIH/NIAID) [E] (b) (6); Lerner, Andrea (NIH/NIAID) [E] (b) (6); McGowan, John J. (NIH/NIAID) [E] (b) (6); Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6)
Subject: Clearance: 390335 McSally (Wuhan Institute of Virology)
Hi, all –
Please see below. We are now being asked to clear the draft response to Senator McSally and Rep. Gaetz. The response was drafted by OER.
Please provide your clearance on the draft response and submit it to NIAID OCGR Correspondence by **COB today, Monday, May 4**. OLPA, OSP, SARI, and FIC are also clearing.
Thank you,
Kara

From: Harris, Kara (NIH/NIAID) [E] (b) (6)
Sent: Thursday, April 23, 2020 12:42 PM
To: NIAID BUGS (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Lerner, Andrea (NIH/NIAID) [E] (b) (6); Marston,

Hilary (NIH/NIAID) [E] (b) (6); Eisinger, Robert (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); McGowan, John J. (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); Auchincloss, Hugh (NIH/NIAID) [E] (b) (6)

Cc: NIAID OCGR Correspondence (b) (6); NIAID OCGR Leg (b) (6)

Subject: FYI: 390335 McSally (Wuhan Institute of Virology)

FYI ONLY

Attached is correspondence from Senator Martha McSally and Rep. Matt Gaetz to Dr. Collins (with copy to the Secretary). They are writing with concerns about NIH's relationship with the Wuhan Institute of Virology.

Congress of the United States
Washington, DC 20515

April 21, 2020

The Honorable Francis Collins, M.D.
Director, U.S. National Institutes of Health
600 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

Thank you for your leadership in confronting the coronavirus pandemic. We are writing to express our deep concerns regarding the National Institutes of Health's (NIH) past and current relationship with China's controversial bio-agent laboratory the Wuhan Institute of Virology (WIV) and to ensure no additional U.S. tax dollars are directed to this notorious institution.

On Friday evening, President Donald Trump announced his intention to cut NIH funding for WIV following reports that the agency has been supporting secretive and treacherous laboratory research at the WIV for many years.[1,2] According to the NIH's website, the WIV is currently authorized to receive taxpayer funding for animal research (Assurance ID# F16-00279).[3]

Taxpayers' money should not be sent to a dangerous Chinese state-run bio-agent laboratory that lacks any meaningful oversight from U.S. authorities and is run by adversaries with a history of lab leaks, including SARS, and deception about the causes and extent of deadly disease outbreaks, including COVID-19.

We respectfully request that all active grants, sub-grants and contracts awarded to WIV be canceled immediately and that WIV be stripped of its eligibility to receive taxpayer funds from the NIH in the future.

Additionally, please provide the following details about the NIH's relationship with the WIV:

- When did WIV first start receiving funding from the NIH?
- How much total taxpayer funding, by year, has WIV received from the NIH?
- List all active *and* inactive NIH grants, sub-grants or contracts that have in any way supported research at WIV. For each grant, please include:
    - Project title
    - Project number
    - Grantee institution

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[1] Taxpayer-funded Animal Experiments Tied To Chinese 'Wet Markets' and Wuhan Laboratory, Carlin Becker - https://www.washingtonexaminer.com/news/taxpayer-funded-animal-experiments-tied-to-chinese-wet-markets-and-wuhan-laboratory

[2] Trump Says He'll End Obama-Era Funding To Chinese Lab That May Have Spawned The Coronavirus. David Krayden - https://dailycaller.com/2020/04/18/donald-trump-end-funding-china-lab-coronavrus-covid-19/

[3] NIH website, Institutions with a PHS Approved Animal Welfare Assurance - https://olaw.nih.gov/assured/app/index.html#FOREIGN

- Start and end dates
- Fiscal Year 2019 funding
- Total funding since grant's inception
- Details about WIV's involvement in the project

Thank you for your efforts and assistance in this matter. We look forward to working with you to ensure no future NIH funds are directed to the WIV. If you have any questions regarding this letter, please contact and Ed Kim with Sen. Martha McSally (edward_kim@mcsally.senate.gov) or Devin Murphy with Rep. Matt Gaetz (devin.murphy@mail.house.gov).

Sincerely,

Martha McSally
U.S. Senator

Matt Gaetz
Member of Congress

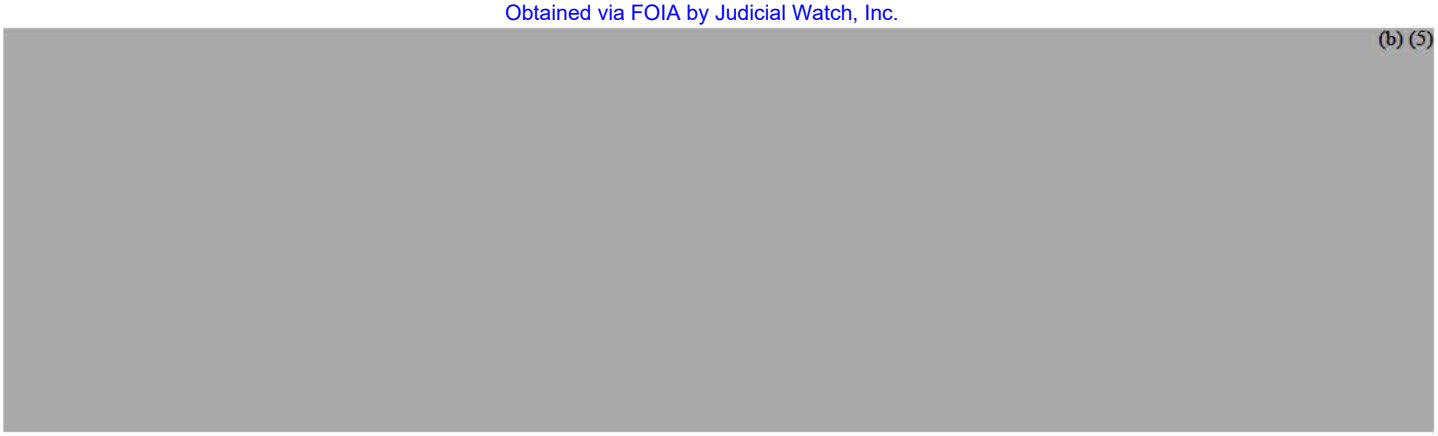
Cc: The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

(b) (5)



From: Schuster, Claire (NIH/NIAID) [E]
To: nCoV extramural response
Cc: NIAID BUGS
Subject: FW: COVID-19 Implementation Plan and Research Updates - 4.27.20
Date: Tuesday, April 28, 2020 10:47:16 AM
Attachments: 2020.04.27 COVID-19 Implementation Plan.docx
NIAID COVID-19 Full Weekly Update 4.27.20.docx

Sharing as an FYI –
Thanks,
Claire

From: Bushar, Nicholas (NIH/NIAID) [E] (b) (6)
Sent: Monday, April 27, 2020 10:20 PM
To: NIAID OD AM (b) (6); NIAID Coronavirus Response SWAT 2020 (b) (6); NIAID COVID-19 DivDir Sync (b) (6) (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6)
Cc: Bozick, Brooke (NIH/OD) [E] (b) (6); Shaffer, Meredith (NIH/NIAID) [E] (b) (6); Barron, Karyl (NIH/NIAID) [E] (b) (6); Miller, Katherine (NIH/NIAID) [E] (b) (6); DMID Word Nerds (b) (6); NIAID OCGR Leg (b) (6); Parker, Marie (NIH/NIAID) [E] (b) (6); Giovanni, Maria (NIH/NIAID) [C] (b) (6); Tartakovsky, Mike (NIH/NIAID) [E] (b) (6); Chandramouliswaran, Ishwar (NIH/NIAID) [E] (b) (6)
Subject: COVID-19 Implementation Plan and Research Updates - 4.27.20

All –
Please find attached:

- **COVID-19 Research Implementation Plan** - 4/27
  - Note: the implementation plan includes an appendix of NIAID-supported ongoing and planned COVID-19 interventional clinical trials and observational studies.
- **Full COVID-19 Research Updates** - 4/27

Recurring updates of these and other COVID-19-related items and trackers will also be stored on the COVID-19 sharepoint here.
Best,
Nick

Nicholas Bushar, Ph.D.
Chief, Policy, Planning and Reporting Section
Policy, Planning, and Evaluation (PP&E) Branch
Office of Strategic Planning, Initiative Development, and Analysis, NIAID
National Institutes of Health (NIH)
Phone: (b) (6)

QUESTION:

This is Dan Evon from the fact-checking website Snopes. We've been receiving questions about a recent article published in the Daily Mail that claims the Obama administration provided a $3.7 million grant to the Wuhan Institute of Virology, and I was hoping to get some more information from you.

The Daily Mail appears to be referring to NIAID award R01AI110964. That award went to the EcoHealth Alliance in New York and subsequently funded a research paper from the Wuhan Institute.

Has NIH issued any direct grants to the Wuhan Institute of Virology? The NIH RePORT tool shows funding to Wuhan University in 2019 and 2018, but not (unless I missed something) from previous years.

Did NIH provide a $3.7 million grant to the Wuhan Institute of Virology between 2008 and 2016? Can you tell me more about the grants awarded to Wuhan University in 2018 and 2019?

Any information you can provide would be greatly appreciated.

PROPOSED NIAID RESPONSE:

(b) (5)

[redacted]

From: Abbey, Lillian (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: Action requested ASAP: Review proposed NIAID responses to follow-up questions on Wuhan Institute of Virology -- additional subawardees
Date: Wednesday, April 22, 2020 10:59:01 AM

Apologies, Erik, but wanted to follow up on this morning's request below. Seems ok, but want to make sure the highlighted sentence is accurate. Thank you!

From: Abbey, Lillian (NIH/NIAID) [E]
Sent: Wednesday, April 22, 2020 9:09 AM
To: Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>
Subject: FW: Action requested ASAP: Review proposed NIAID responses to follow-up questions on Wuhan Institute of Virology -- additional subawardees
Sorry, Erik, but I want to run the highlighted sentence by you...based on what DEA provided, Chase tweaked the language a bit, and I want to make sure it is still accurate.
Thank you, and happy Wednesday!
Lillian

From: Crawford, Chase (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, April 22, 2020 8:55 AM
To: Helfman, Mark (NIH/NIAID) [E] (b) (6); Abbey, Lillian (NIH/NIAID) [E] (b) (6); Selgrade, Sara (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Leg (b) (6); NIAID BUGS (b) (6); NIAID DEA DART (b) (6)
Subject: RE: Action requested ASAP: Review proposed NIAID responses to follow-up questions on Wuhan Institute of Virology -- additional subawardees
Hi Mark and Lillian,
Are there any objections to the revised sentence highlighted below? Thanks again for your help in developing/reviewing these responses. -- Chase

(3) do we know why the subaward amount for Wuhan Institute of Virology went down in 2019? Just random fluctuation?

(b) (5)

From: Helfman, Mark (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 4:59 PM
To: Crawford, Chase (NIH/NIAID) [E] (b) (6); Abbey, Lillian (NIH/NIAID) [E] (b) (6); NIAID DEA DART (b) (6)
Cc: NIAID OCGR Leg (b) (6); NIAID BUGS (b) (6)
Subject: RE: Action requested ASAP: Review proposed NIAID responses to follow-up questions on Wuhan Institute of Virology -- additional subawardees
Hi Chase. DEA would like to add one comment, regarding item #3. (b) (5)

--

Mark Helfman
Technical Writer and Editor, Division of Extramural Activities
National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
Phone: (b) (6) | Email: (b) (6) | Office: 4G29

From: Crawford, Chase (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 4:50 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); NIAID DEA DART (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Leg (b) (6); NIAID BUGS (b) (6)
Subject: RE: Action requested ASAP: Review proposed NIAID responses to follow-up questions on Wuhan Institute of Virology -- additional subawardees
Thanks, Lillian. Much appreciated. -- Chase

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 4:48 PM
To: Crawford, Chase (NIH/NIAID) [E] (b) (6); NIAID DEA DART (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Leg (b) (6); NIAID BUGS (b) (6)
Subject: RE: Action requested ASAP: Review proposed NIAID responses to follow-up questions on Wuhan Institute of Virology -- additional subawardees
Chase – we have a suggested addition/edit in red font in the response to #4, see below.
Thanks,
Lillian

From: Crawford, Chase (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 4:13 PM
To: NIAID BUGS (b) (6); NIAID DEA DART (b) (6) Abbey, Lillian (NIH/NIAID) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Leg (b) (6)
Subject: Action requested ASAP: Review proposed NIAID responses to follow-up questions on Wuhan Institute of Virology -- additional subawardees
Thanks to all for your assistance in gathering the background information used to develop the proposed NIAID responses below. **Can you review ASAP and let us know if you have any concerns/edits?** Thanks again, Chase

(1) who was the original/main project awardee,

EcoHealth Alliance

(2) what entity made the subaward to the WIV, and

EcoHealth Alliance

(3) do we know why the subaward amount for Wuhan Institute of Virology went down in 2019? Just random fluctuation?

(b) (5)

(4) who were the other subawardees (i.e., the specific institutes in countries listed by NIH/OD [China, Thailand, Cambodia, Laos, Vietnam, Malaysia, Indonesia, and

Myanmar]).

(b) (5)

[redacted]

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 12:38 PM
To: Fenton, Matthew (NIH/NIAID) [E] (b) (6); Crawford, Chase (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS (b) (6); NIAID DEA DART (b) (6); NIAID OCGR Leg (b) (6)
Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Thanks, Matthew. The personnel at East China Normal University coordinate the field sampling from the sites in China.
Lillian

From: Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 11:37 AM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Crawford, Chase (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS (b) (6); NIAID DEA DART (b) (6); NIAID OCGR Leg (b) (6)
Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Lillian et al. – the current grant (year 6) also awards some consultant funds to East China Normal University.
Matthew

Type 2, revised NOA (the first NOA forgot to include funds for the 2 sites below)
Currently in year 6 (budget period ends 6/30/2020)
Funded Chinese research sites:
Institute of Pathogen Biology, Beijing $75,600 (1 year)
Wuhan Institute of Virology, Wuhan $76,301 (1 year)
Chinese collaborators also located at:
East China Normal University, Shanghai $49,750 (1 year consultant costs)

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To: Crawford, Chase (NIH/NIAID) [E] (b) (6)
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Subject: FW: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Chase – Erik notes that the vast majority of the sites on Mark's list were part of the prior award and are no longer active (grant was renewed last May). The current award just lists the China sites and Singapore. Therefore, we've provided information on what's active in the 2019 renewal below. Also, Erik confirmed that the change in funding level to the subaward under the renewal is just a normal fluctuation; there were minor tweaks made to the focus of the grant under the renewal, and therefore changes to subawards as well. It's not one continuous project.

Thanks,
Lillian

List of all subawardees for R01AI110964:

1. Wuhan Institute of Virology, CHINA (Active) – This site is the main virology lab for the project. They received field samples from sites in China and used sequencing to identify the presence of animal coronaviruses. They also characterized any isolated viruses to determine host receptor binding and other in vitro and in vivo characterization.
2. Institute of Pathogen Biology, CHINA (Active) – This site manages the human subject work to understand study human exposure to animal coronaviruses, including the sampling, serology, and questionnaires administered after acute illness.
3. Duke-NUS, SINGAPORE (Active) - The collaborator at Duke-NUS will act as a consultant on the project, and provide her expertise on serological testing, virus characterization, and PCR detection of viruses. Work at this site will not involve any processing of any samples.

The sites below were part of the prior award, and all had the same role. Samples were collected from animals from each of these sites (urban centers, rural areas, and live animal markets), and were sent to WIV to and analyzed to determine what coronaviruses are present and what receptors the viruses use to infect cells. The individual sites listed below managed sample collection within each country.

4. San Pya Clinic, BURMA
5. Institut Pasteur du Cambodge, CAMBODIA
6. Primate Research Center at Bogor Agricultural University, INDONESIA
7. Conservation Medicine, Ltd, MALAYSIA
8. King Chulalongkorn Memorial Hospital, THAILAND
9. Hanoi Agricultural University, VIETNAM
10. National Animal Health Laboratory, LAOS – Per email from PI dated 9/27/2018, they were unable to begin work at this site due to difficulties with the local government.

From: Helfman, Mark (NIH/NIAID) [E] (b) (6)
Sent: Monday, April 20, 2020 5:13 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Crawford, Chase (NIH/NIAID) [E]

(b) (6)

Cc: Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Stover, Kathy (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg (b) (6); NIAID DEA DART (b) (6); NIAID BUGS (b) (6)

Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Hello, Chase and Lillian. Here's the information from DEA.

List of all subawardees for R01AI110964:

1. Wuhan Institute of Virology, CHINA
2. Institute of Pathogen Biology, CHINA
3. San Pya Clinic, BURMA
4. Institut Pasteur du Cambodge, CAMBODIA
5. Primate Research Center at Bogor Agricultural University, INDONESIA
6. Conservation Medicine, Ltd, MALAYSIA
7. King Chulalongkorn Memorial Hospital, THAILAND
8. Hanoi Agricultural University, VIETNAM
9. National Animal Health Laboratory, LAOS

East China Normal University is listed as consultant, not subawardee – DMID/OCGR, do you want to include it?

Regarding the subaward amount for Wuhan Institute of Virology in 2019, we awarded the amount requested in the renewal application. We defer to DMID for further details and the descriptions of the activities supported.
Please contact me directly if you'd like to discuss further.

--

Mark Helfman
Technical Writer and Editor, Division of Extramural Activities
National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
Phone: (b) (6) | Email: (b) (6) | Office: 4G29

From: Helfman, Mark (NIH/NIAID) [E] (b) (6)
Sent: Friday, April 17, 2020 4:59 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Crawford, Chase (NIH/NIAID) [E] (b) (6); NIAID DEA DART (b) (6); NIAID BUGS (b) (6)
Cc: Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6) Stover, Kathy (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg (b) (6)
Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Yes, Lillian, we will get the information requested in red. Thank you for taking care of #3! Have a

good weekend.

--

Mark Helfman
Technical Writer and Editor, Division of Extramural Activities
National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
Phone: (b) (6) | Email: (b) (6) Office: 4G29

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
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Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Chase, with regard to Q #3, the PO Erik Stemmy noted that 2019 should have been the first year of the grant renewal. So the budget would have changed to reflect the work proposed in the renewal application (eRA is down this weekend so he can't get more specific re: details at this time).
I assume DEA DART will respond to the Q in red but let us know if Bugs can help.
Sincerely,
Lillian

From: Crawford, Chase (NIH/NIAID) [E] (b) (6)
Sent: Friday, April 17, 2020 4:21 PM
To: NIAID DEA DART (b) (6); NIAID BUGS (b) (6)
Cc: Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Stover, Kathy (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg (b) (6)
Subject: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Good Afternoon,
We received the below follow-up questions about subawards from the NIAID-supported EcoHealth Alliance project (R01AI110964). As you may recall NIAID recently responded to multiple Congressional requests for information on NIAID support for research activities at the Wuhan Institute of Virology.

(1) who was the original/main project awardee,

EcoHealth Alliance

(2) what entity made the subaward to the WIV, and

EcoHealth Alliance

(3) do we know why the subaward amount for Wuhan Institute of Virology went down in 2019? Just random fluctuation?

[PLACEHOLDER for DMID/DEA response]

(4) who were the other subawardees (i.e., the specific institutes in countries listed by NIH/OD [China, Thailand, Cambodia, Laos, Vietnam, Malaysia, Indonesia, and Myanmar]).

(b) (5)

(b) (5)

[redacted]

ACTION

Please let us know when it will be possible to obtain a list of all subawardees for R01AI110964
(we understand the QVR website is under maintenance).

Thanks,

Chase

Chase Crawford, D.V.M., M.S.
Public Health Analyst
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS

From: Abbey, Lillian (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees
Date: Tuesday, April 21, 2020 2:00:33 PM

I definitely owe you a beer or something when this is over!!!

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 12:33 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Thanks! The personnel at East China Normal University coordinate the field sampling from the sites in China.

Erik

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 11:50 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: FW: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Erik – here's what I forwarded, below. Thanks for pulling this together so quickly and giving me a call to discuss. I didn't send the pdf since we are focused on current grant but will hold on to that in case it's needed.

Did want you to see what Matthew F. just shared, see directly below. (b) (5) Assume these are personnel who can assist on any aspect of the overall grant but please let us know if there's anything further DMID should note in response to what Matthew has shared.
Thank you!
Lillian

From: Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 21, 2020 11:37 AM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Crawford, Chase (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>; NIAID DEA DART (b) (6); NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Lillian et al. – the current grant (year 6) also awards some consultant funds to East China Normal University.

Matthew

Type 2, revised NOA (the first NOA forgot to include funds for the 2 sites below)

Currently in year 6 (budget period ends 6/30/2020)

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Institute of Pathogen Biology, Beijing	$75,600 (1 year)
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To: Crawford, Chase (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>; NIAID DEA DART <dart@mail.nih.gov>; NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: FW: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Chase – Erik notes that the vast majority of the sites on Mark's list were part of the prior award and are no longer active (grant was renewed last May). The current award just lists the China sites and Singapore. Therefore, we've provided information on what's active in the 2019 renewal below.

Also, Erik confirmed that the change in funding level to the subaward under the renewal is just a normal fluctuation; there were minor tweaks made to the focus of the grant under the renewal, and therefore changes to subawards as well. It's not one continuous project.
Thanks,
Lillian

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Cc: Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Stover, Kathy (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>; NIAID DEA DART <dart@mail.nih.gov>; NIAID BUGS <BUGS@niaid.nih.gov>
Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Hello, Chase and Lillian. Here's the information from DEA.

List of all subawardees for R01AI110964:

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Mark Helfman
Technical Writer and Editor, Division of Extramural Activities
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Subject: RE: Action requested: Follow-up questions on Wuhan Institute of Virology -- additional subawardees

Yes, Lillian, we will get the information requested in red. Thank you for taking care of #3! Have a good weekend.

--

Mark Helfman
Technical Writer and Editor, Division of Extramural Activities
National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
Phone: (b) (6) | Email: (b) (6) | Office: 4G29

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Cc: Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Stover, Kathy (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
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Sincerely,
Lillian

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Cc: Harper, Jill (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Stover, Kathy (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
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Good Afternoon,

We received the below follow-up questions about subawards from the NIAID-supported EcoHealth Alliance project (R01AI110964). As you may recall NIAID recently responded to multiple Congressional requests for information on NIAID support for research activities at the Wuhan Institute of Virology.

(1) who was the original/main project awardee,

EcoHealth Alliance

(2) what entity made the subaward to the WIV, and

EcoHealth Alliance

(3) do we know why the subaward amount for Wuhan Institute of Virology went down in 2019? Just random fluctuation?

[PLACEHOLDER for DMID/DEA response]

(4) who were the other subawardees (i.e., the specific institutes in countries listed by NIH/OD [China, Thailand, Cambodia, Laos, Vietnam, Malaysia, Indonesia, and Myanmar]).

Country	Subawardee	Activities Supported
China	Wuhan Institute of Virology	coronavirus screening and serology of non-human samples, viral pathogenesis, serological testing, host receptor binding, spike (S) protein sequencing, and in vitro and in vivo virus characterization
Cambodia		
Indonesia		
Laos		
Malaysia		
Myanmar		
Thailand		
Vietnam		

ACTION

Please let us know when it will be possible to obtain a list of all subawardees for R01AI110964 (we understand the QVR website is under maintenance).

Thanks,
Chase

Chase Crawford, D.V.M., M.S.
Public Health Analyst
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS

From: Erbelding, Emily (NIH/NIAID) [E]
To: Linde, Emily (NIH/NIAID) [E]
Cc: Stemmy, Erik (NIH/NIAID) [E]; Khurana, Dhana (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]; Connors, Victoria (NIH/NIAID) [E]
Subject: Re: request for a call...
Date: Monday, April 20, 2020 3:08:26 PM

Thanks Emily.

Sent from my iPad

On Apr 20, 2020, at 2:31 PM, Linde, Emily (NIH/NIAID) [E] (b) (6) wrote:

Hi Erik and Emily,
I am looping you in to this request. (b) (5) We will be providing that shortly.
Thanks,
Emily

From: Black, Jodi (NIH/OD) [E] (b) (6)
Sent: Sunday, April 19, 2020 1:59 PM
To: Linde, Emily (NIH/NIAID) [E] (b) (6)
Cc: Bulls, Michelle G. (NIH/OD) [E] (b) (6); Tarwater, Robert (NIH/OD) [E] (b) (6); Dean, Diane (NIH/OD) [E] (b) (6); Ta, Kristin (NIH/OD) [E] (b) (6); Black, Jodi (NIH/OD) [E] (b) (6); Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Subject: FW: request for a call...
HI Emily, I hope all is well and you are having a nice weekend. I'm following up on the outcome of the subcontract from EcoHealth Alliance to Wuhan Institute of Virology (WIV). Please see attached instructing EcoHealth Alliance to discontinue providing funds to WIV. Happy to discuss
Best,
Jodi
Jodi B. Black, PhD, MMSc
Deputy Director
Office of Extramural Research, NIH

From: Michelle Bulls (b) (6)
Date: Wednesday, April 15, 2020 at 3:49 PM
To: Jodi OER (b) (6)
Cc: Mike Lauer (b) (6), Michelle Bulls (b) (6)

Subject: FW: request for a call...

FYI. Urgent.

(b) (5)

(b) (5) This is for convenience and I have some ideas. Waiting to hear back from Emily and will set up time to talk to Jodi tomorrow.

Thanks,

Michelle

From: Linde, Emily (NIH/NIAID) [E] (b) (6)

Sent: Wednesday, April 15, 2020 12:03 PM

To: Bulls, Michelle G. (NIH/OD) [E] (b) (6); Ta, Kristin (NIH/OD) [E] (b) (6); Tarwater, Robert (NIH/OD) [E] (b) (6); Dean, Diane (NIH/OD) [E] (b) (6)

Subject: request for a call...

Hello,

(b) (5)

, – you may have seen some articles.

(b) (5)

Many thanks,

Emily

Emily Linde

Director, Grants Management Program

NIAID, NIH, DHHS

Telephone Number: (b) (6)

Email Address: (b) (6)

<EcoHealth Alliance re AI grant 4 19 20[1].pdf>

From:	Abbey, Lillian (NIH/NIAID) [E]
To:	Erbelding, Emily (NIH/NIAID) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]
Cc:	NIAID BUGS
Subject:	RE: ACTION by 3PM TODAY (4/16): Draft NIAID response to Senate Qs - Wuhan Institute of Virology
Date:	Thursday, April 16, 2020 12:44:21 PM
Attachments:	image001.png

Yes, this is the leg item, not public. Public statement was what Christina M shared with you earlier and that references the Reporter link.

From: Erbelding, Emily (NIH/NIAID) [E] (b) (6)
Sent: Thursday, April 16, 2020 12:38 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: RE: ACTION by 3PM TODAY (4/16): Draft NIAID response to Senate Qs - Wuhan Institute of Virology

No suggested edits from me.
2 clarifying questions from me (yes/no is ok):

1. this is in response to congressional inquiry, not to be made public?
2. The prior statement that pointed to the Reporter link will be the public statement?

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Thursday, April 16, 2020 12:17 PM
To: Erbelding, Emily (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: FW: ACTION by 3PM TODAY (4/16): Draft NIAID response to Senate Qs - Wuhan Institute of Virology

Emily, Cristina, Erik and Alan,
The legislative group has taken the materials we sent and info received from GM to develop the attached response for our review by 3PM today. Please let us know if you have any suggested edits or comments.
Thank you,
Lillian

From: Crawford, Chase (NIH/NIAID) [E] (b) (6)
Sent: Thursday, April 16, 2020 12:06 PM
To: NIAID BUGS <BUGS@niaid.nih.gov>; NIAID DEA DART <dart@mail.nih.gov>
Cc: Harper, Jill (NIH/NIAID) [E] (b) (6); Johnson, Martin S. (NIH/NIAID) [E] (b) (6); Billet, Courtney (NIH/NIAID) [E] (b) (6); Stover, Kathy (NIH/NIAID) [E] (b) (6); Routh, Jennifer (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: ACTION by 3PM TODAY (4/16): Draft NIAID response to Senate Qs - Wuhan Institute of Virology

Good Afternoon,

Using information provided by DMID, OCGR-Leg has drafted the **attached proposed response** to recent Congressional requests for information on NIAID support for research activities at the **Wuhan Institute of Virology** (additional background on Congressional interest can be found in the email chain below the signature line). As you may recall the Wuhan Institute of Virology has been supported through subawards from an NIAID-supported EcoHealth Alliance project (R01AI110964). NIAID also has been asked "Would you provide the funding history (year, IC) for the Wuhan Institute of Virology?" We have included a funding table in the draft response using subaward amounts outlined in the NoAs for R01AI110964. Please confirm the subaward amounts.

ACTION

By 3p.m. today (4/16), please review the attached draft NIAID response and provide any edits in track changes.

Please let us know if you have any questions.

Thanks,

Chase

Chase Crawford, D.V.M., M.S.
Public Health Analyst
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS

From: Crawford, Chase (NIH/NIAID) [E] (b) (6)
Sent: Monday, April 13, 2020 5:41 PM
To: NIAID BUGS <BUGS@niaid.nih.gov>
Cc: Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: Request for information: Senate Qs - Wuhan Institute of Virology

Hi BUGS,

Staff to Senator Marco Rubio (R-FL) has forwarded an email to Building 1 from the White Coat Waste Project (see bottom of email chain). The forwarded message links to recent articles in The Daily Mail and the Washington Examiner on NIH support for previous coronavirus studies involving the Wuhan Institute of Virology. Building 1 has asked if NIAID has any information related to this research that we can share with staff to Senators Rubio and Mike Braun (R-IN).

To help us better understand this congressional request, is there any background information that you can provide on the activities discussed in the articles referenced below?

Thanks,

Chase

(b) (6)

From: LaMontagne, Karen (NIH/OD) [E] (b) (6)
Sent: Monday, April 13, 2020 4:23 PM
To: NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: Senate Qs - Wuhan Institute of Virology

Hi, NIAID,

Separately, we have heard from the offices of Senators Rubio and Braun about these linked articles:

White Coat Waste
Daily Mail
Washington Examiner

Both offices have asked if there's any information we can share with them related to this matter. Thanks in advance for anything you can provide.

Karen

From: Michelle Mitchell (b) (6)

Date: Monday, April 13, 2020 at 3:42 PM

To: Karen LaMontagne (b) (6)

Subject: Sen. Rubio question - NIH funding Wuhan virus lab

Hey Karen,

Sen. Rubio's staff, Ansley Rhyne, forwarded the email below that she received regarding NIH funding for the Wuhan Institute of Virology. Her boss, along with Rep. Gaetz are working on a letter to ensure no taxpayer dollars are sent to that Institute.

Ansley requested our input. Would you ask NIAID for any information on this issue that we could be shared with Ansley?

Thank you.

MM

From: Justin Goodman <justin@whitecoatwaste.org>

Sent: Monday, April 13, 2020 2:36 PM

To:

Subject: Laura- NIH funding Wuhan virus lab

I hope you had a nice weekend and are staying safe and healthy. I wanted to make sure you saw that our taxpayer watchdog group just exposed that **the National Institutes of Health (NIH) has been sending tax dollars to the controversial Wuhan Institute of Virology for years, including for dangerous lab experiments on coronavirus-infected bats captured from caves.** The Daily Mail, Washington Examiner, Drudge and others ran stories about the troubling find over the weekend.

We're working with Rep. Matt Gaetz (R-FL) and others on a sign-on letter about this and would love to work with you and Senator Rubio as well to ensure no more tax dollars are shipped to the Wuhan Institute of Virology.

I'd be happy to send over more info if you're interested and answer any questions you may have.

Thanks for looking,

Justin

Justin Goodman, M.A.
Vice President, Advocacy and Public Policy
White Coat Waste Project
*Taxpayers shouldn't be forced to pay $20 billion+ for **wasteful** government animal experiments.*
PO Box 26029
Washington, DC 20001
Phone: 860.882.2492
Donate | Blog | Web | Twitter | Facebook

From: Post, Diane (NIH/NIAID) [E]
To: RDBViral
Subject: FW: COVID-19 Strategic Plan, Implementation Plan, and Weekly Research Updates - 4.13.20
Date: Tuesday, April 14, 2020 9:33:08 AM
Attachments: NIAID COVID-19 Strategic Plan Final 10April 2020.docx
2020.04.13 COVID-19 Implementation Plan.docx
NIAID COVID-19 Full Weekly Update 4.13.20.docx

Hi Everyone,

Attached are the SARS-CoV-2 strategic plan and implementation plan. Take a look and let me know if you have any comments/edits.

Thanks
Diane

From: Bushar, Nicholas (NIH/NIAID) [E] (b) (6)
Sent: Monday, April 13, 2020 6:29 PM
To: NIAID OD AM (b) (6); NIAID Coronavirus Response SWAT 2020 <NIAIDCoronavirusResponseSWAT2020@mail.nih.gov>; NIAID COVID-19 DivDir Sync <NIAIDCOVID-19DivDirSync@mail.nih.gov>
Cc: Bozick, Brooke (NIH/OD) [E] (b) (6); Shaffer, Meredith (NIH/NIAID) [E] (b) (6); Barron, Karyl (NIH/NIAID) [E] (b) (6); Miller, Katherine (NIH/NIAID) [E] (b) (6); DMID Word Nerds <DMIDWordNerds@niaid.nih.gov>; NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>; Parker, Marie (NIH/NIAID) [E] (b) (6)
Subject: COVID-19 Strategic Plan, Implementation Plan, and Weekly Research Updates - 4.13.20

All –

Please find attached:

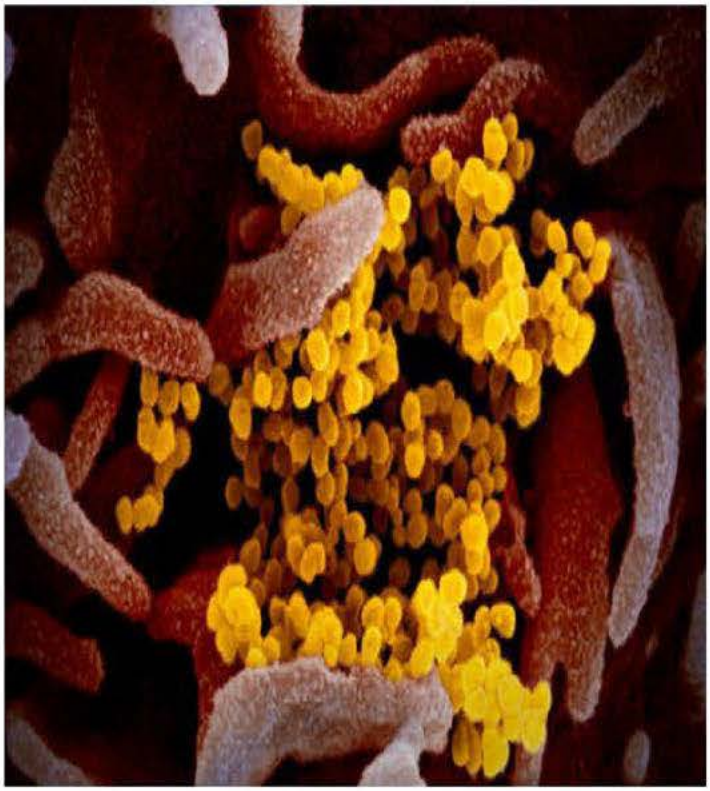
- **NIAID Strategic Plan for COVID-19 Research**
- **COVID-19 Implementation Plan** - 4/13
  - Please note: the implementation plan is intended to be for **internal use only**.
- **Full COVID-19 Research Updates** - 4/13

Moving forward, we will continue to regularly update the Implementation Plan and full research updates. We plan to send out recurring versions of these documents to this group **every other Monday**. Recurring updates of these and other COVID-19-related items and trackers will also be stored on the COVID-19 sharepoint here.

Many thanks to everyone who contributed to the development and review of all of these COVID-19 planning and tracking documents.

Best,
Nick

Nicholas Bushar, Ph.D.
Chief, Policy, Planning and Reporting Section
Policy, Planning, and Evaluation (PP&E) Branch
Office of Strategic Planning, Initiative Development, and Analysis, NIAID
National Institutes of Health (NIH)
Phone: (b) (6)



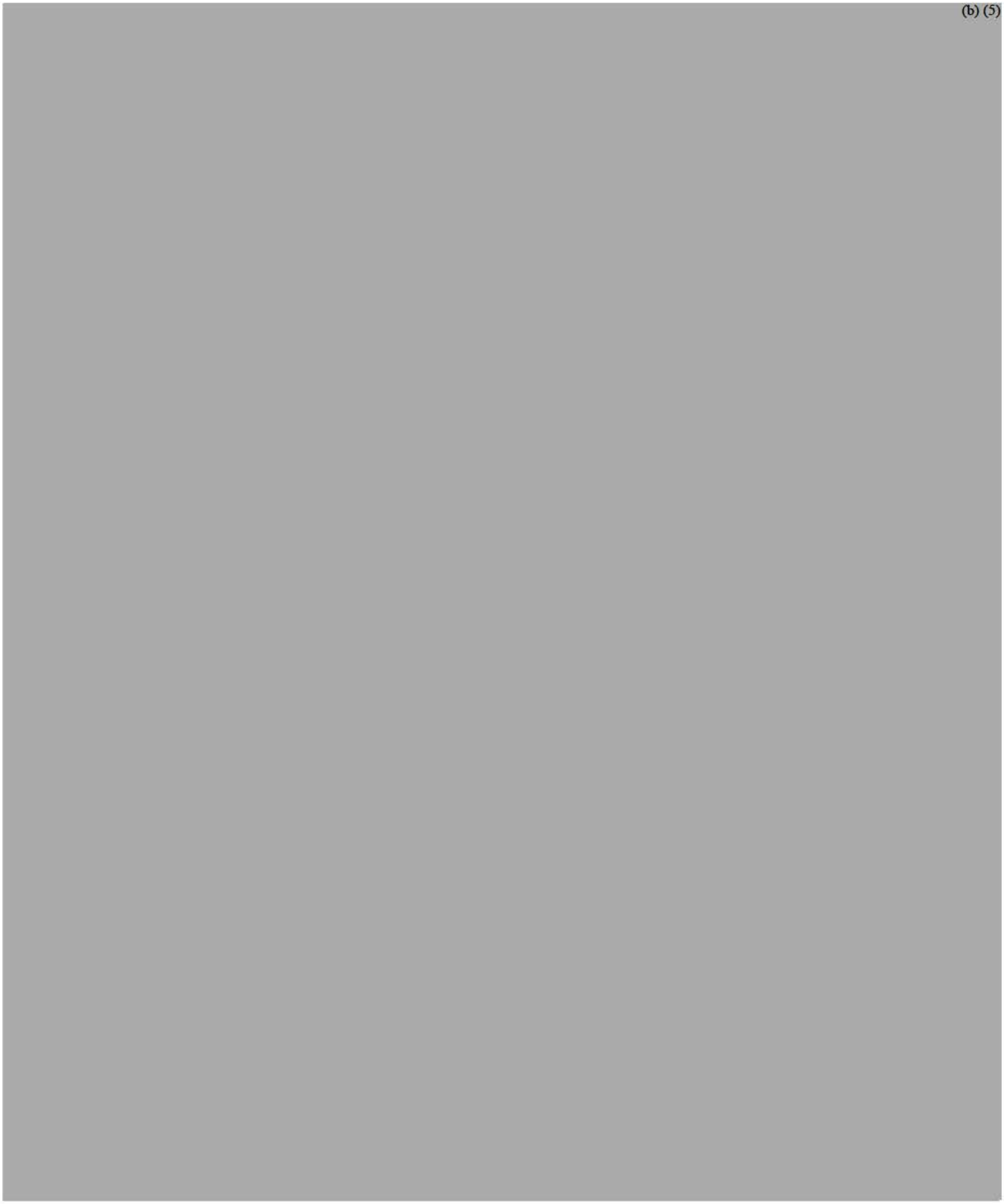
This scanning electron microscope image shows SARS-CoV-2 (yellow), the virus that causes COVID-19, isolated from a patient in the United States, emerging from the surface of cells (pink) cultured in the lab. Credit: NIAID-RML

NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

April 10, 2020

NIH National Institute of Allergy and Infectious Diseases

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA



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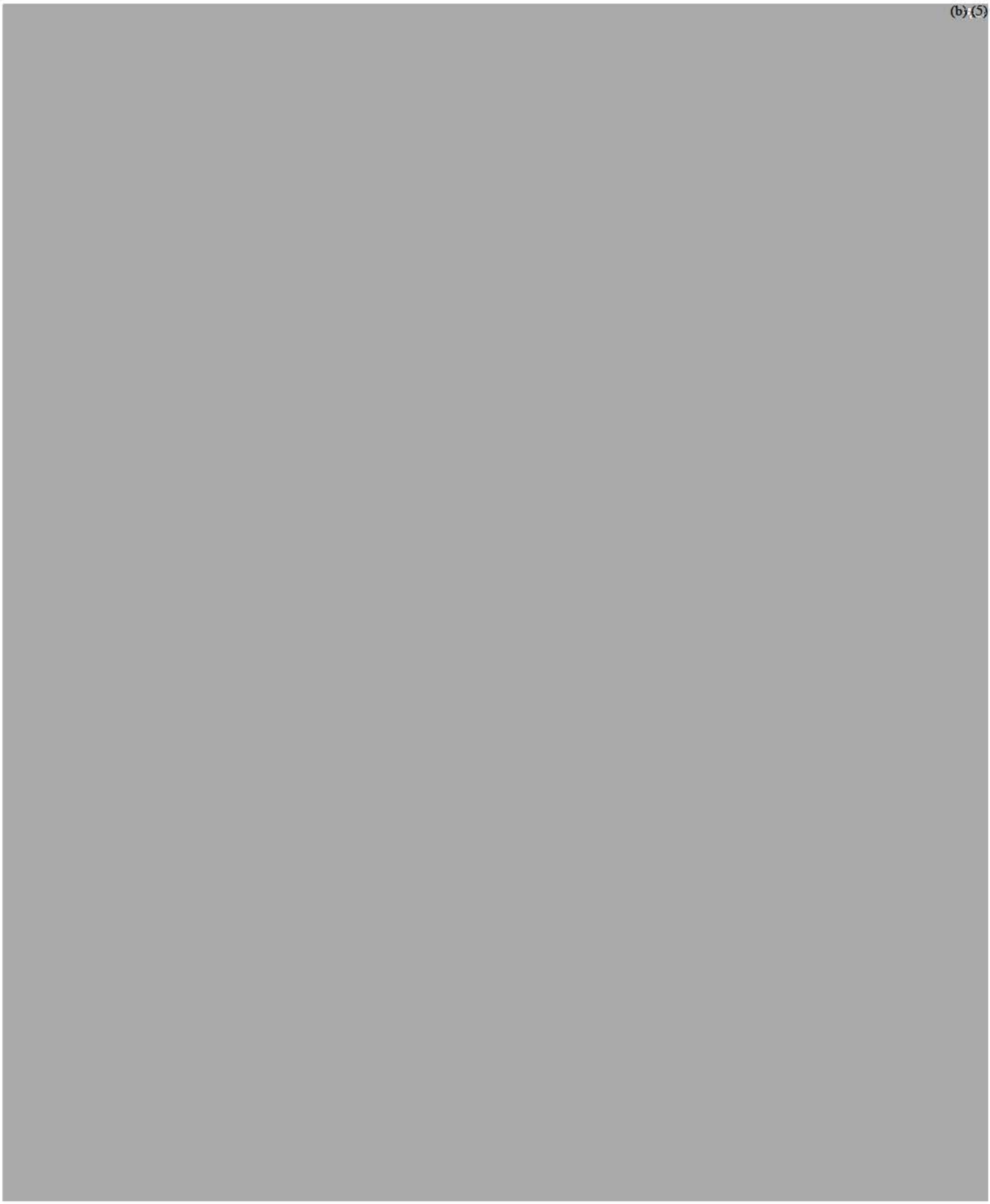

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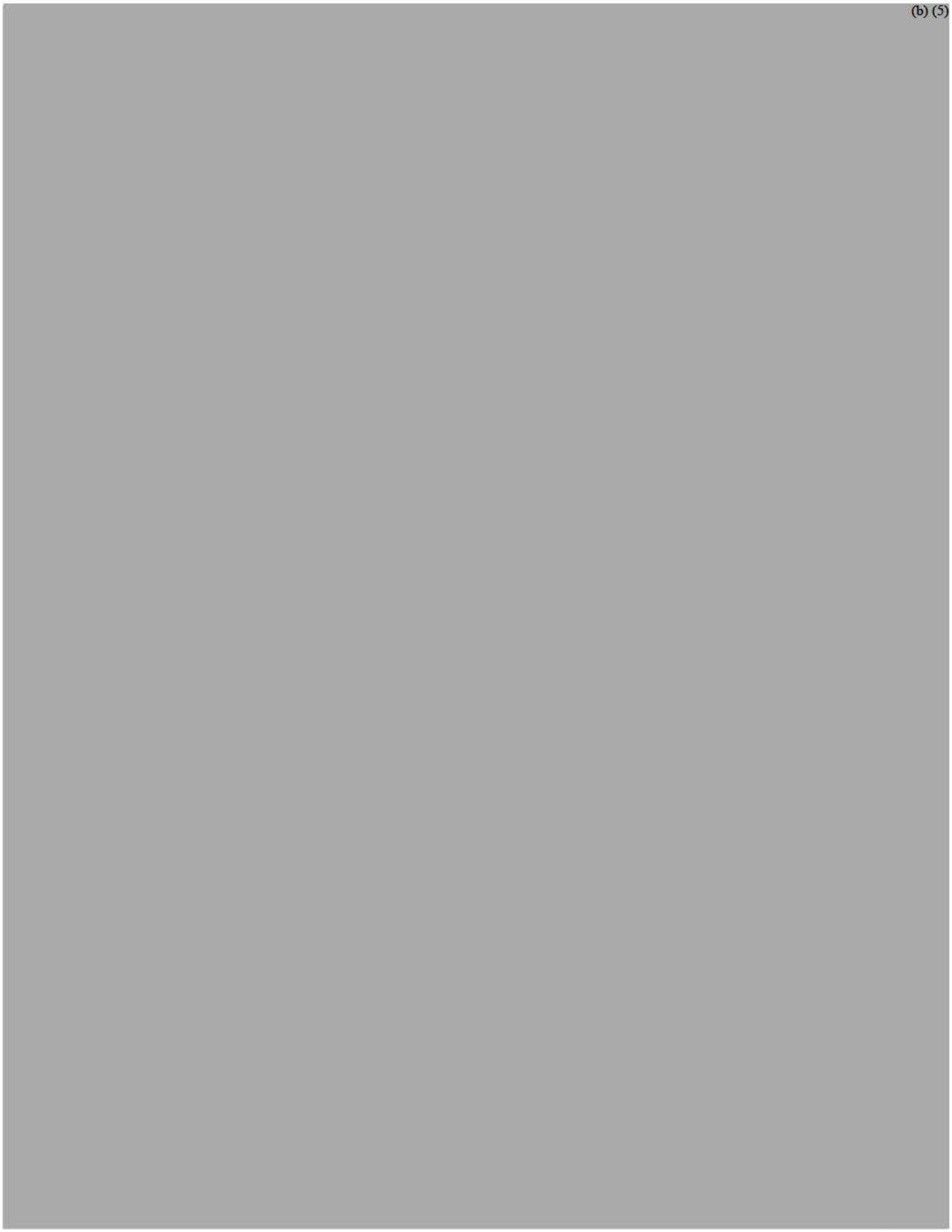

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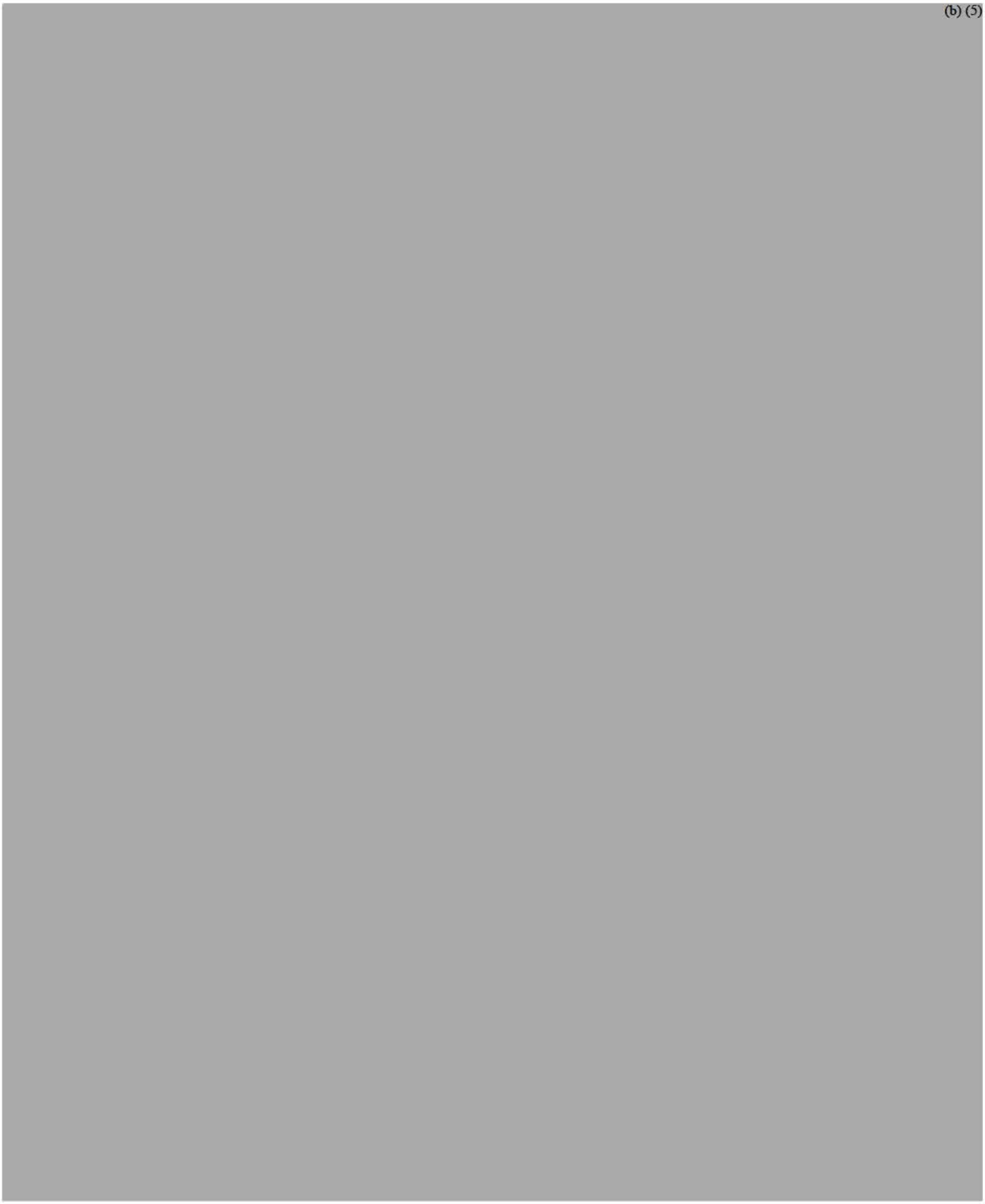

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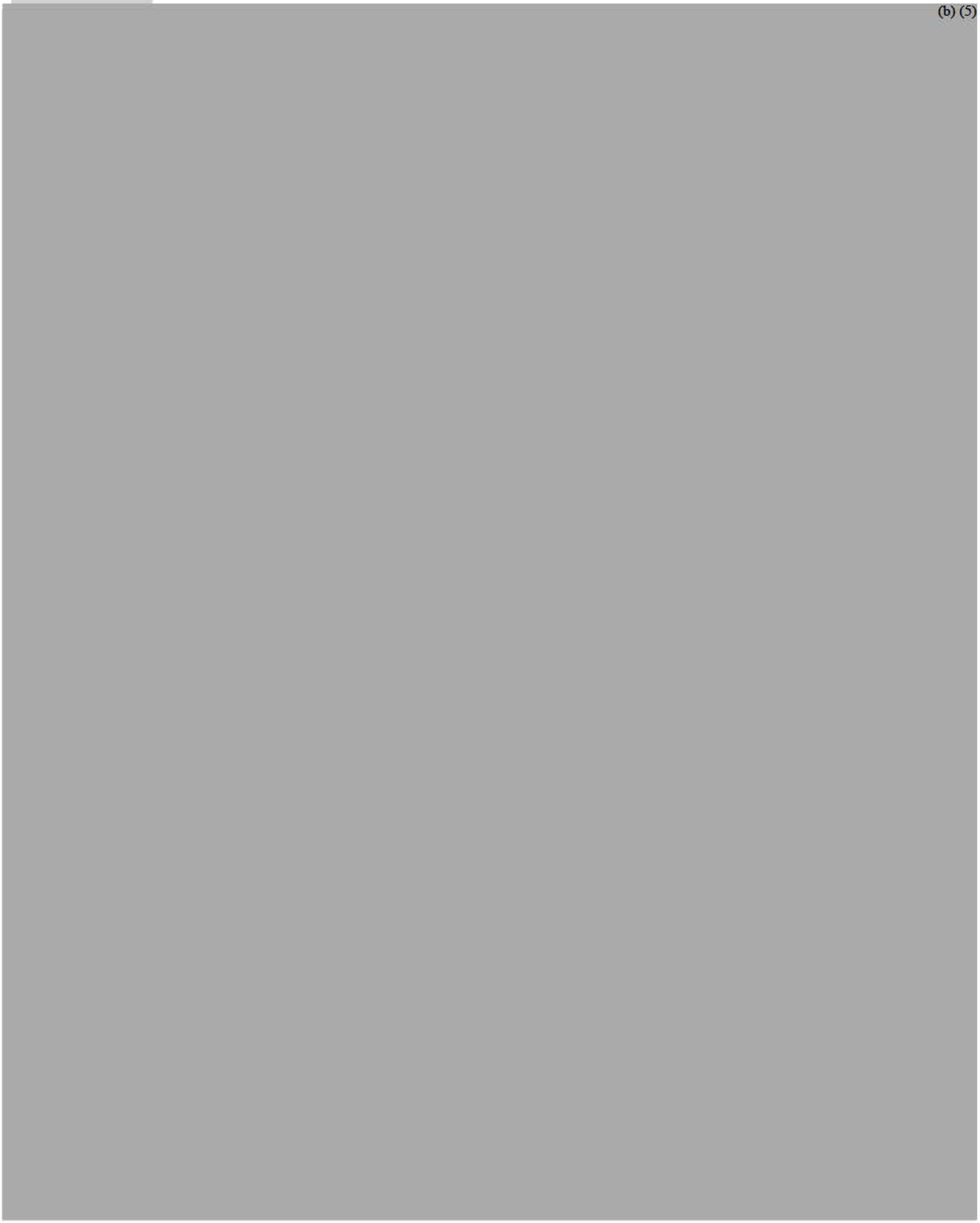

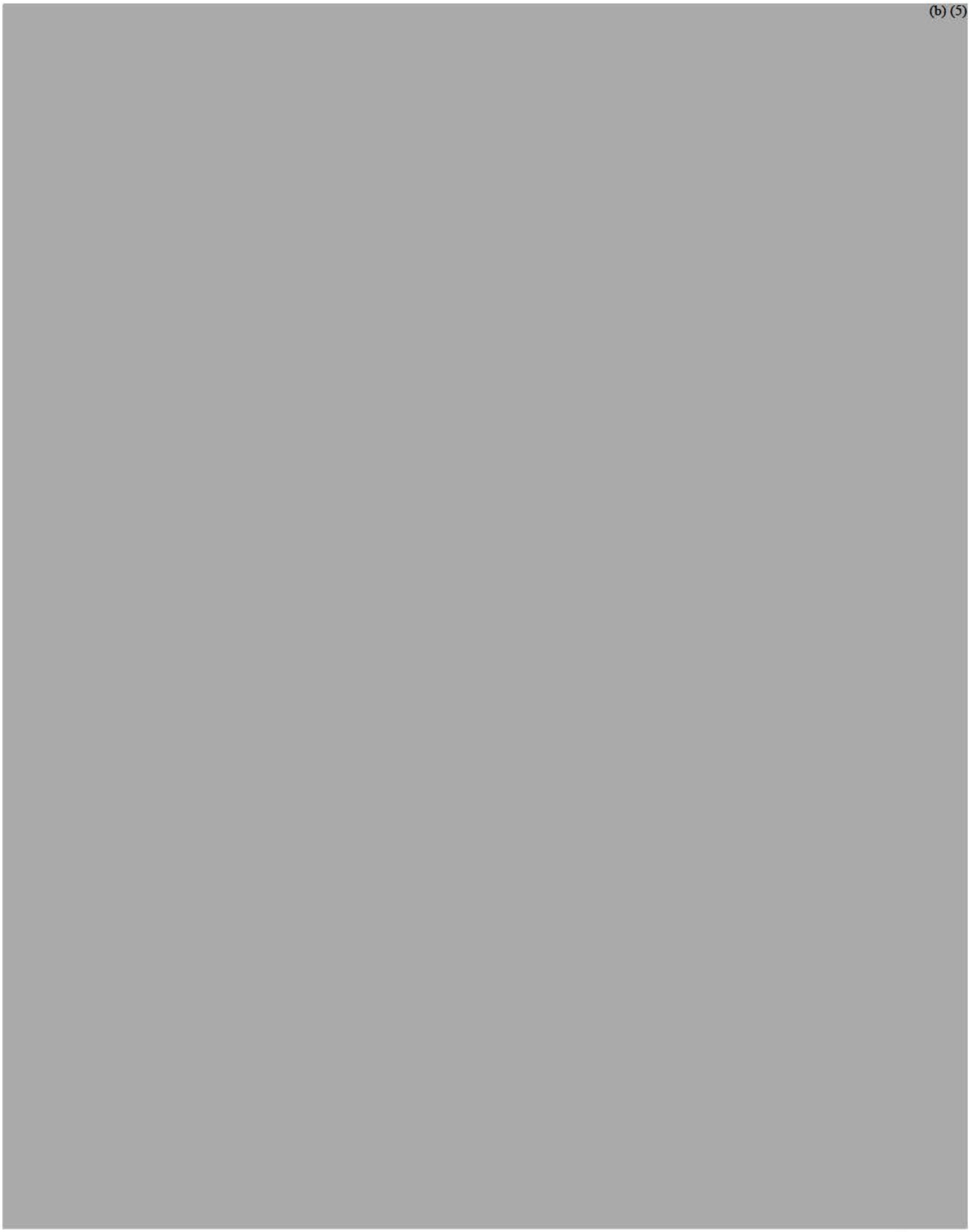

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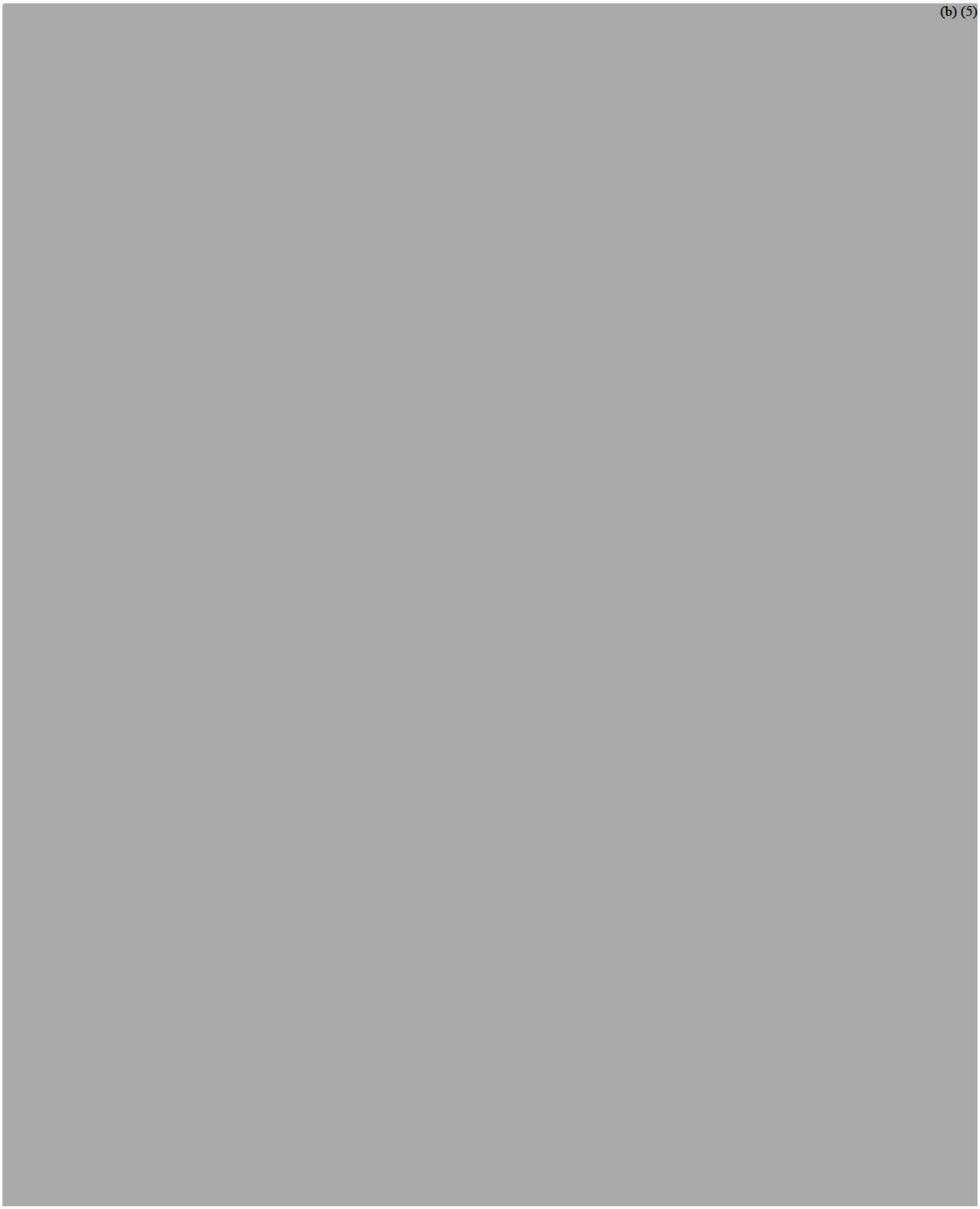

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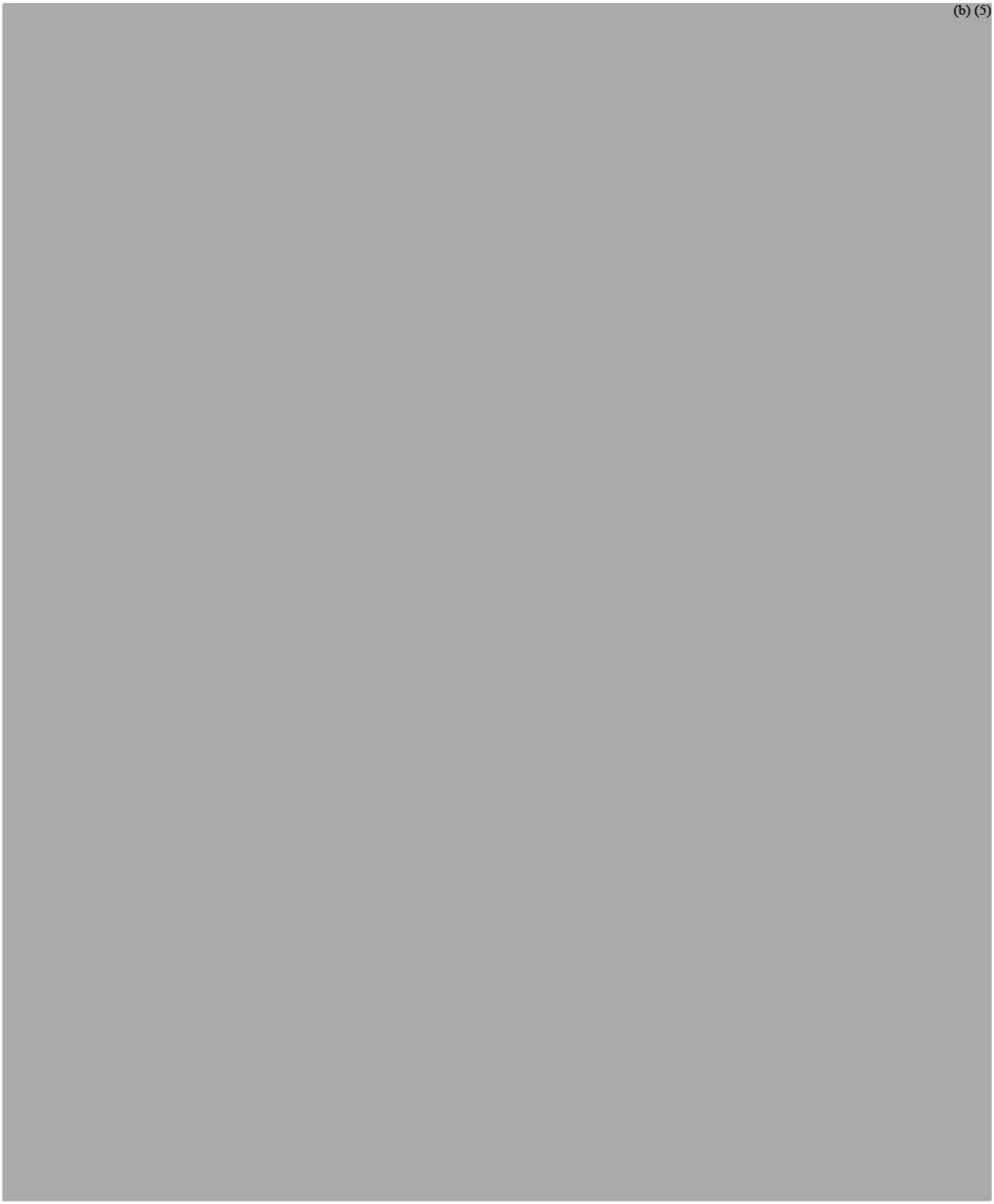

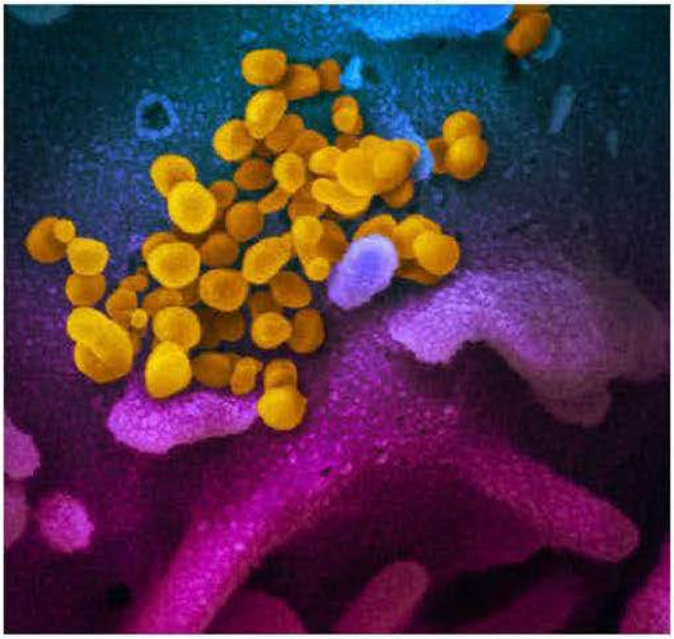

NIAID COVID-19 RESEARCH IMPLEMENTATION PLAN

April 13, 2020

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

NIH National Institute of Allergy and Infectious Diseases

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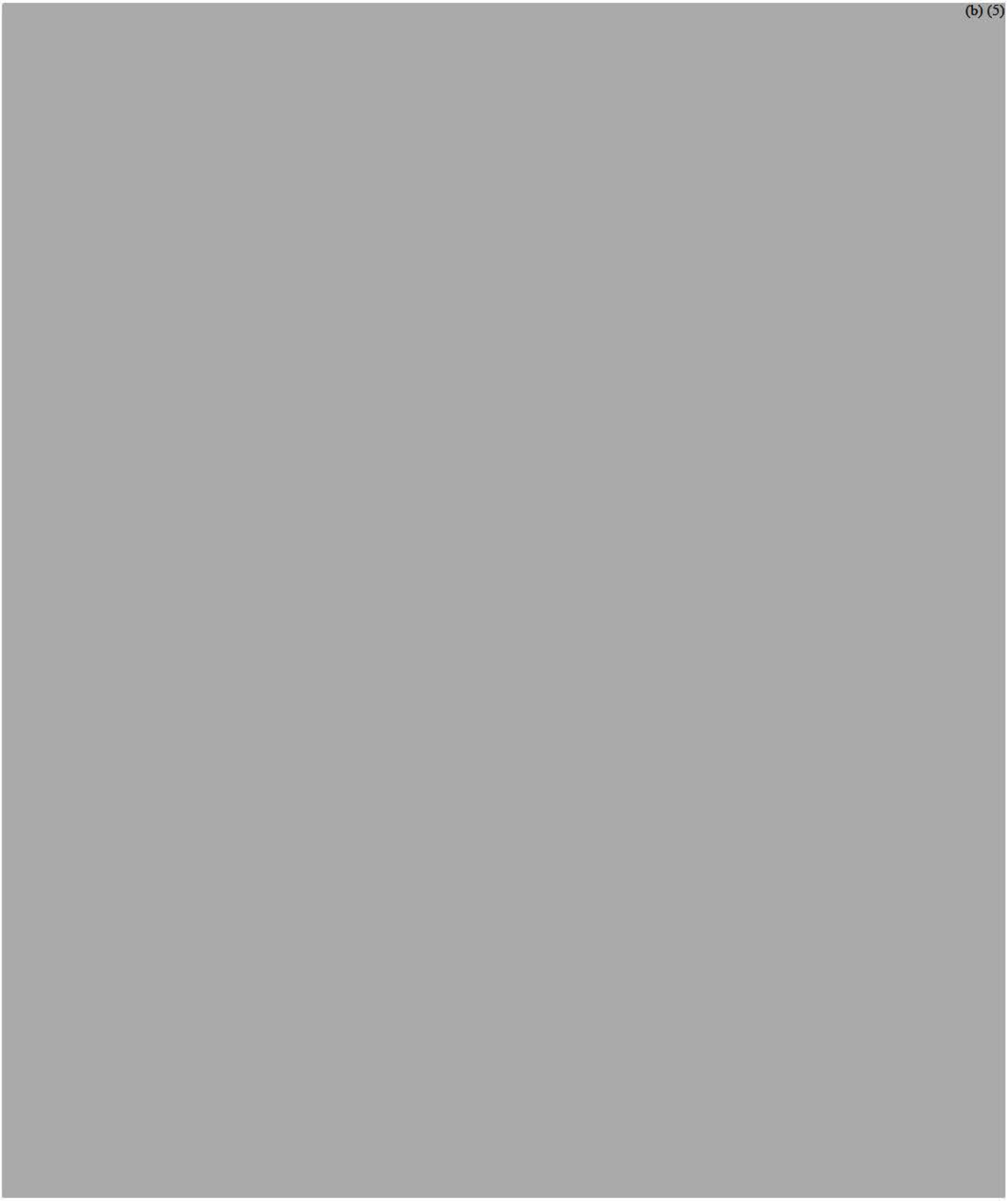

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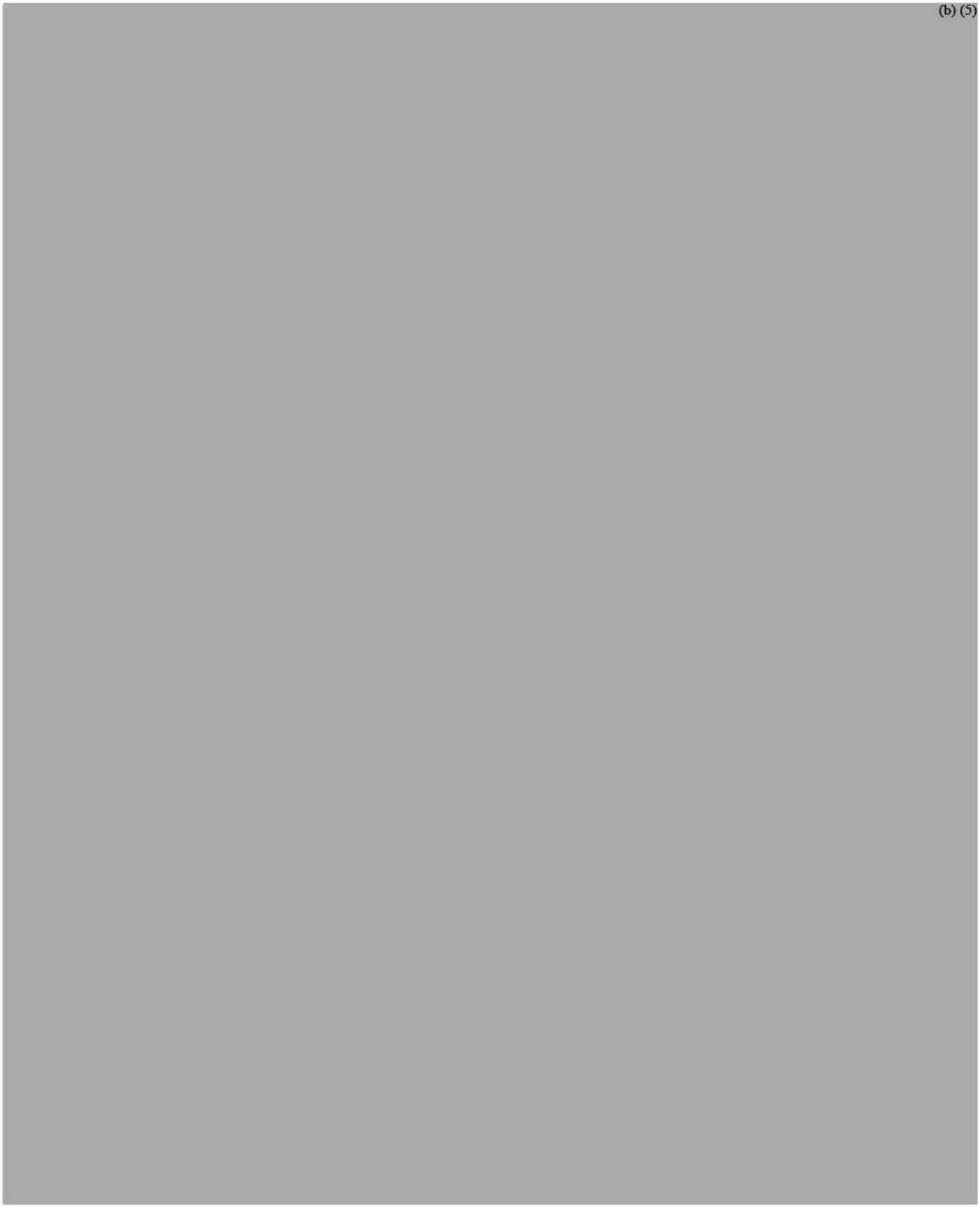

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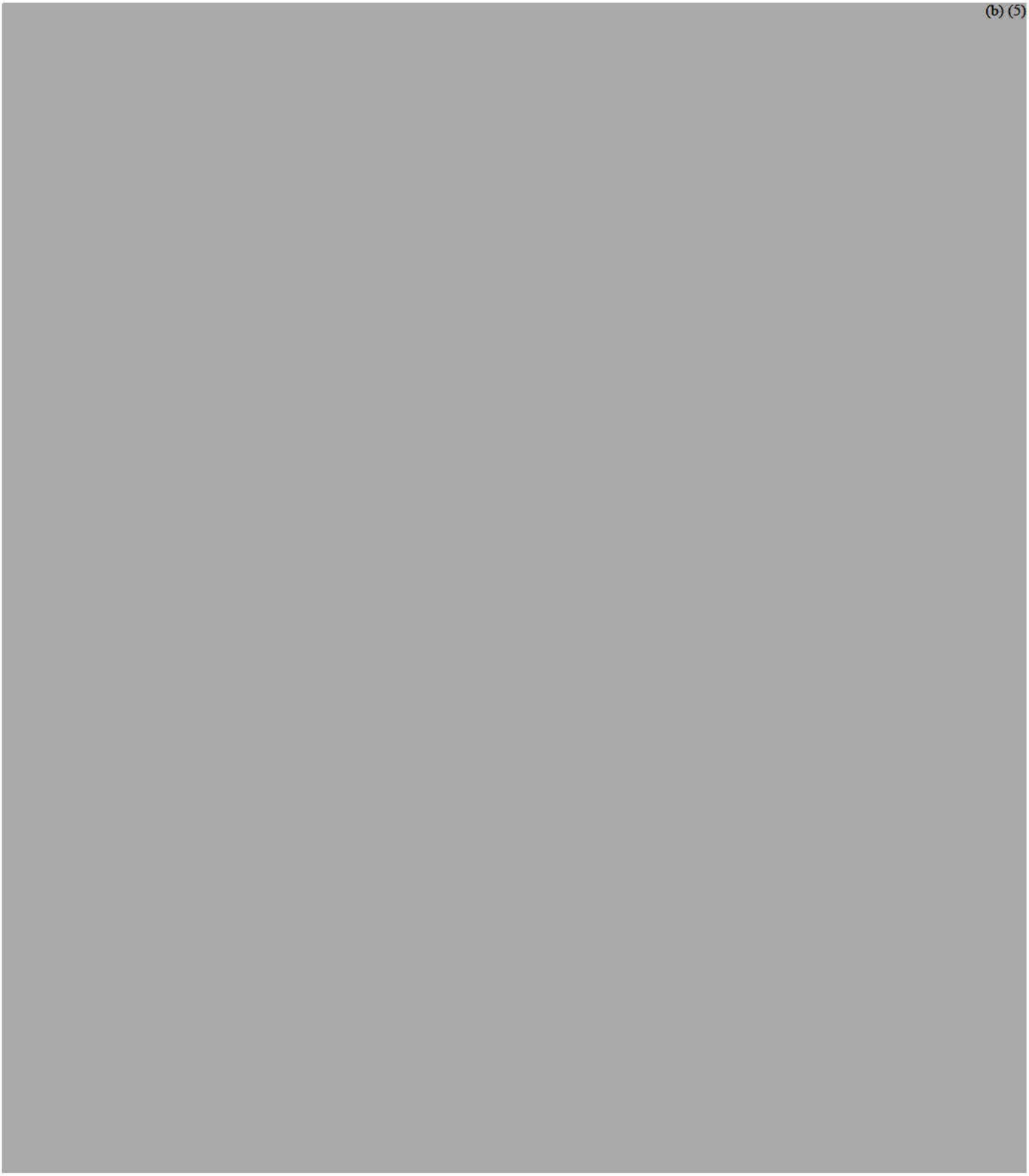

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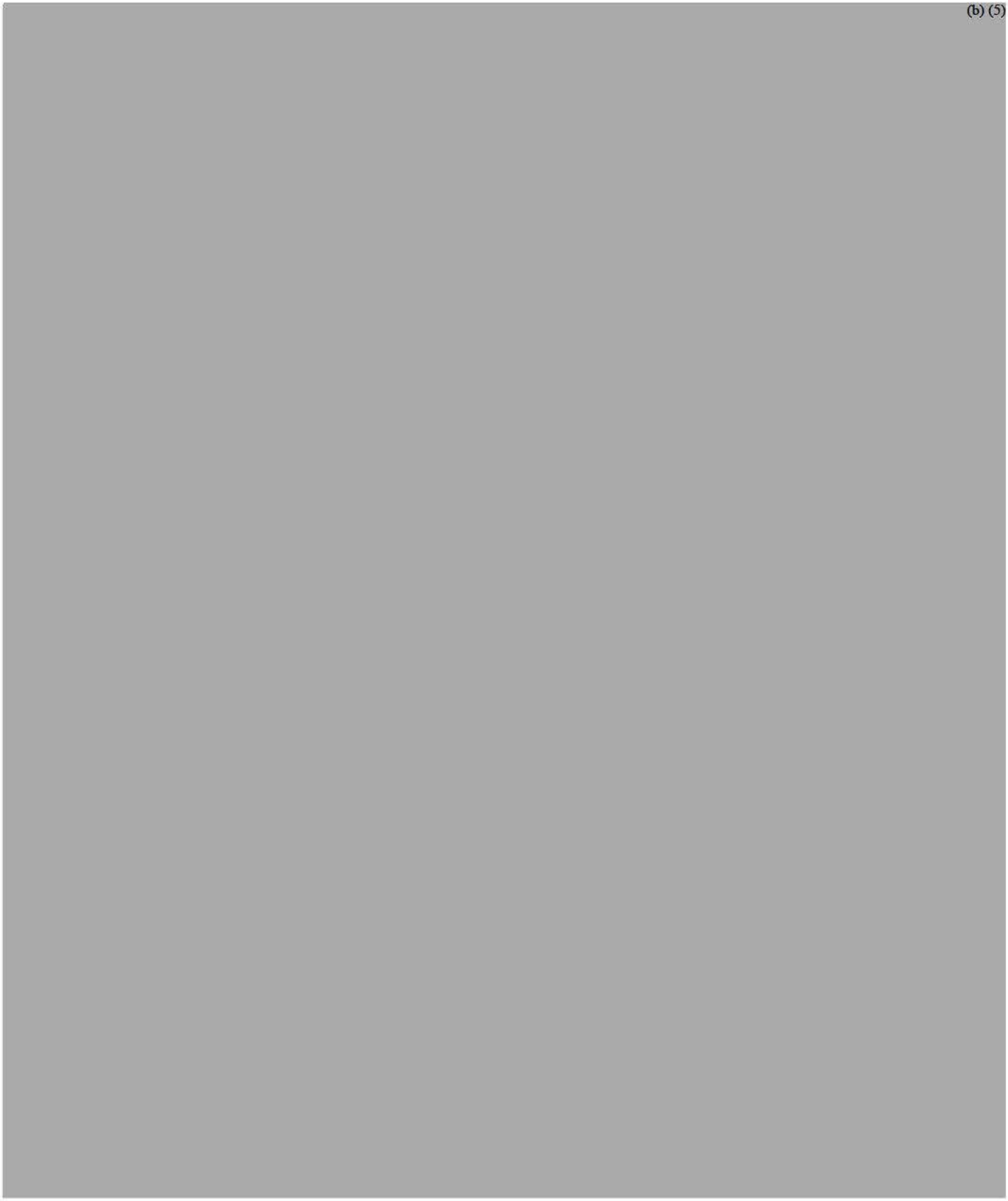

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National Institute of Allergy and Infectious Diseases

April 13, 2020

NIAID SARS-CoV-2 Research Updates

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From: Coomes, Stephanie (NIH/NIAID) [E]
To: nCoV extramural response; NIAID BUGS; Erbelding, Emily (NIH/NIAID) [E]
Subject: FW: SARS-CoV-2 Research Updates - March 16
Date: Monday, March 16, 2020 8:03:12 PM
Attachments: NIAID SARS-CoV-2 Short Research Summary 3.16.20.docx
NIAID SARS-CoV-2 Full Weekly Update 3.16.20.docx

From: Bushar, Nicholas (NIH/NIAID) [E] (b) (6)
Sent: Monday, March 16, 2020 7:12 PM
To: NIAID Coronavirus Response SWAT 2020 <NIAIDCoronavirusResponseSWAT2020@mail.nih.gov>; NIAID PRWG <NIAIDPRWG@mail.nih.gov>; NIAID OD AM <NIAIDODAM@niaid.nih.gov>
Cc: Bozick, Brooke (NIH/OD) [E] (b) (6); Shaffer, Meredith (NIH/NIAID) [E] (b) (6); Barron, Karyl (NIH/NIAID) [E] (b) (6); Miller, Katherine (NIH/NIAID) [E] (b) (6); Li, Haiqing (NIH/NIAID) [E] (b) (6); DMID Word Nerds <DMIDWordNerds@niaid.nih.gov>; NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>; Parker, Marie (NIH/NIAID) [E] (b) (6); Schieber, Gretchen (NIH/NIAID) [E] (b) (6)
Subject: SARS-CoV-2 Research Updates - March 16

All -

With apologies for a slight delay, please find updates on the SARS-CoV-2 research response activities as of **3.16.2020**.

1. Digest form – NIAID Short Research Summary. Updates to last week's summary are indicated in red.
2. Longer reference form – NIAID Full Weekly update

These documents and the full tracker are also available on the NIAID SARS-CoV-2 Sharepoint. Please note: the link to the sharepoint was updated, so please use this link to access the site moving forward.

Best,
Nick

Nicholas Bushar, Ph.D.
Chief, Policy, Planning and Reporting Section
Policy, Planning, and Evaluation (PP&E) Branch
Office of Strategic Planning, Initiative Development, and Analysis, NIAID
National Institutes of Health (NIH)
Phone: (b) (6)

March 16, 2020

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March 16, 2020

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March 16, 2020

NIAID SARS-CoV-2 Research Updates

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From: Coomes, Stephanie (NIH/NIAID) [E]
To: nCoV extramural response
Cc: NIAID BUGS; Erbelding, Emily (NIH/NIAID) [E]
Subject: Fwd: SARS-CoV-2 Research Updates - March 8
Date: Sunday, March 8, 2020 10:47:28 PM
Attachments: NIAID SARS-CoV-2 Short Research Summary 3.8.20.docx
ATT00001.htm
NIAID SARS-CoV-2 Full Weekly Update 3.8.20 .docx
ATT00002.htm

FYI - updates from across NIAID

Begin forwarded message:

From: "Bushar, Nicholas (NIH/NIAID) [E]" (b) (6)
Date: March 8, 2020 at 4:40:49 PM EDT
To: NIAID Coronavirus Response SWAT 2020 <NIAIDCoronavirusResponseSWAT2020@mail.nih.gov>, "Cassetti, Cristina (NIH/NIAID) [E]" (b) (6), "Marston, Hilary (NIH/NIAID) [E]" (b) (6), "Pierson, Theodore (NIH/NIAID) [E]" (b) (6), "Munster, Vincent (NIH/NIAID) [E]" (b) (6), "Higgs, Elizabeth (NIH/NIAID) [E]" (b) (6), "McNay, Laura (NIH/NIAID) [E]" (b) (6), "Read, Sarah (NIH/NIAID) [E]" (b) (6), "Morabito, Kaitlyn (NIH/VRC) [E]" (b) (6), "Bok, Karin (NIH/VRC) [E]" (b) (6), "Leitner, Wolfgang (NIH/NIAID) [E]" (b) (6), "Lapham, Cheryl (NIH/NIAID) [E]" (b) (6), "Stumpo, Dante (NIH/NIAID) [E]" (b) (6), "Dominique, Joyelle (NIH/NIAID) [E]" (b) (6), "Bryant, Paula (NIH/NIAID) [E]" (b) (6), "Johnson, Martin S. (NIH/NIAID) [E]" (b) (6), "Graham, Barney (NIH/VRC) [E]" (b) (6), "Schneider, Johanna (NIH/NIAID) [E]" (b) (6), "Derocco, Amanda (NIH/NIAID) [E]" (b) (6), "Patterson, Jean (NIH/NIAID) [E]" (b) (6), "Handley, Gray (NIH/NIAID) [E]" (b) (6), "Deckhut, Alison (NIH/NIAID) [E]" (b) (6), "Touchette, Nancy (NIH/NIAID) [E]" (b) (6), "Lerner, Andrea (NIH/NIAID) [E]" (b) (6), "Young, Monique (NIH/VRC) [E]" (b) (6), "Stemmy, Erik (NIH/NIAID) [E]" (b) (6), "Corbett, Kizzmekia (NIH/VRC) [E]" (b) (6), "Yang, Linda (NIH/NIAID) [E]" (b) (6), "Ranjan, Mukul (NIH/NIAID) [E]" (b) (6), "Sorenson, Robert (NIH/NIAID) [C]" (b) (6), "Chen, Ping (NIH/NIAID) [E]" (b) (6), "Bernabe, Gayle (NIH/NIAID) [E]" (b) (6), "Rosa, William (NIH/NIAID) [E]" (b) (6), "Lu, Tami (NIH/NIAID) [E]" (b) (6),

NIAID OD AM <NIAIDODAM@niaid.nih.gov>
Cc: "Bozick, Brooke (NIH/OD) [E]" (b) (6), "Shaffer, Meredith (NIH/NIAID) [E]" (b) (6), "Barron, Karyl (NIH/NIAID) [E]" (b) (6), "Miller, Katherine (NIH/NIAID) [E]" (b) (6), "Li, Haiqing (NIH/NIAID) [E]" (b) (6), DMID Word Nerds <DMIDWordNerds@niaid.nih.gov>, NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: SARS-CoV-2 Research Updates - March 8

All -

Attached please find updates on the SARS-CoV-2 research response activities as of **3.8.2020**.

1. Digest form – NIAID Short Research Summary. Updates to last week's summary are indicated in red.
2. Longer reference form – NIAID Full Weekly update

These documents and the full tracker are also available on the NIAID SARS-CoV-2 Sharepoint.

Best,
Nick

Nicholas Bushar, Ph.D.
Chief, Policy, Planning and Reporting Section
Policy, Planning, and Evaluation (PP&E) Branch
Office of Strategic Planning, Initiative Development, and Analysis, NIAID
National Institutes of Health (NIH)
Phone: (b) (6)

March 8, 2020

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From: Coomes, Stephanie (NIH/NIAID) [E]
To: nCoV extramural response
Cc: NIAID BUGS
Subject: FW: SARS-CoV-2 Research Updates - Feb 22
Date: Monday, February 24, 2020 11:46:49 AM
Attachments: NIAID SARS-CoV-2 Short Research Summary 2.22.20.docx
NIAID SARS-CoV-2 Full Weekly Update 2.22.20.docx

FYI- SARS-CoV-2 updates from across NIAID

From: Bushar, Nicholas (NIH/NIAID) [E] (b) (6)
Sent: Sunday, February 23, 2020 2:17 PM
To: NIAID Coronavirus Response SWAT 2020 <NIAIDCoronavirusResponseSWAT2020@mail.nih.gov>; Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Marston, Hilary (NIH/NIAID) [E] (b) (6); Pierson, Theodore (NIH/NIAID) [E] (b) (6); Munster, Vincent (NIH/NIAID) [E] (b) (6); Higgs, Elizabeth (NIH/NIAID) [E] (b) (6); McNay, Laura (NIH/NIAID) [E] (b) (6); Read, Sarah (NIH/NIAID) [E] (b) (6); Morabito, Kaitlyn (NIH/VRC) [E] (b) (6); Bok, Karin (NIH/VRC) [E] (b) (6); Leitner, Wolfgang (NIH/NIAID) [E] (b) (6); Lapham, Cheryl (NIH/NIAID) [E] (b) (6); Stumpo, Dante (NIH/NIAID) [E] (b) (6); Dominique, Joyelle (NIH/NIAID) [E] (b) (6); Bryant, Paula (NIH/NIAID) [E] (b) (6); Johnson, Martin S. (NIH/NIAID) [E] (b) (6); Graham, Barney (NIH/VRC) [E] < (b) (6); Schneider, Johanna (NIH/NIAID) [E] (b) (6); Derocco, Amanda (NIH/NIAID) [E] (b) (6); Patterson, Jean (NIH/NIAID) [E] (b) (6); Handley, Gray (NIH/NIAID) [E] (b) (6); Deckhut, Alison (NIH/NIAID) [E] (b) (6); Touchette, Nancy (NIH/NIAID) [E] (b) (6); Lerner, Andrea (NIH/NIAID) [E] (b) (6); Young, Monique (NIH/VRC) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Corbett, Kizzmekia (NIH/VRC) [E] (b) (6); Yang, Linda (NIH/NIAID) [E] (b) (6); Ranjan, Mukul (NIH/NIAID) [E] (b) (6); Sorenson, Robert (NIH/NIAID) [C] (b) (6); Chen, Ping (NIH/NIAID) [E] (b) (6); Bernabe, Gayle (NIH/NIAID) [E] (b) (6); Rosa, William (NIH/NIAID) [E] (b) (6); Lu, Tami (NIH/NIAID) [E] (b) (6)
Cc: Bozick, Brooke (NIH/OD) [E] (b) (6); Shaffer, Meredith (NIH/NIAID) [E] (b) (6); Barron, Karyl (NIH/NIAID) [E] (b) (6); Miller, Katherine (NIH/NIAID) [E] (b) (6); Li, Haiqing (NIH/NIAID) [E] (b) (6); DMID Word Nerds <DMIDWordNerds@niaid.nih.gov>
Subject: SARS-CoV-2 Research Updates - Feb 22

All -

Attached please find updates on the SARS-CoV-2 research response activities as of **2.22.2020**.

1. Digest form – NIAID Research Summary. Updates to last week's summary are indicated in red.

2. Longer reference form – NIAID Full Weekly update

These documents and the full tracker are also available on the NIAID SARS-CoV-2 Sharepoint.

Best,
Nick

February 22, 2020

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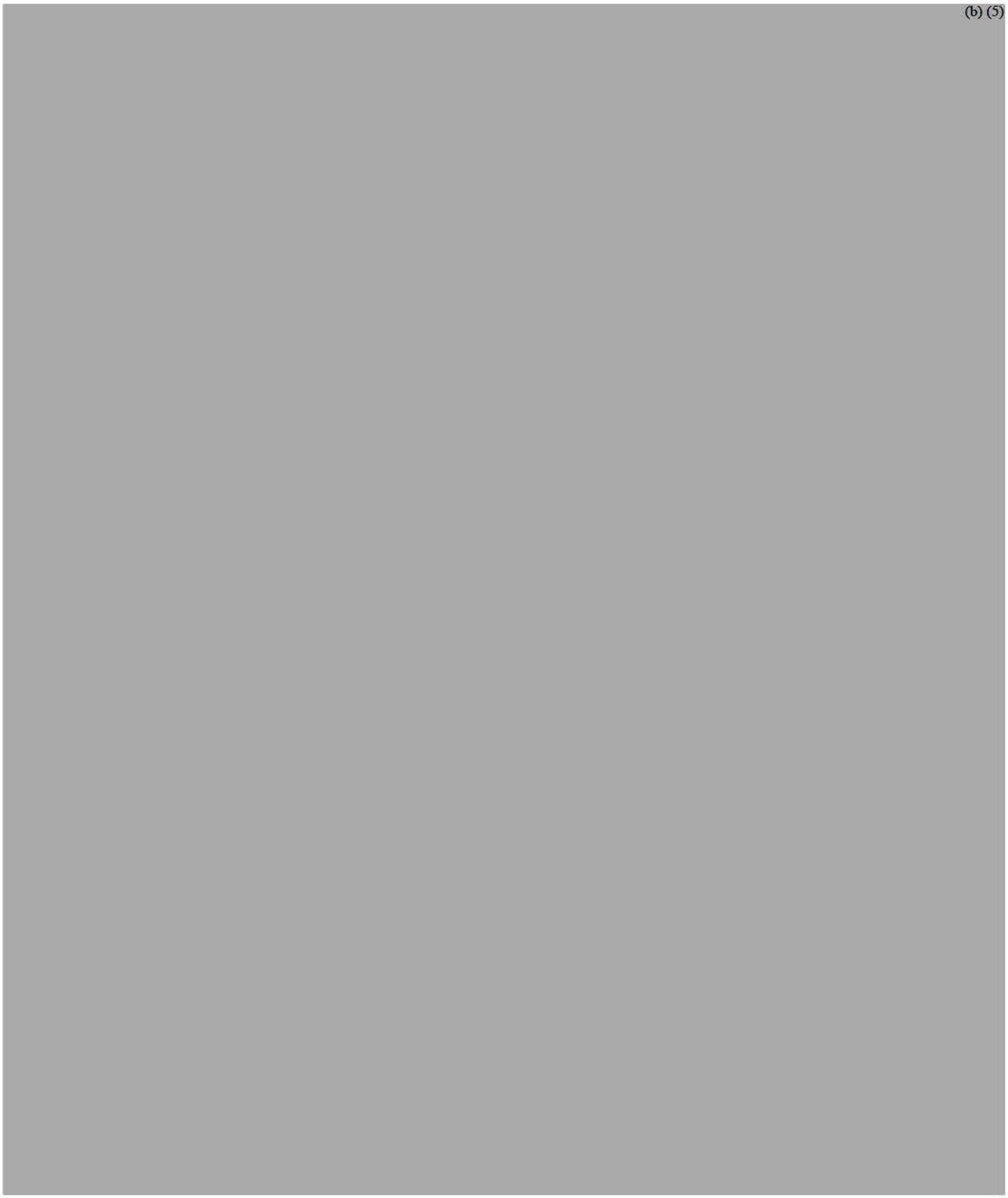

February 22, 2020

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From: Coomes, Stephanie (NIH/NIAID) [E]
To: nCoV extramural response; NIAID BUGS
Subject: FW: SARS-CoV-2 Research Updates - Feb 16
Date: Tuesday, February 18, 2020 8:27:54 AM
Attachments: NIAID SARS-CoV-2 Research Summary 2.16.20.docx
NIAID SARS-CoV-2 Full Weekly Update 2.16.20.docx

Good morning –

Attached are the latest NIAID updates on coronavirus activities.

Thanks!
Stephanie

From: Bushar, Nicholas (NIH/NIAID) [E] (b) (6)
Sent: Sunday, February 16, 2020 12:25 PM
To: NIAID Coronavirus Response SWAT 2020 <NIAIDCoronavirusResponseSWAT2020@mail.nih.gov>; Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Marston, Hilary (NIH/NIAID) [E] (b) (6); Pierson, Theodore (NIH/NIAID) [E] (b) (6); Munster, Vincent (NIH/NIAID) [E] (b) (6); Higgs, Elizabeth (NIH/NIAID) [E] (b) (6); McNay, Laura (NIH/NIAID) [E] (b) (6); Read, Sarah (NIH/NIAID) [E] (b) (6); Morabito, Kaitlyn (NIH/VRC) [E] (b) (6); Bok, Karin (NIH/VRC) [E] (b) (6); Leitner, Wolfgang (NIH/NIAID) [E] (b) (6); Lapham, Cheryl (NIH/NIAID) [E] (b) (6); Stumpo, Dante (NIH/NIAID) [E] (b) (6); Dominique, Joyelle (NIH/NIAID) [E] (b) (6); Bryant, Paula (NIH/NIAID) [E] (b) (6); Johnson, Martin S. (NIH/NIAID) [E] (b) (6); Graham, Barney (NIH/VRC) [E] (b) (6); Schneider, Johanna (NIH/NIAID) [E] (b) (6); Derocco, Amanda (NIH/NIAID) [E] (b) (6); Patterson, Jean (NIH/NIAID) [E] (b) (6); Handley, Gray (NIH/NIAID) [E] (b) (6); Deckhut, Alison (NIH/NIAID) [E] (b) (6); Touchette, Nancy (NIH/NIAID) [E] (b) (6); Lerner, Andrea (NIH/NIAID) [E] (b) (6); Young, Monique (NIH/VRC) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Corbett, Kizzmekia (NIH/VRC) [E] (b) (6); Yang, Linda (NIH/NIAID) [E] (b) (6); Ranjan, Mukul (NIH/NIAID) [E] (b) (6); Sorenson, Robert (NIH/NIAID) [C] (b) (6); Chen, Ping (NIH/NIAID) [E] (b) (6); Bernabe, Gayle (NIH/NIAID) [E] (b) (6); Rosa, William (NIH/NIAID) [E] (b) (6); Lu, Tami (NIH/NIAID) [E] (b) (6)
Cc: Bozick, Brooke (NIH/OD) [E] (b) (6); Shaffer, Meredith (NIH/NIAID) [E] (b) (6); Barron, Karyl (NIH/NIAID) [E] (b) (6); Miller, Katherine (NIH/NIAID) [E] (b) (6); Li, Haiqing (NIH/NIAID) [E] (b) (6); DMID Word Nerds <DMIDWordNerds@niaid.nih.gov>
Subject: SARS-CoV-2 Research Updates - Feb 16

All -

Attached please find updates on the SARS-CoV-2 research response activities as of **2.16.2020**.
Thanks again to the division leads for sending compiled information.

1. Digest form – NIAID Research Summary. Updates to last week's summary are indicated in red.
2. Longer reference form – NIAID Full Weekly update

These documents and the full tracker are also available on the NIAID SARS-CoV-2 Sharepoint.

Best,
Nick

Nicholas Bushar, Ph.D.
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Phone: (b) (6)

February 16, 2020

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February 16, 2020

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*No new updates from 2/8

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From: Lavelle, Judith (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: URGENT: Interview request: SADS-CoV and nCoV2019
Date: Wednesday, January 29, 2020 2:02:32 PM
Attachments: s41586-018-0010-9.pdf

Jeff Wang
Radio Free Asia
(202) 530 4900 | wangj@rfa.org
Subject: SADS-CoV and nCoV2019
Deadline: 4pm today, 1/29
Hi Erik,
This radio reporter has asked for 5-min phone interview with you before 4pm ET today. He is interested in a 2018 report on SADS-CoV, which affected Chinese swine, and its relationship (if any) to the current outbreak. He wants to know:

1. Could there be several different origins of the coronavirus outbreaking now in China?
2. How is the 2018 *Nature* article attached related to this crisis?

The interview would be recorded for broadcast. Would you be available to speak with Jeff? If so, I can send for clearance downtown and let connect you both over email.
Very best,
Judy
Judith Lavelle
Technical Writer-Editor
National Institute of Allergy and Infectious Diseases
5601 Fishers Ln., Room 6G37
Rockville, MD 20852
O: (b) (6) | M: (b) (6)
Pronouns: she/her | @jude_lavelle

LETTER

https://doi.org/10.1038/s41586-018-0010-9

Fatal swine acute diarrhoea syndrome caused by an HKU2-related coronavirus of bat origin

Peng Zhou[1,12], Hang Fan[2,12], Tian Lan[3,4,12], Xing-Lou Yang[1], Wei-Feng Shi[5], Wei Zhang[1], Yan Zhu[1], Ya-Wei Zhang[2], Qing-Mei Xie[3,4], Shailendra Mani[6], Xiao-Shuang Zheng[1], Bei Li[1], Jin-Man Li[2], Hua Guo[1], Guang-Qian Pei[2], Xiao-Ping An[2], Jun-Wei Chen[3,4], Ling Zhou[3,4], Kai-Jie Mai[3,4], Zi-Xian Wu[3,4], Di Li[3,4], Danielle E. Anderson[6], Li-Biao Zhang[7], Shi-Yue Li[8], Zhi-Qiang Mi[2], Tong-Tong He[2], Feng Cong[9], Peng-Ju Guo[9], Ren Huang[9], Yun Luo[1], Xiang-Ling Liu[1], Jing Chen[1], Yong Huang[2], Qiang Sun[2], Xiang-Li-Lan Zhang[2], Yuan-Yuan Wang[2], Shao-Zhen Xing[2], Yan-Shan Chen[3,4], Yuan Sun[3,4], Juan Li[5], Peter Daszak[10]*, Lin-Fa Wang[6]*, Zheng-Li Shi[1]*, Yi-Gang Tong[2,11]* & Jing-Yun Ma[3,4]*

Cross-species transmission of viruses from wildlife animal reservoirs poses a marked threat to human and animal health[1]. Bats have been recognized as one of the most important reservoirs for emerging viruses and the transmission of a coronavirus that originated in bats to humans via intermediate hosts was responsible for the high-impact emerging zoonosis, severe acute respiratory syndrome (SARS)[2–10]. Here we provide virological, epidemiological, evolutionary and experimental evidence that a novel HKU2-related bat coronavirus, swine acute diarrhoea syndrome coronavirus (SADS-CoV), is the aetiological agent that was responsible for a large-scale outbreak of fatal disease in pigs in China that has caused the death of 24,693 piglets across four farms. Notably, the outbreak began in Guangdong province in the vicinity of the origin of the SARS pandemic. Furthermore, we identified SADS-related CoVs with 96–98% sequence identity in 9.8% (58 out of 591) of anal swabs collected from bats in Guangdong province during 2013–2016, predominantly in horseshoe bats (*Rhinolophus* spp.) that are known reservoirs of SARS-related CoVs. We found that there were striking similarities between the SADS and SARS outbreaks in geographical, temporal, ecological and aetiological settings. This study highlights the importance of identifying coronavirus diversity and distribution in bats to mitigate future outbreaks that could threaten livestock, public health and economic growth.

The emergence of SARS in southern China in 2002, which was caused by a previously unknown coronavirus (SARS-CoV)[11–15] and has led to more than 8,000 human infections and 774 deaths (http://www.who.int/csr/sars/en/), highlights two new frontiers in emerging infectious diseases. First, it demonstrates that coronaviruses are capable of causing fatal diseases in humans. Second, the identification of bats as the reservoir for SARS-related coronaviruses, and the fact that SARS-CoV[3–10] probably originated in bats, firmly establishes that bats are an important source of highly lethal zoonotic viruses, such as Hendra, Nipah, Ebola and Marburg viruses[16].

Here we report on a series of fatal swine disease outbreaks in Guangdong province, China, approximately 100 km from the location of the purported index case of SARS. Most strikingly, we found that the causative agent of this swine acute diarrhoea syndrome (SADS) is a novel HKU2-related coronavirus that is 98.48% identical in genome sequence to a bat coronavirus, which we detected in 2016 in bats in a cave in the vicinity of the index pig farm. This new virus (SADS-CoV) originated from the same genus of horseshoe bats (*Rhinolophus*) as SARS-CoV.

From 28 October 2016 onwards, a fatal swine disease outbreak was observed in a pig farm in Qingyuan, Guangdong province, China, very close to the location of the first known index case of SARS in 2002, who lived in Foshan (Extended Data Fig. 1a). Porcine epidemic diarrhoea virus (PEDV, a coronavirus) had caused prior outbreaks at this farm, and was detected in the intestines of deceased piglets at the start of the outbreak. However, PEDV could no longer be detected in deceased piglets after 12 January 2017, despite accelerating mortality (Fig. 1a), and extensive testing for other common swine viruses yielded no results (Extended Data Table 1). These findings suggested that this was an outbreak of a novel disease. Clinical signs are similar to those caused by other known swine enteric coronaviruses[17,18] and include severe and acute diarrhoea and acute vomiting, leading to death due to rapid weight loss in newborn piglets that are less than five days of age. Infected piglets died 2–6 days after disease onset, whereas infected sows suffered only mild diarrhoea and most sows recovered within two days. The disease caused no signs of febrile illness in piglets or sows. The mortality rate was as high as 90% in piglets that were five days or younger, whereas in piglets that were older than eight days, the mortality dropped to 5%. Subsequently, SADS-related outbreaks were found in three additional pig farms within 20–150 km of the index farm (Extended Data Fig. 1a) and, by 2 May 2017, the disease had caused the death of 24,693 piglets at these four farms (Fig. 1a). In farm A alone, 64% (4,659 out of 7,268) of all piglets that were born in February died. The outbreak has abated, and measures that were taken to control SADS included separation of sick sows and piglets from the rest of the herd. A qPCR test described below was used as the main diagnostic tool to confirm SADS-CoV infection.

A sample collected from the small intestine of a diseased piglet was analysed by metagenomics analysis using next-generation sequencing (NGS) to identify potential aetiological agents. Of the 15,256,565 total reads obtained, 4,225 matched sequences of the bat CoV HKU2, which was first detected in Chinese horseshoe bats in Hong Kong and Guangdong province, China[19]. By de novo assembly and targeted PCR, we obtained a 27,173-bp CoV genome that shared 95% sequence identity to HKU2-CoV (GenBank accession number NC_009988). Thirty-three full genome sequences of SADS-CoV were subsequently obtained (8 from farm A, 5 from farm B, 11 from farm C and 9 from farm D) that were 99.9% identical to each other (Supplementary Table 1).

[1]CAS Key Laboratory of Special Pathogens and Biosafety, Wuhan Institute of Virology, Chinese Academy of Sciences, Wuhan, China. [2]Beijing Institute of Microbiology and Epidemiology, Beijing, China. [3]College of Animal Science, South China Agricultural University, Guangzhou, China. [4]Key Laboratory of Animal Health Aquaculture and Environmental Control, Guangzhou, China. [5]Key Laboratory of Etiology and Epidemiology of Emerging Infectious Diseases in Universities of Shandong, Taishan Medical College, Taian, China. [6]Programme in Emerging Infectious Diseases, Duke-NUS Medical School, Singapore, Singapore. [7]Guangdong Key Laboratory of Animal Conservation and Resource Utilization, Guangdong Public Laboratory of Wild Animal Conservation and Utilization, Guangdong Institute of Applied Biological Resources, Guangzhou, China. [8]School of Public Health, Wuhan University, Wuhan, China. [9]Guangdong Key Laboratory of Laboratory Animals, Guangdong Laboratory Animals Monitoring Institute, Guangzhou, China. [10]EcoHealth Alliance, New York, NY, USA. [11]School of Life Sciences, North China University of Science and Technology, Tangshan, China. [12]These authors contributed equally: Peng Zhou, Hang Fan, Tian Lan. *e-mail: daszak@ecohealthalliance.org; linfa.wang@duke-nus.edu.sg; zlshi@wh.iov.cn; tong.yigang@gmail.com; majy2400@scau.edu.cn

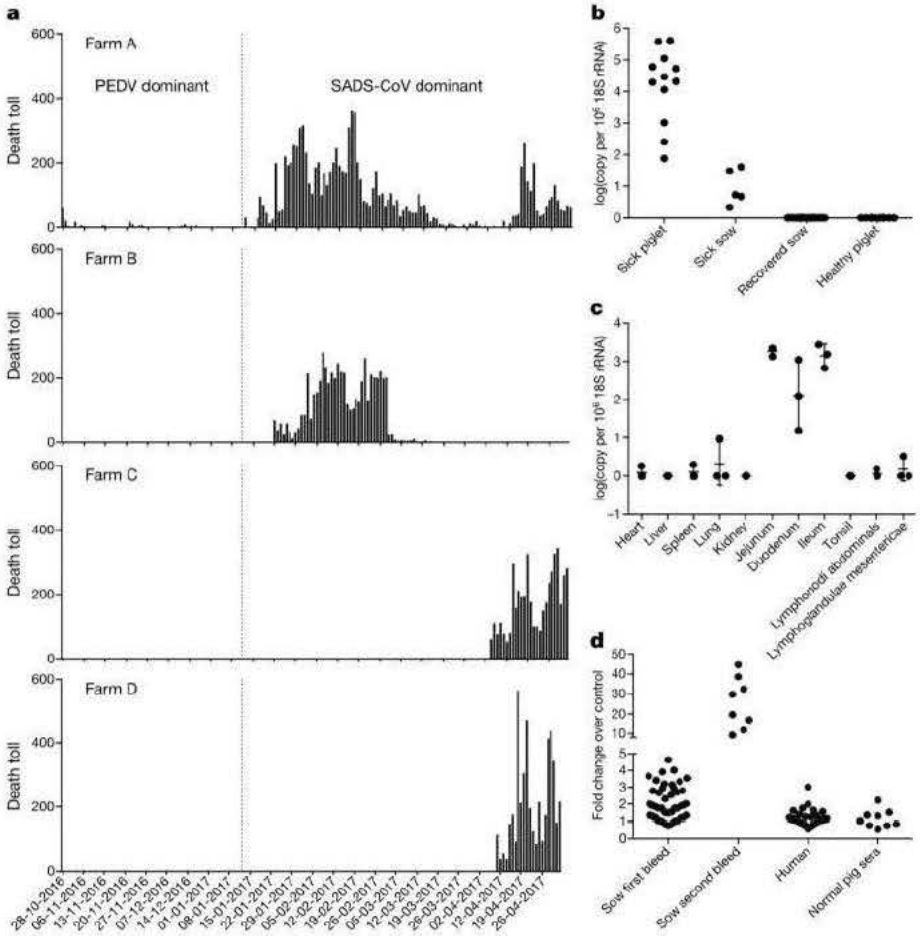

Fig. 1 | Detection of SADS-CoV infection in pigs in Guangdong, China. **a**, Records of daily death toll on the four farms from 28 October 2016 to 2 May 2017. **b**, Detection of SADS-CoV by qPCR. The *y* axis shows the log(copy number per 10^6 copies of 18S rRNA). $n = 12$ sick piglets, 5 sick sows, 16 recovered sows and 10 healthy piglets. **c**, Tissue distribution of SADS-CoV in diseased pigs. $n = 3$. Data are mean ± s.d.; dots represent individual values. **d**, Detection of SADS-CoV antibodies. $n = 46$ sows from whom serum was first taken in the first three weeks of the outbreak (First bleed), $n = 8$ sows from whom serum was taken again (Second bleed) at more than one month after the onset of the outbreak, $n = 8$ sera from healthy pig controls, $n = 35$ human sera from pig farmers.

Using qPCR targeting the nucleocapsid gene (Supplementary Table 2), we detected SADS-CoV in acutely sick piglets and sows, but not in recovered or healthy pigs on the four farms, nor in nearby farms that showed no evidence of SADS. The virus replicated to higher titres in piglets than in sows (Fig. 1b). SADS-CoV displayed tissue tropism of the small intestine (Fig. 1c), as observed for other swine enteric coronaviruses[20]. Retrospective PCR analysis revealed that SADS-CoV was present on farm A during the PEDV epidemic, where the first strongly positive SADS-CoV sample was detected on 6 December 2016. From mid-January onwards, SADS-CoV was the dominant viral agent detected in diseased animals (Extended Data Fig. 1b). It is possible that the presence of PEDV early in the SADS-CoV outbreak may have somehow facilitated or enhanced spillover and amplification of SADS. However the fact that the vast majority of piglet mortality occurred after PEDV infection had become undetectable suggests that SADS-CoV itself causes a lethal infection in pigs that was responsible for these large-scale outbreaks, and that PEDV does not directly contribute to its severity in individual pigs. This was supported by the absence of PEDV and other known swine diarrhoea viruses during the peak and later phases of the SADS outbreaks in the four farms (Extended Data Table 1).

We rapidly developed an antibody assay based on the S1 domain of the spike (S) protein using a luciferase immunoprecipitation system[21]. Because SADS occurs acutely and has a rapid onset in piglets, serological investigation was conducted only in sows. Among 46 recovered sows tested, 12 were seropositive for SADS-CoV within three weeks of infection (Fig. 1d). To investigate possible zoonotic transmission, serum samples from 35 farm workers who had close contact with sick pigs were also analysed using the same luciferase immunoprecipitation system approach and none were positive for SADS-CoV.

Although the overall genome identity of SADS-CoV and HKU2-CoV is 95%, the S gene sequence identity is only 86%, suggesting that the previously reported HKU2-CoV is not the direct progenitor of SADS-CoV, but that they may have originated from a common ancestor. To test this hypothesis, we developed a SADS-CoV-specific qPCR assay based on its RNA-dependent RNA polymerase (*RdRp*) gene (Supplementary Table 2) and screened 591 bat anal swabs collected between 2013 and 2016 from seven different locations in Guangdong province (Extended Data Fig. 1a). A total of 58 samples (9.8%) tested positive (Extended Data Table 2), all were from *Rhinolophus* spp. bats that are also the natural reservoir hosts of SARS-related coronaviruses[3–10]. Four complete genome sequences with the highest *RdRp* PCR-fragment sequence identity to that of SADS-CoV were determined by NGS. They are very similar in size (27.2 kb) compared to SADS-CoV (Fig. 2a) and we tentatively call them SADS-related coronaviruses (SADSr-CoV). Overall sequence identity between SADSr-CoV and SADS-CoV ranges from 96 to 98%. Most importantly, the S protein of SADS-CoV shared more than 98% sequence identity with sequences of two of the SADSr-CoVs (samples 162149 and 141388), compared to 86% with HKU2-CoV. The major sequence differences among the four SADSr-CoV genomes were found in the predicted coding regions of the *S* and *NS7a* and *NS7b* genes (Fig. 2a). In addition, the coding region

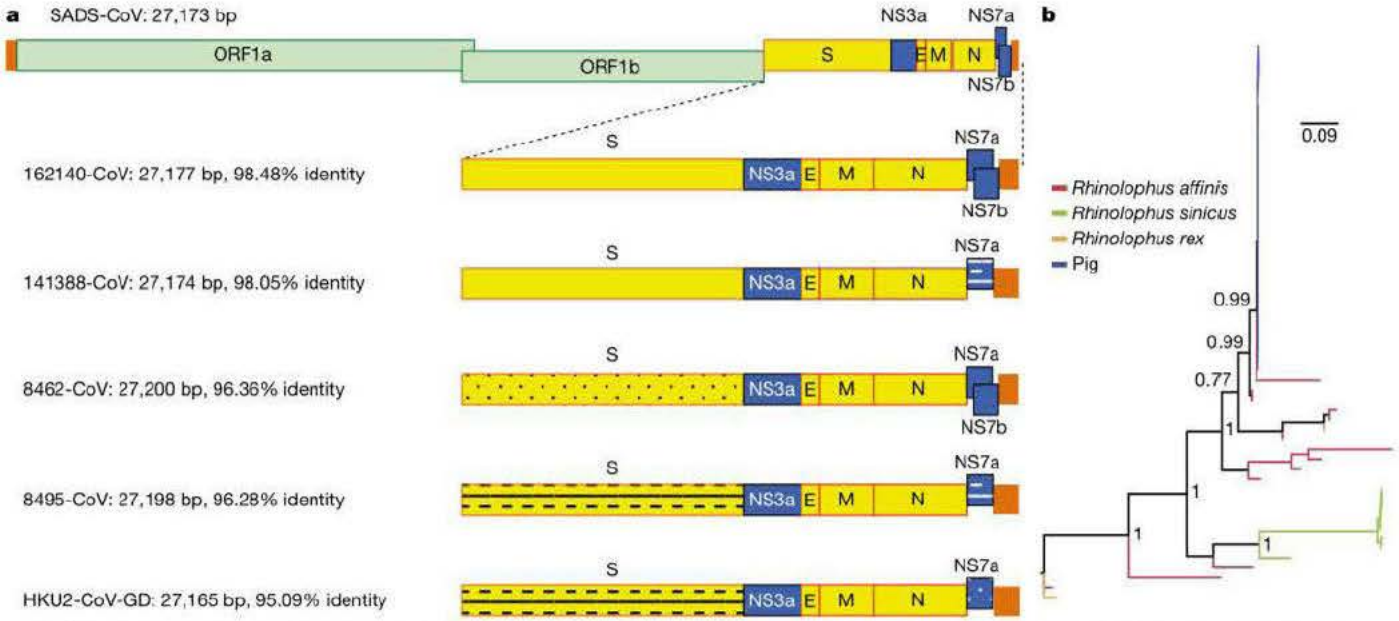

Fig. 2 | Genome and phylogenetic analysis of SADS-CoV and SADSr-CoV. a, Genome organization and comparison. Colour-coding for different genomic regions as follows. Green, non-structural polyproteins *ORF1a* and *ORF1b*; yellow, structural proteins *S*, *E*, *M* and *N*; blue, accessory proteins *NS3a*, *NS7a* and *NS7b*; Orange, untranslated regions. The level of sequence identity of SADSr-CoV to SADS-CoV is illustrated by different patterns of boxes: Solid colour, highly similar; Dotted fill, moderately similar; Dashed fill, least similar. **b**, Phylogenetic analysis of 57 *S1* sequences (33 from SADS-CoV and 24 from SADSr-CoV). Different colours represent different host species as shown on the left. Scale bar, nucleotide substitutions per site.

of the S protein N-terminal (S1) domain was determined from 19 bat SADSr-CoVs to enable more detailed phylogenetic analysis.

The phylogeny of S1 and the full-length genome revealed a high genetic diversity of alphacoronaviruses among bats and strong coevolutionary relationships with their hosts (Fig. 2b and Extended Data Fig. 2), and showed that SADS-CoVs were more closely related to SADSr-CoVs from *Rhinolophus affinis* than from *Rhinolophus sinicus*, in which HKU2-CoV was found. Both phylogenetic and haplotype network analyses demonstrated that the viruses from the four farms probably originated from their reservoir hosts independently (Extended Data Fig. 3), and that a few viruses might have undergone further genetic recombination (Extended Data Fig. 4). However, molecular clock analysis of the 33 SADS-CoV genome sequences failed to establish a positive association between sequence divergence and sampling date. Therefore, we speculate that either the virus was introduced into pigs from bats multiple times, or that the virus was introduced into pigs once, but subsequent genetic recombination disturbed the molecular clock.

For viral isolation, we tried to culture the virus in a variety of cell lines (see Methods for details) using intestinal tissue homogenates as starting material. Cytopathogenic effects were observed in Vero cells only after five passages (Extended Data Fig. 5a, b). The identity of SADS-CoV was verified in Vero cells by immunofluorescence microscopy (Extended Data Fig. 5c, d) and by whole-genome sequencing (GenBank accession number MG557844). Similar results were obtained by other groups[22,23].

Known coronavirus host cell receptors include angiotensin-converting enzyme 2 (ACE2) for SARS-related CoV, aminopeptidase N (APN) for certain alphacoronaviruses, such as human (H)CoV-229E, and dipeptidyl peptidase 4 (DPP4) for Middle East respiratory syndrome (MERS)-CoV[24–26]. To investigate the receptor usage of SADS-CoV, we tested live or pseudotyped SADS-CoV infection on HeLa cells that expressed each of the three molecules. Whereas the positive control worked for SARS-related CoV and MERS-CoV pseudoviruses, we found no evidence of enhanced infection or entry for SADS-CoV, suggesting that none of these receptors functions as a receptor for virus entry for SADS-CoV (Extended Data Table 3).

To fulfill Koch's postulates for SADS-CoV, two different types of animal challenge experiments were conducted (see Methods for details). The first challenge experiment was conducted with specific pathogen-free piglets that were infected with a tissue homogenate of SADS-CoV-positive intestines. Two days after infection, 3 out of 7 animals died in the challenge group whereas 4 out of 5 survived in the control group. Incidentally, the one piglet that died in the control group was the only individual that did not receive colostrum due to a shortage in the supply. It is thus highly likely that lack of nursing and

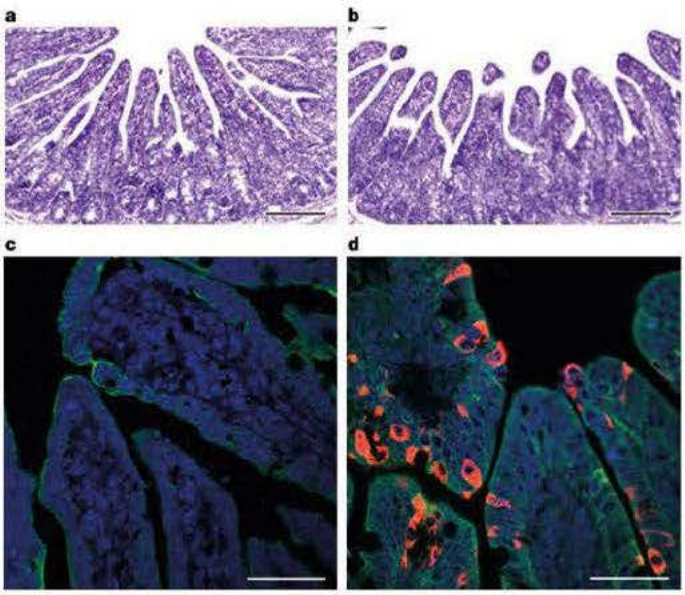

Fig. 3 | Immunohistopathology of SADS-CoV infected tissues. **a**–**d**, Sections of jejunum tissue from control (**a**, **c**) and infected (**b**, **d**) farm piglets four days after inoculation were stained with haematoxylin and eosin (**a**, **b**) or rabbit anti-SADSr-CoV N serum (red), DAPI (blue) and mouse antibodies against epithelial cell markers cytokeratin 8, 18 and 19 (green) in (**c**, **d**). SADS-CoV N protein is evident in epithelial cells and deeper in the tissue of infected piglets, which exhibit villus shortening. Scale bars, 200 μm (**a**, **b**) and 50 μm (**c**, **d**). The experiment was conducted three times independently with similar results.

inability to access colostrum was responsible for the death (Extended Data Table 4). For the second challenge, healthy piglets were acquired from a farm in Guangdong that had been free of diarrheal disease for a number of weeks before the experiment, and were infected with the cultured isolate of SADS-CoV or tissue-culture medium as control. Of those inoculated with SADS-CoV, 50% (3 out of 6) died between 2 and 4 days after infection, whereas all control animals survived (Extended Data Table 5). All animals in the infected group suffered watery diarrhoea, rapid weight loss and intestinal lesions (determined after euthanasia upon experiment termination, Extended Data Tables 4, 5). Histopathological examination revealed marked villus atrophy in SADS-CoV inoculated farm piglets four days after inoculation but not in control piglets (Fig. 3a, b) and viral N protein-specific staining was observed mainly in small intestine epithelial cells of the inoculated piglets (Fig. 3c, d).

The current study highlights the value of proactive viral discovery in wildlife, and targeted surveillance in response to an emerging infectious disease event, as well as the disproportionate importance of bats as reservoirs of viruses that threaten veterinary and public health[1]. It also demonstrates that by using modern technological platforms, such as NGS, luciferase immunoprecipitation system serology and phylogenetic analysis, key experiments that traditionally rely on the isolation of live virus can be performed rapidly before virus isolation.

Online content

Any Methods, including any statements of data availability and Nature Research reporting summaries, along with any additional references and Source Data files, are available in the online version of the paper at https://doi.org/10.1038/s41586-018-0004-7.

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Competing interests The authors declare no competing interests.

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METHODS

Sample collection. Bats were captured and sampled in their natural habitat in Guangdong province (Extended Data Fig. 1) as described previously[4]. Faecal swab samples were collected in viral transport medium (VTM) composed of Hank's balanced salt solution at pH 7.4 containing BSA (1%), amphotericin (15 μg ml^{-1}), penicillin G (100 units ml^{-1}) and streptomycin (50 μg ml^{-1}). Stool samples from sick pigs were collected in VTM. When appropriate and feasible, intestinal samples were also taken from deceased animals. Samples were aliquoted and stored at −80 °C until use. Blood samples were collected from recovered sows and workers on the farms who had close contact with sick pigs. Serum was separated by centrifugation at 3,000*g* for 15 min within 24 h of collection and preserved at 4 °C. Human serum collection was approved by the Medical Ethics Committee of the Wuhan School of Public Health, Wuhan University and Hummingbird IRB. Human, pigs and bats were sampled without gender or age preference unless indicated (for example, piglets or sows). No statistical methods were used to predetermine sample size.

Virus isolation. The following cells were used for virus isolation in this study: Vero (cultured in DMEM and 10% FBS); *Rhinolophus sinicus* primary or immortalized cells generated in our laboratory (all cultured in DMEM/F12 and 15% FBS): kidney primary cells (RsKi9409), lung primary cells (RsLu4323), lung immortalized cells (RsLuT), brain immortalized cells (RsBrT) and heart immortalized cells (RsHeT); and swine cell lines: two intestinal porcine enterocytes cell lines, IPEC (RPMI1640 and 10% FBS) and SIEC (DMEM and 10% FBS), three kidney cell lines PK15, LLC-PK1 (DMEM and 10% FBS for both) and IBRS (MEM and 10% FBS), and one pig testes cell line, ST (DMEM and 10% FBS). All cell lines were tested free of mycoplasma contamination, species were confirmed and authenticated by microscopic morphologic evaluation. None of the cell lines was on the list of commonly misidentified cell lines (by the ICLAC).

Cultured cell monolayers were maintained in their respective medium. PCR-positive pig faecal samples or the supernatant from homogenized pig intestine (in 200 μl VTM) were spun at 8,000*g* for 15 min, filtered and diluted 1:2 with DMEM supplemented with 16 μg ml^{-1} trypsin before addition to the cells. After incubation at 37 °C for 1 h, the inoculum was removed and replaced with fresh culture medium containing antibiotics (below) and 16 μg ml^{-1} trypsin. The cells were incubated at 37 °C and observed daily for cytopathic effect (CPE). Four blind passages (three-day interval between every passage) were performed for each sample. After each passage, both the culture supernatant and cell pellet were examined for the presence of virus by RT–PCR using the SADS-CoV primers listed in Supplementary Table 2. Penicillin (100 units ml^{-1}) and streptomycin (15 μg ml^{-1}) were included in all tissue culture media.

RNA extraction, *S1* gene amplification and qPCR. Whenever commercial kits were used, the manufacturer's instructions were followed without modification. RNA was extracted from 200 μl of swab samples (bat), faeces or homogenized intestine (pig) with the High Pure Viral RNA Kit (Roche). RNA was eluted in 50 μl of elution buffer and used as the template for RT–PCR. Reverse transcription was performed using the SuperScript III kit (Thermo Fisher Scientific).

To amplify *S1* genes from bat samples, nested PCR was performed with primers designed based on HKU2-CoV (GenBank accession number NC_009988.1)[19] (Supplementary Table 2). The 25-μl first-round PCR mixture contained 2.5 μl 10× PCR reaction buffer, 5 pmol of each primer, 50 mM $MgCl_2$, 0.5 mM dNTP, 0.1 μl Platinum Taq Enzyme (Thermo Fisher Scientific) and 1 μl cDNA. The 50-μl second-round PCR mixture was identical to the first-round PCR mixture except for the primers. Amplification of both rounds was performed as follows: 94 °C for 5 min followed by 60 cycles at 94 °C for 30 s, 50 °C for 40 s, 72 °C for 2.5 min, and a final extension at 72 °C for 10 min. PCR products were gel-purified and sequenced.

For qPCR analysis, primers based on SADS-CoV *RdRp* and *N* genes were used (Supplementary Table 2). RNA extracted from above was reverse-transcribed using PrimeScript RT Master Mix (Takara). The 10 μl qPCR reaction mix contained 5 μl 2× SYBR premix Ex TaqII (Takara), 0.4 μM of each primer and 1 μl cDNA. Amplification was performed as follows: 95 °C for 30 s followed by 40 cycles at 95 °C for 5 s, 60 °C for 30 s, and a melting curve step.

Luciferase immunoprecipitation system assay. The SADS-CoV *S1* gene was codon-optimized for eukaryotic expression, synthesized (GenScript) and cloned in frame with the Renilla luciferase gene (Rluc) and a Flag tag in the pREN2 vector[21]. pREN2-S1 plasmids were transfected into Cos-1 cells using Lipofectamine 2000 (Thermo Fisher Scientific). At 48 h post-transfection, cells were collected, lysed and a luciferase assay was performed to determine Rluc expression for both the empty vector (pREN2) and the pREN2-S1 construct. For testing of unknown pig or human serum samples, 1 μl of serum was incubated with 10 million units of Rluc alone (vector) or Rluc-S1, respectively, together with 3.5 μl of a 30% protein A/G UltraLink resin suspension (Pierce, Thermo Fisher Scientific). After extensive washing to remove unbounded luciferase-tagged antigens, the captured luciferase amount was determined using the commercial luciferase substrate kit (Promega). The ratio of Rluc-S1:Rluc (vector) was used to determine the specific S1 reactivity of pig and human sera. Commercial Flag antibody (Thermo Fisher Scientific) was used as the positive control, and various pig sera (from uninfected animals in China or Singapore; or pigs infected with PEDV, TGEV or Nipah virus) were used as a negative control.

Protein expression and antibody production. The *N* gene from SADSr-CoV 3755 (GenBank accession number MF094702), which shares a 98% amino acid sequence identity to the SADS-CoV N protein, was inserted into pET-28a+ (Novagen) for prokaryotic expression. Transformed *Escherichia coli* were grown at 37 °C for 12–18 h in medium containing 1 mM IPTG. Bacteria were collected by centrifugation and resuspended in 30 ml of 5 mM imidazole and lysed by sonication. The lysate, from which N protein expression was confirmed with an anti-His-tag antibody, was applied to Ni^{2+} resin (Thermo Fisher Scientific). The purified N protein, at a concentration of 400 μg ml^{-1}, was used to immunize rabbits for antibody production following published methods[27]. After immunization and two boosts, rabbits were euthanized and sera were collected. Rabbit anti-N protein serum was used 1:10,000 for subsequent western blots.

Amplification, cloning and expression of human and swine genes. Construction of expression clones for human *ACE2* in pcDNA3.1 has been described previously[5,28]. Human *DPP4* was amplified from human cell lines. Human *APN* (also known as *ANPEP*) was commercially synthesized. Swine *APN* (also known as *ANPEP*), *DPP4* and *ACE2* were amplified from piglet intestine. Full-length gene fragments were amplified using specific primers (provided upon request). Human *ACE2* was cloned into pCDNA3.1 fused with a His tag. Human *APN* and *DPP4*, swine *APN*, *DPP4* and *ACE2* were cloned into pCAGGS fused with an S tag. Purified plasmids were transfected into HeLa cells. After 24 h, expression human or swine genes in HeLa cells was confirmed by immunofluorescence assay using mouse anti-His tag or mouse anti-S tag monoclonal antibodies (produced in house) followed by Cy3-labelled goat anti-mouse/rabbit IgG (Proteintech Group).

Pseudovirus preparation. The codon-humanized *S* genes of SADS-CoV or MERS-CoV cloned into pcDNA3.1 were used for pseudovirus construction as described previously[5,28]. In brief, 15 μg of each pHIV-Luc plasmid (pNL4.3.Luc.R-E-Luc) and the S-protein-expressing plasmid (or empty vector control) were co-transfected into 4 × 10^6 HEK293T cells using Lipofectamine 3000 (Thermo Fisher Scientific). After 4 h, the medium was replaced with fresh medium. Supernatants were collected 48 h after transfection and clarified by centrifugation at 3,000*g*, then passed through a 0.45-μm filter (Millipore). The filtered supernatants were stored at −80 °C in aliquots until use. To evaluate the incorporation of S proteins into the core of HIV virions, pseudoviruses in supernatant (20 ml) were concentrated by ultracentrifugation through a 20% sucrose cushion (5 ml) at 80,000*g* for 90 min using a SW41 rotor (Beckman). Pelleted pseudoviruses were dissolved in 50 μl phosphate-buffered saline (PBS) and examined by electron microscopy.

Pseudovirus infection. HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared using Lipofectamine 2000 (Thermo Fisher Scientific). Pseudoviruses prepared above were added to HeLa cells overexpressing APN, ACE2 or DPP4 24 h after transfection. The unabsorbed viruses were removed and replaced with fresh medium at 3 h after infection. The infection was monitored by measuring the luciferase activity conferred by the reporter gene carried by the pseudovirus, using the Luciferase Assay System (Promega) as follows: cells were lysed 48 h after infection, and 20 μl of the lysates was taken for determining luciferase activity after the addition of 50 μl of luciferase substrate.

Examination of known CoV receptors for SADS-CoV entry/infection. HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared using Lipofectamine 2000 (Thermo Fisher Scientific) in a 96-well plate, with mock-transfected cells as controls. SADS-CoV grown in Vero cells was used to infect HeLa cells transiently expressing APN, ACE2 or DPP4. The inoculum was removed after 1 h of absorption and washed twice with PBS and supplemented with medium. SARS-related-CoV WIV16[7] and MERS-CoV HIV-pseudovirus were used as positive control for human/swine ACE2 or human/swine DPP4, respectively. After 24 h of infection, cells were washed with PBS and fixed with 4% formaldehyde in PBS (pH 7.4) for 20 min at room temperature. SARS-related-CoV WIV16 replication was detected using rabbit antibody against the SARS-related-CoV Rp3 N protein (made in house, 1:100) followed by Cy3-conjugated goat anti-rabbit IgG (1:50, Proteintech)[7]. SADS-CoV replication was monitored using rabbit antibody against the SADSr-CoV 3755 N protein (made in house, 1:50) followed by FITC-conjugated goat anti-rabbit IgG (1:50, Proteintech). Nuclei were stained with DAPI (Beyotime). Staining patterns were examined using confocal microscopy on a FV1200 microscope (Olympus). Infection of MERS-CoV HIV-pseudovirus was monitored by luciferase 48 h after infection.

High-throughput sequencing, pathogen screening and genome assembly. Tissue from the small intestine of deceased pigs was homogenized and filtered through 0.45-μm filters before nucleic acid extraction and ribosomal RNA was depleted using the NEBNext rRNA Depletion Kit (New England Biolabs). Metagenomics analysis of both RNA and DNA viruses was performed. For RNA virus screening, the sequencing library was constructed using Ion Total RNA-Seq Kit v2 (Thermo Fisher Scientific). For DNA virus screening, NEBNext Fast DNA Fragmentation

& Library Prep Set for Ion Torrent (New England Biolabs) was used for library preparation. Both libraries were sequenced on an Ion S5 sequencer (Thermo Fisher Scientific). An analysis pipeline was applied to the sequencing data, which included the following analysis steps: (1) raw data quality filtering; (2) host genomic sequence filtering; (3) BLASTn search against the virus nucleotide database using BLAST; (4) BLASTx search against the virus protein database using DIAMOND v.0.9.0; (5) contig assembling and BLASTx search against the virus protein database. For whole viral genome sequencing, amplicon primers (provided upon request) were designed using the Thermo Fisher Scientific online tool with the HKU2-CoV and the SADS-CoV farm A genomes as references, and the sequencing libraries were constructed using NEBNext Ultra II DNA Library Prep Kit for Illumina and sequenced on an MiSeq sequencer. PCR and Sanger sequencing was performed to fill gaps in the genome. Genome sequences were assembled using CLC Genomic Workbench v.9.0. 5′-RACE was performed to determine the 5′-end of the genomes using SMARTer RACE 5′/3′ Kit (Takara). Genomes were annotated using Clone Manager Professional Suite 8 (Sci-Ed Software).

Phylogenetic analysis. SADS-CoV genome sequences and other representative coronavirus sequences (obtained from GenBank) were aligned using MAFFT v.7.221. Phylogenetic analyses with full-length genome, *S* gene and *RdRp* were performed using MrBayes v.3.2. Markov chain Monte Carlo was run for 20–50 million steps using the GTR+G+I model (general time reversible model of nucleotide substitution with a proportion of invariant sites and γ-distributed rates among sites). The first 10% was removed as burn-in. The association between phylogenies and phenotypes (for example, host species and farms) was assessed by BaTS beta-build2, with the trees obtained in the previous step used as input. For SADS-CoVs, a median-joining network analysis was performed using PopART v.1.7, with $\varepsilon = 0$. Phylogenetic analysis of the 33 full-length SADS-CoV genome sequences was performed using RAxML v.8.2.11, with GTRGAMMA as the nucleotide substitution model and 1,000 bootstrap replicates. The maximum likelihood tree was used to test the molecular clock using TempEst v.1.5. Potential genetic recombination events in our datasets were detected using RDP v.4.72.

Animal infection studies. Experiments were carried out strictly in accordance with the recommendations of the Guide for the Care and Use of Laboratory Animals of the National Institutes of Health. The use of animals in this study was approved by the South China Agricultural University Committee of Animal Experiments (approval number 201004152).

Two different animal challenge experiments were conducted. Pigs were used without gender preference. In the first experiment, which was conducted before the virus was isolated, we used three-day old specific pathogen-free (SPF) piglets of the same breeding line, cared for at a SPF facility, fed with colostrum (except one). These piglets were bred and reared to be free of PEDV, CSFV, SIV, PCV2 and PPV infections, and were routinely tested for viral infections using PCR. We also conducted NGS to further confirm that these were animals were free of infection of the above viruses before the animal experiment, and to demonstrate that the animals were free of SADS-CoV infection. The intestinal tissue samples from healthy and diseased animals (intestinal samples excised from euthanized piglets, then ground to make slurry for the inoculum and NGS was performed to confirm no other pig pathogens were found in the samples), were used to feed two groups of 5 (control) and 7 (infection) animals, respectively. For the second experiment, isolated SADS-CoV was used to infect healthy piglets from a farm in Guangdong, which had been free of diarrheal disease for a number of weeks. These piglets were from the same breed as those on SADS-affected farms, to eliminate potential host factor differences and to more accurately reproduce the conditions that occurred during the outbreak in the region. Both groups of piglets were cared for at a known pig disease-free facility. Again, qPCR and NGS were used to make sure that there was no other known swine diarrhoea virus present in the virus inoculum or any of the experimental animals. Two groups (6 for each group) of three-day old piglets were inoculated with SADS-CoV culture supernatant or normal cell culture medium as control. NGS and qPCR were used to confirm that there were no other known swine pathogens in the inoculum.

For both experiments, animals were recorded daily for signs of diseases, such as diarrhoea, weight loss and death. Faecal swabs were collected daily from all animals and screened for known swine diarrhoea viruses by qPCR. Weight loss was calculated as the percentage weight loss compared the original weight at day 0 with a threshold of >5%. It is important to point out that piglets when they are three days old tend to suffer from diarrhoea and weight loss when they are taken away from sows and the natural breast-feeding environment even without infection. At experimental endpoints, piglets were humanely euthanized and necropsies performed. Pictures were taken to record gross pathological changes to the intestines. Ileal, jejunal and duodenal tissues were taken from selected animals and stored at −80 °C for further analysis.

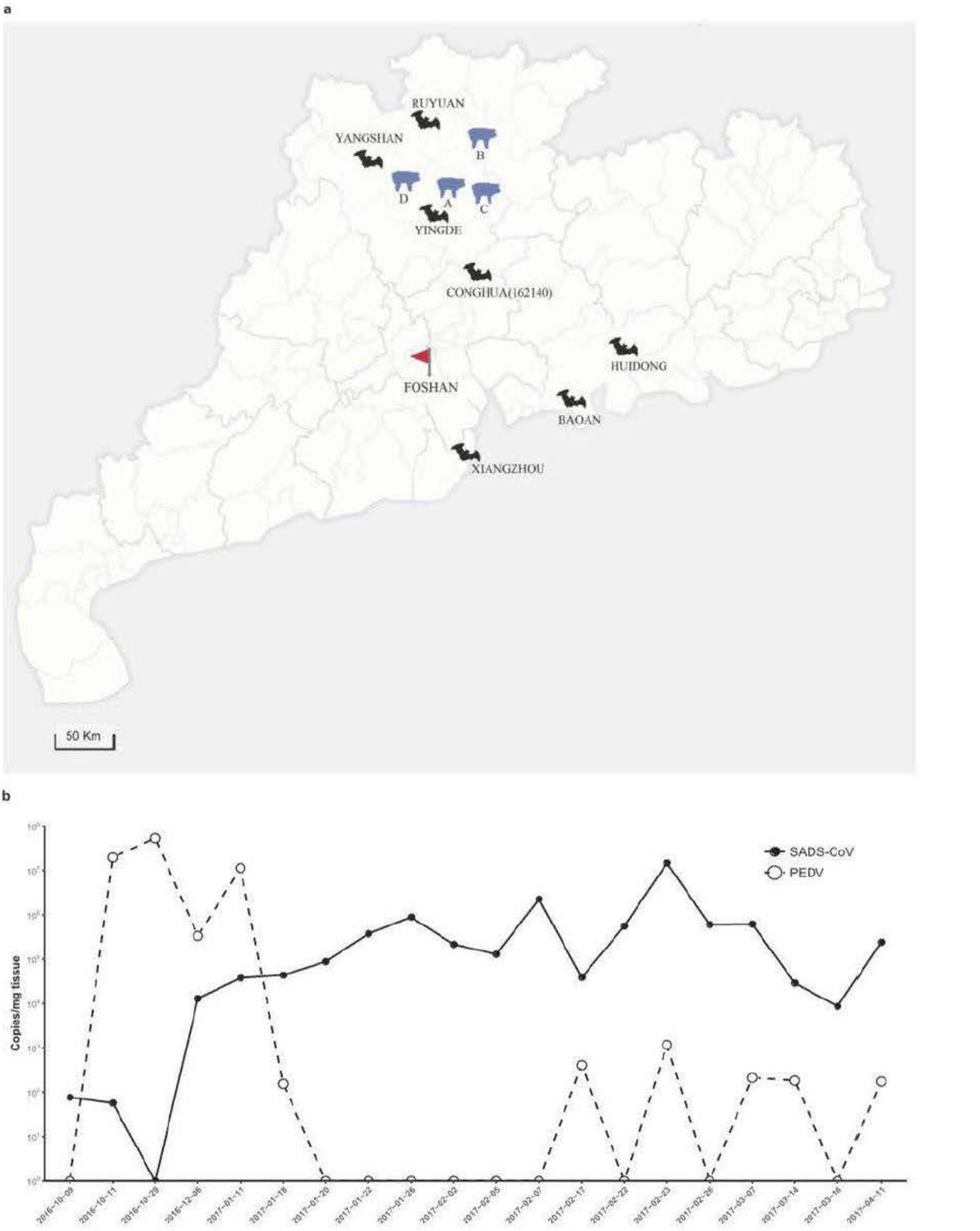
Haematoxylin and eosin and immunohistochemistry analysis. Frozen (−80 °C) small intestinal tissues including duodenum, jejunum and ileum taken from the experimentally infected pigs were pre-frozen at −20 °C for 10 min. Tissues were then embedded in optimal cutting temperature (OCT) compound and cut into 8-μm sections using the Cryotome FSE machine (Thermo Fisher Scientific). Mounted microscope slides were fixed with paraformaldehyde and stained with haematoxylin and eosin for histopathological examination.

For immunohistochemistry analysis, a rabbit antibody raised against the SADSr-CoV 3755 N protein was used for specific staining of SADS-CoV antigen. Slides were blocked by incubating with 10% goat serum (Beyotime) at 37 °C for 30 min, followed by overnight incubation at 4 °C with the rabbit anti-3755 N protein serum (1:1,000) and mouse anti-cytokeratin 8+18+19 monoclonal antibody (Abcam), diluted 1:100 in PBST buffer containing 5% goat serum. After washing, slides were then incubated for 50 min at room temperature with Cy3-conjugated goat-anti-rabbit IgG (Proteintech) and FITC-conjugated goat-anti-mouse IgG (Proteintech), diluted 1:100 in PBST buffer containing 5% goat serum. Slides were stained with DAPI (Beyotime) and observed under a fluorescence microscope (Nikon).

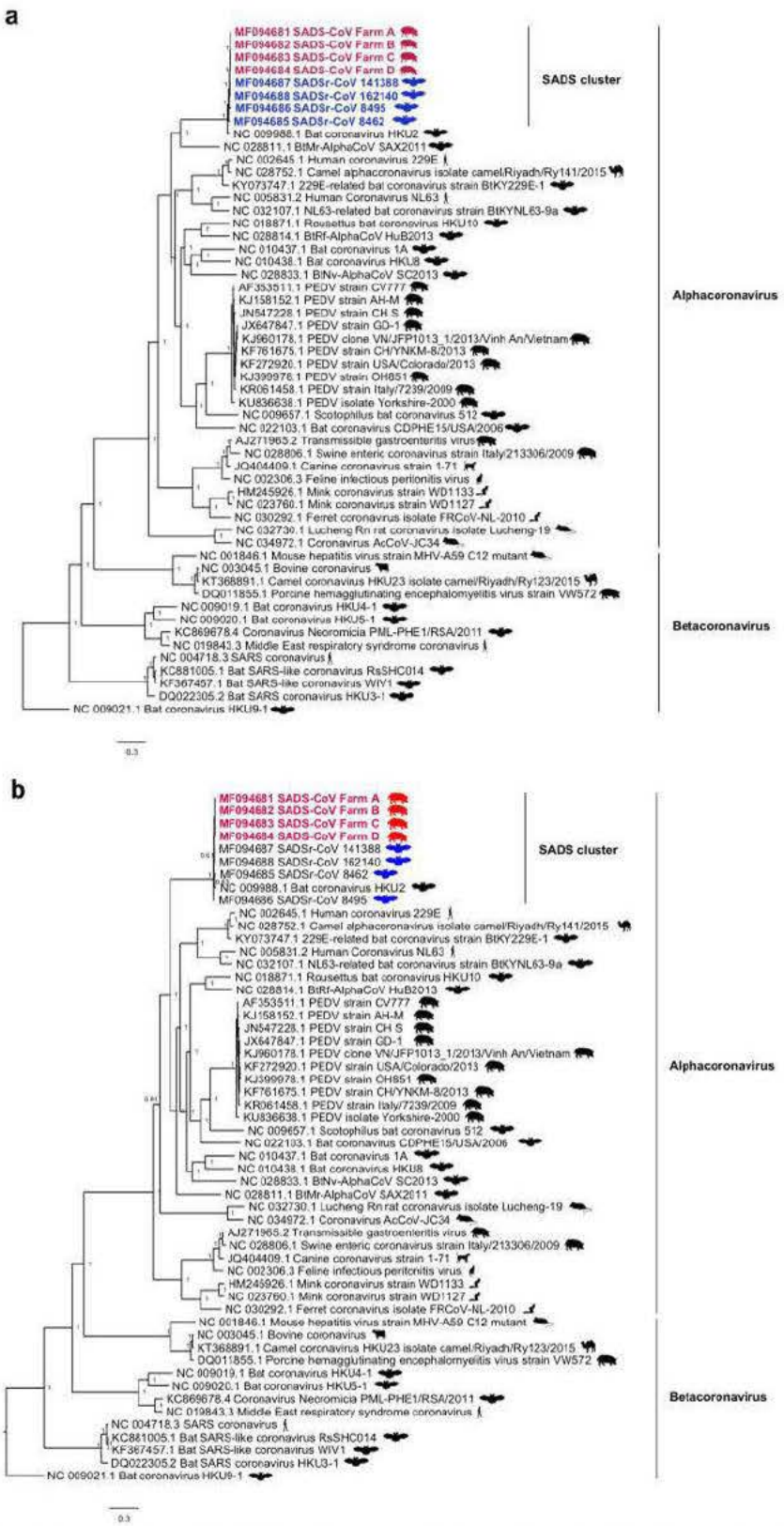
Reporting Summary. Further information on experimental design is available in the Nature Research Reporting Summary linked to this paper.

Data availability. Sequence data that support the findings of this study have been deposited in GenBank with accession codes MF094681–MF094688, MF769416–MF769444, MF094697–MF094701, MF769406–MF769415 and MG557844. Raw sequencing data that support the findings of this study have been deposited in the Sequence Read Achieve (SRA) with accession codes SRR5991648, SRR5991649, SRR5991650, SRR5991651, SRR5991652, SRR5991654, SRR5991655, SRR5991656, SRR5991657, SRR5991658 and SRR5995595.

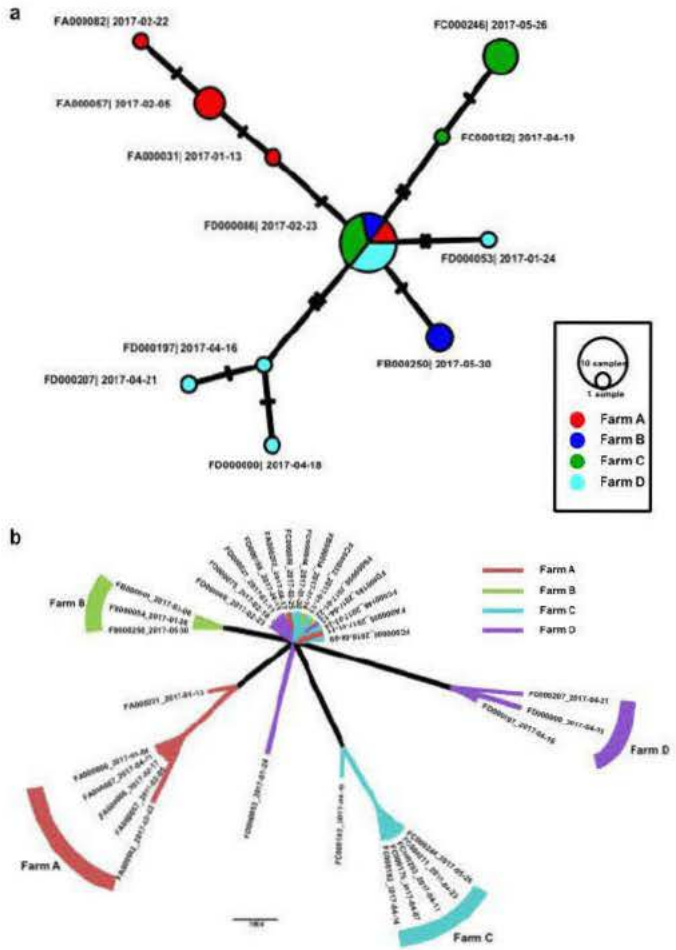
27. Harlow, E. & Lane, D. *Antibodies: A Laboratory Manual* (Cold Spring Harbor Laboratory Press, New York, 1988).
28. Ren, W. et al. Difference in receptor usage between severe acute respiratory syndrome (SARS) coronavirus and SARS-like coronavirus of bat origin. *J. Virol.* **82**, 1899–1907 (2008).



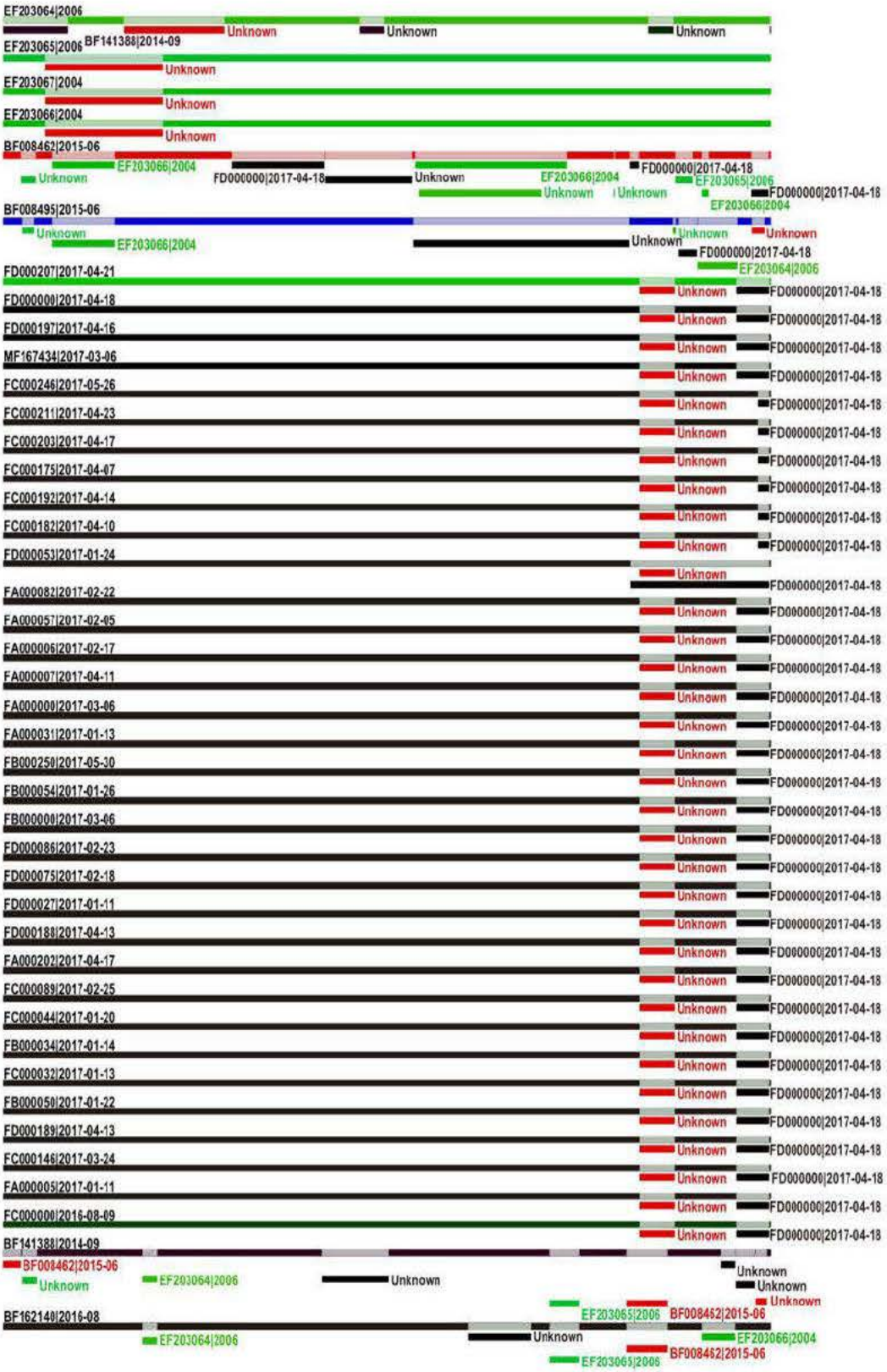
Extended Data Fig. 1 | Map of outbreak locations and sampling sites in Guangdong province, China and the co-circulation of PEDV and SADS-CoV during the initial outbreak on farm A. a, SADS-affected farms are labelled (farms A–D) with blue swine silhouettes following the temporal sequence of the outbreaks. Bat sampling sites are indicated with black bat silhouettes. The bat SADSr-CoV that is most closely related to SADS-CoV (sample 162140) originated in Conghua. The red flag marks Foshan city, the site of the SARS index case. **b**, Pooled intestinal samples ($n = 5$ or more biological independent samples) were collected at dates given on the x axis from deceased piglets and analysed by qPCR. The viral load for each piglet is shown as copy number per milligram of intestine tissue (y axis).



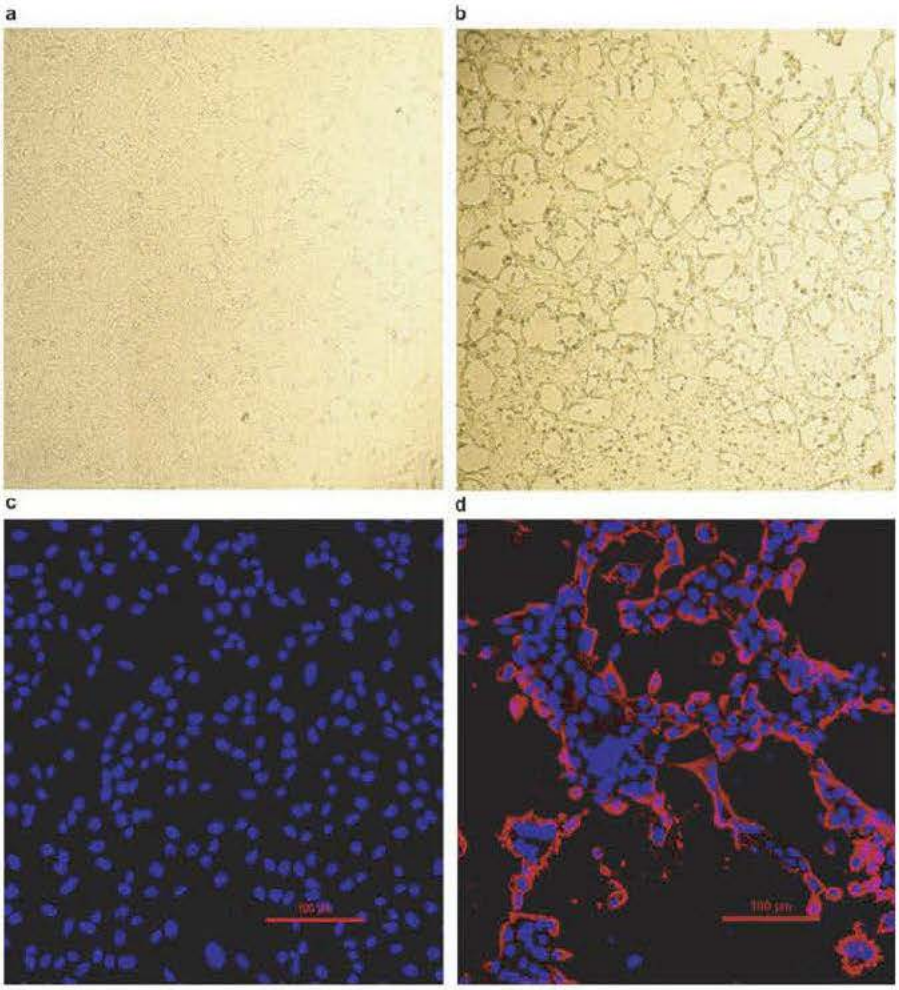
Extended Data Fig. 2 | Bayesian phylogenetic tree of the full-length genome and the *ORF1a* and *ORF1b* sequences of SADS-CoV and related coronaviruses. a, Bayesian phylogenetic tree of the full-length genome. **b**, Bayesian phylogenetic tree of the *ORF1a* and *ORF1b* sequences. Trees were constructed using MrBayes with the average standard deviation of split frequencies under 0.01. The host of each sequence is represented as a silhouette. Newly sequenced SADS-CoVs are highlighted in red, bat SADSr-CoVs are shown in blue and previously published sequences are shown in black. Scale bars, nucleotide substitutions per site.



Extended Data Fig. 3 | Phylogeny and haplotype network analyses of the 33 SADS-CoV strains from the four farms. a, Phylogenetic tree constructed using MrBayes. The GTR+GAMMA model was applied and 20 million steps were run, with the first 10% removed as burn in. Viruses from different farms are labelled with different colours. Scale bar, nucleotide substitutions per site. **b**, Median-joining haplotype network constructed using ProART. In this analysis, $\varepsilon = 0$ was used. The size of the circles represents the number of samples. The larger the circle, the more samples it includes.



Extended Data Fig. 4 | Recombination analysis for SADS-CoV and related CoVs. The potential genetic recombination events were detected using RDP. For each virus strain, different colours represent different sources of the genomes.



Extended Data Fig. 5 | Isolation and antigenic characterization of SADS-CoV. a, **b**, Vero cells are shown 20 h after infection with mock (**a**) or SADS-CoV (**b**). **c**, **d**, Mock or SADS-CoV-infected samples stained with rabbit serum raised against the recombinant SADSr-CoV N protein (red) and DAPI (blue). The experiment was conducted independently three times with similar results. Scale bars, 100 μm.

Extended Data Table 1 | List of all known swine viruses tested by PCR at the beginning of the of SADS outbreak investigation on the four farms

	PEDV	PDCoV	TGEV	RV	PBV	PSV	SVA	SIV	NADC30	PRV	FMDV	CSFV	PCV2	PCV3	APPV	PPV	Norovirus
Farm A	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND	-
Farm B	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND	-
Farm C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND
Farm D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND

Faeces, intestine or faecal swabs collected from January to April 2017 were tested. Sampling type and number of samples per farm were as follows. Farm A: 1 fecal sample, 20 intestinal sample and 6 faecal swabs; farm B: 1 faecal sample and 15 intestinal samples; farm C: 2 intestinal sample and 1 faecal swab; farm D: 5 faecal sample and 1 faecal swab. The dash indicates a negative PCR result. ND, not determined. APPV, atypical porcine pestivirus; CSFV, classical swine fever virus; FMDV, foot and mouth disease virus; NADC30, porcine reproductive and respiratory syndrome virus, strain NADC30; PBV, porcine picobirnavirus; PCV2, porcine circovirus 2; PCV3, porcine circovirus 3; PDCoV, porcine deltacoronavirus; PEDV, porcine epidemic diarrhoea virus; PPV, porcine parvovirus; PRV, porcine pseudorabies virus; PSV, porcine sapelovirus; RV, porcine rotavirus; SIV, swine influenza virus; SVA, porcine senecavirus A; TGEV, porcine transmissible gastroenteritis virus.

Extended Data Table 2 | List of SADSr-CoVs detected in bats in Guangdong, China

Sampling			PCR analysis	
Time (Month-Year)	Location	Bat Species	Fecal swabs sampled	PCR Positive
Jun 13	Yingde	*Rhinolophus sinicus*	1	0
		Pipistrellus abramus	8	0
		Myotis ricketti	2	0
Jul 13	Yangshan	*Pipistrellus abramus*	1	0
		Hipposideros pratti	36	0
Jul 13; May 14; Jun 15; Aug 16	Ruyuan	*Rhinolophus sinicus*	27	5
		Rhinolophus affinis	11	0
		Rhinolophus macrotis	3	0
		Rhinolophus pusillus	41	3
		Rhinolophus rex	9	7
		Hipposideros pratti	7	0
Sep 14; Jun 15; Aug 16	Conghua	*Rhinolophus sinicus*	70	2
		Rhinolophus affinis	34	7
		Rhinolophus pusillus	11	2
		Hipposideros pomona	10	0
		Myotis ricketti	1	0
Jun 13; Nov 13; Aug 14; Jun 15	Huidong	*Rhinolophus sinicus*	37	4
		Rhinolophus affinis	59	27
		Rhinolophus macrotis	15	0
		Rhinolophus pusillus	1	0
		Hipposideros pomona	2	0
		Myotis ricketti	84	0
Jun 15	Baoan	*Rhinolophus sinicus*	55	1
Sep 14	Xiangzhou	*Rhinolophus pusillus*	28	0
		Hipposideros pomona	38	0
		Total	591	58 (9.8%)

See Extended Data Fig. 1 for sampling sites in relation to SARS and SADS outbreak locations.

Extended Data Table 3 | Test of SADS-CoV entry and infection in Hela cells expressing known coronavirus receptors

	HuAPN*	HuACE2*	HuDPP4*	SwAPN*	SwACE2*	SwDPP4*
SADS-CoV	-	-	-	-	-	-
SARS-related-CoV	NA	+	NA	NA	+	NA
MERS-CoV†	NA	NA	+	NA	NA	NA
Expression‡	+ (S-tag)	+ (HIS-tag)	+ (S-tag)	+ (S-tag)	+ (S-tag)	+ (S-tag)

*Gene accession numbers for the genes used in this study: human APN, M22324.1; human ACE2, NM_021804; human DPP4, NM_001935.3; SwAPN (swine APN), NM_214277.1; SwACE2 (swine ACE2), NM_001116542.1; SwDPP4 (swine DPP4), NM_214257.1.
†For MERS-CoV infection, HIV-pseudovirus was used.
‡Expression of APN, ACE2 and DPP4 was confirmed by antibodies against fused tags.

Extended Data Table 4 | Experimental infection of SPF piglets using intestine tissue homogenate

a

Group	Animal Number	Age (days)	Inoculum material	SADS-CoV titer (copy/ml)	Inoculum volume	Inoculation route	Data recorded on day one and (day two) post challenge				
							Death	Weight loss	Watery diarrhea	SADS-CoV (+ve)	PEDV/PDCoV/RV (+ve)
Infected	7	3	PCR positive intestine slurry	1.55×10^6	4 ml	Oral + milk	0/7 (3/7)	4/7 (5/7)	5/7 (7/7)	6/7 (7/7)	0/7 (0/7)
Control	5	3	PCR negative intestine slurry	0	4 ml	Oral + milk	0/5 (1/5)	1/5 (3/5)	0/5 (1/5)	0/5 (0/5)	0/5 (0/5)

b

Group	Days post challenge	Piglet-I1*	Piglet-I2*	Piglet-I3*	Piglet-I4*	Piglet-I5†	Piglet-I6†	Piglet-I7†
Infected	0	0.565	0.66	0.6	0.68	0.49	0.57	0.62
	1	0.555	0.635	0.685	0.715	0.4	0.475	0.565
	2	0.51	0.52	0.665	0.785			

Group		Piglet-C1*	Piglet-C2*	Piglet-C3*	Piglet-C4†‡	Piglet-C5*
Control	0	0.67	0.59	0.5	0.53	0.525
	1	0.765	0.53	0.49	0.51	0.535
	2	0.765	0.53	0.575		0.505

Experimental details can be found in the Methods. **a**, Animals were recorded every day for signs of disease, including weight loss, diarrhoea and death. PCR on DNA from faecal swabs was carried out to monitor the presence of SADS-CoV or other pig viruses. **b**, Daily body weight record of all piglets. Weights are in kg.
*Euthanized on the indicated day for further analysis.
†Animal died during the experiment.
‡The only animal that did not receive colostrum in this experiment due to shortage in supply.

Extended Data Table 5 | Experimental animal infection of farm piglets using cultured SADS-CoV

a

Group	Animal Number	Age (days)	Inoculum material	SADS-CoV titer ($TCID_{50}$/ml)	Inoculum volume	Inoculation route	Data recorded on day two and (day four) post challenge				
							Death	Weight loss	Watery diarrhea	SADS-CoV (+ve)	PEDV/PDCoV/RV (+ve)
Infected	6	3	Cultured SADS-CoV	10^6.625	6 ml	Oral + milk	1/6 (3/6)	4/6 (6/6)	6/6 (6/6)	6/6 (6/6)	0/6 (0/6)
Control	6	3	Mock culture supernatant	0	6 ml	Oral + milk	0/6 (0/6)	3/6 (3/6)	5/6 (3/6)	0/6 (0/6)	0/6 (0/6)

b

Group	Days post challenge	Piglet-I1†	Piglet-I2†	Piglet-I3*	Piglet-I4*	Piglet-I5*	Piglet-I6†
Infected	0	1.5	1.54	2.32	1.92	1.54	2.165
	1	1.41	1.575	2.58	1.885	1.46	2.08
	2	1.23	1.39	2.615	1.73	1.54	1.365
	3			2.115	1.54	1.335	1.725
	4						1.505
		Piglet-C1*	**Piglet-C2***	**Piglet-C3***	**Piglet-C4***	**Piglet-C5***	**Piglet-C6***
Control	0	1.955	2.055	2.8	1.835	1.835	1.83
	1	1.765	1.955	1.9	1.68	1.645	1.93
	2		2.12	1.675	1.93	1.515	1.9
	3		2.25	1.69	2.18	1.66	2.38
	4				2.27	1.555	2.58

Experimental details can be found in the Methods. **a**, Animals were recorded every day for signs of disease, including weight loss, diarrhoea and death. PCR on DNA from faecal swabs was carried out to monitor the presence of SADS-CoV or other pig viruses. **b**, Daily body weight record of all piglets. Weights are in kg.

*Euthanized on the indicated day for further analysis.

†Animal died during the experiment.

nature research

Corresponding author(s): Peter Daszak, Lin-Fa Wang, Yi-Gang Tong, Jing-Yun Ma and Zheng-Li Shi

☐ Initial submission ☐ Revised version ☒ Final submission

Life Sciences Reporting Summary

Nature Research wishes to improve the reproducibility of the work that we publish. This form is intended for publication with all accepted life science papers and provides structure for consistency and transparency in reporting. Every life science submission will use this form; some list items might not apply to an individual manuscript, but all fields must be completed for clarity.

For further information on the points included in this form, see Reporting Life Sciences Research. For further information on Nature Research policies, including our data availability policy, see Authors & Referees and the Editorial Policy Checklist.

Experimental design

1. Sample size

Describe how sample size was determined.

For the three main figures: figure 1 calculated all sick pigs or used more than five samples in epidemiology, or used three animals in tissue distribution (meets the minimal statistical requirements). Figure 2 used most of the representative CoV genomes thus should be adequate. For all other tables or figures that sample size involved, we used more than three samples per group. For animal experiments, we used at least five animal per group.

2. Data exclusions

Describe any data exclusions.

No data exclusion.

3. Replication

Describe whether the experimental findings were reliably reproduced.

As epidemiology study, we presented all results including positive or negative here. The authors guarantee the findings are reliably reproducible. At least three independent experiments were performed, which was stated in the text.

4. Randomization

Describe how samples/organisms/participants were allocated into experimental groups.

Animals were randomly assigned to groups prior to any experimentation.

5. Blinding

Describe whether the investigators were blinded to group allocation during data collection and/or analysis.

SADS-CoV histology was performed in a blinded manner.

Note: all studies involving animals and/or human research participants must disclose whether blinding and randomization were used.

6. Statistical parameters

For all figures and tables that use statistical methods, confirm that the following items are present in relevant figure legends (or in the Methods section if additional space is needed).

n/a	Confirmed	
☐	☒	The exact sample size (*n*) for each experimental group/condition, given as a discrete number and unit of measurement (animals, litters, cultures, etc.)
☐	☒	A description of how samples were collected, noting whether measurements were taken from distinct samples or whether the same sample was measured repeatedly
☐	☒	A statement indicating how many times each experiment was replicated
☒	☐	The statistical test(s) used and whether they are one- or two-sided (note: only common tests should be described solely by name; more complex techniques should be described in the Methods section)
☒	☐	A description of any assumptions or corrections, such as an adjustment for multiple comparisons
☒	☐	The test results (e.g. *P* values) given as exact values whenever possible and with confidence intervals noted
☐	☒	A clear description of statistics including central tendency (e.g. median, mean) and variation (e.g. standard deviation, interquartile range)
☐	☒	Clearly defined error bars

See the web collection on statistics for biologists for further resources and guidance.

Software

Policy information about availability of computer code

7. Software

Describe the software used to analyze the data in this study.	BLAST+ v2.2.3, CLC Genomic Workbench v9.0, Clone Manager v8, MAFFT v7.221, MrBayes v3.2, DIAMOND v0.9.0, BaTS beta-build2, PopART v1.7, RAxML v8.2.11, TempEst v1.5, RDP v4.72.

For manuscripts utilizing custom algorithms or software that are central to the paper but not yet described in the published literature, software must be made available to editors and reviewers upon request. We strongly encourage code deposition in a community repository (e.g. GitHub). *Nature Methods* guidance for providing algorithms and software for publication provides further information on this topic.

Materials and reagents

Policy information about availability of materials

8. Materials availability

Indicate whether there are restrictions on availability of unique materials or if these materials are only available for distribution by a for-profit company.	There is no restriction to material availability.

9. Antibodies

Describe the antibodies used and how they were validated for use in the system under study (i.e. assay and species).	1, rabbit anti-HKU2-NP polyclonal antibody, made by ourselves, validated by immunogen in a WB (titer 1: 10000); 2, anti-HIS tag monoclonal antibody (Proteintect Group), validated in a WB (titer 1: 1000); 3, anti-S tag monoclonal antibody, made by ourselves, validated in a WB (titer 1: 10000); 4, cyanin 3-labeled goat anti-mouse/rabbit IgG (Proteintech Group), validated in IFA (titer 1: 1000); 5, mouse anti-FLAG tag antibody (Thermo Fisher Scientific), validated in a WB (titer 1: 1000); 6, mouse anti-Cytokeratin 8+18+19 mAb (Abcam), validated in IHC (1:100); 7, FITC conjugated goat-anti-rabbit IgG (Proteintech), validated in IHC (1:100);

10. Eukaryotic cell lines

a. State the source of each eukaryotic cell line used.	1, African green monkey origin, Vero from ATCC; 2, bat origin Rhinolophus sinicus (made by ourselves), Kidney primary RsKi9409, lung primary RsLu4323, lung immortalized RsLuT, brain immortalized RsBrT and heart immortalized RsHeT; all bats were made in house; 3, Swine cells: intestinal IPEC and SIEC, kidney PK15, LLC-PK1 and IBRS, testes cell ST; all swine cells were from ATCC; 4, human cells: Hela and HEK293T were from ATCC.
b. Describe the method of cell line authentication used.	All monkey and human cells were from ATCC with authentication. Swine cells (commercially available) were gifts of collaborators and were originally from ATCC with authentication. They were authentication by microscope observation during culture. Bat cells made by ourselves were from organ or cultured and immortalized. We guarantee they were from the organs described but there was no further authentication.
c. Report whether the cell lines were tested for mycoplasma contamination.	We confirm that all cells were tested as mycoplasma negative.
d. If any of the cell lines used are listed in the database of commonly misidentified cell lines maintained by ICLAC, provide a scientific rationale for their use.	None of the cell lines used are listed in the ICLAC database.

Animals and human research participants

Policy information about studies involving animals; when reporting animal research, follow the ARRIVE guidelines

11. Description of research animals

Provide details on animals and/or animal-derived materials used in the study.	Swine used in animal infection study aged between 2-4 days. The first experiment used healthy Chinese Bamaxiang SPF piglets that were cultured free of SADS-CoV or other known swine disease agents. The second experiment used healthy duroc-landrace-yokshire piglets (not SPF) that were not affected by SADS-CoV before. No gender preference when choose the animal. Piglets were from same breed and at same age and were randomly assigned into groups for the experiments.

Policy information about studies involving human research participants

12. Description of human research participants

Describe the covariate-relevant population characteristics of the human research participants.	Pig farm workers were bleed for testing possible spillover of SADS-CoV. These workers are also adult male who had close contact with sick pigs. Non of them had clinical signs of diseases during sampling.

From: Werner, Alyssa (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]
Cc: Ford, Andrew (NIH/NIAID) [E]; DMID GrantOps; Bateman, Karen (NIH/NIAID) [E]; Abbey, Lillian (NIH/NIAID) [E]
Subject: RE: Rapid FOA guidance
Date: Monday, January 27, 2020 8:34:41 AM
Attachments: Coronavirus Run.xlsx

Good Morning-

I have pulled FY20 applications (all statuses, all ICs). The breakout is below- two of the AI applications belong to DAIT, one of which is a $2.3M U19. Please let me know if you need any additional information.

Row Labels	Count of Appl ID
AI	57
GM	3
HL	1
NS	1
OD	1
Grand Total	**63**

From: Bateman, Karen (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 7:00 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6); Werner, Alyssa (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA guidance

I am not seeing any NHLBI extramural research on coronavirus, but I am copying Alyssa, who can do a more complete search next week. I know she found some relevant projects in DAIT and at NIGMS.
-Karen

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 6:11 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6); Bateman, Karen (NIH/NIAID) [E] (b) (6); Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA guidance

Sorry, I don't have one yet but I think you can simply pass along this message: we're developing a NOSI to highlight that interested investigators can apply to NIH's new Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement, Clinical Trial Optional) and that her IC may want to watch for it coming through the NIH Funding Opportunity Announcement Module (**FOAM**) in case they'd like to sign on.

You could ask if there is someone in particular we should target and we can follow up with them.

Karen is looking for a NHLBI contact. I'll share the updated NOSI with you soon.
Thank you,
Lillian

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 3:56 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6); Bateman, Karen (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA guidance

Great. Is there an updated NOSI version I should send her?

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 3:53 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6); Bateman, Karen (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA guidance

Thanks Erik, that's a great idea...she would know who to raise this with.
Lillian

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 3:34 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6)>; Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6); Bateman, Karen (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA guidance

Hi Lillian,
I think the only contact I have is a NIGMS. The Chief of the NIGMS Scientific Review Office was my

PhD mentor. I can certainly reach out to her. Would that be a good place to start? I don't really know anyone on the program side.

Erik

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 3:30 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6); Bateman, Karen (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA guidance

Hi Erik – DEA was wondering if you had contacts at NIGMS and NHLBI you might want to contact now to let them know we were planning to put out this NOSI so that they could talk with their leadership about possibly signing on and joining us. Do you have contacts at those ICs? No worries if not.
Thanks,
Lillian

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 9:50 AM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA guidance

Hi Lillian,
Please see the attached draft NOSI, and let me know if we missed addressing any of the required points. If I understood your email correctly, BUGS will fill out the award details, application/submission info, etc? Please also feel free to edit the justification as needed if you think it's necessary.

Thanks so much for your help!
Erik

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 2:16 PM
To: Embry, Alan (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6); Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Subject: Rapid FOA guidance

Dear Alan and Erik – we secured additional guidance from DEA, please see note from Andrea below. We told her we'd work with you on the required scientific content and she'll help with the admin requirements.

To facilitate development of the notice, I've created a template for you to complete where highlighted. Please be sure to address the points highlighted below within the highlighted sections of the Word document. Don't hesitate to let us know if there's anything we can do to help.

Thank you,
Lillian

From: Wurster, Andrea (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 12:56 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA

Here are two to the urgent award FOA (https://grants.nih.gov/grants/guide/pa-files/pa-18-935.html) :

https://grants.nih.gov/grants/guide/notice-files/NOT-HL-19-724.html
https://grants.nih.gov/grants/guide/notice-files/NOT-AR-20-016.html

Here is the policy that gives general outlines for the process:

https://nih-extramural-intranet.od.nih.gov/d/node/9609

and note within the policy that "Urgent Guide Notices will include, at a minimum, the justification for the urgent announcement, specific research aims and objectives, submission deadlines (generally, rolling submission), and any special submission requirements, review criteria, reporting requirements and other specific award conditions."

Otherwise they should mimic a general NOSI.

As I mentioned in IMWG, we will need to establish internal review practices (sooner rather than later) once the applications come in. As of now, no applications have been submitted to the Urgent Award FOA.

If you know who will be leading the scientific content on this, I am happy to work with them.

Andrea

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)

Sent: Wednesday, January 22, 2020 12:27 PM
To: Wurster, Andrea (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: FW: Rapid FOA

Hi Andrea – do you have any samples for an Urgent Award Notice that we should follow, per this guidance: https://www.niaid.nih.gov/grants-contracts/urgent-award-mechanism?
Thank you,
Lillian

From: Marston, Hilary (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 12:18 PM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Eisinger, Robert (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Mulach, Barbara (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA

Good to go, please see attached

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 9:54 AM
To: Marston, Hilary (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Eisinger, Robert (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Mulach, Barbara (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA

Thanks, Hilary – will wait to hear from you.
Lillian

From: Marston, Hilary (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 9:52 AM
To: Abbey, Lillian (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Eisinger, Robert (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Mulach, Barbara (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA

We still need ASF's sign off but hoping he will approve today. DEA (Susan and Matthew) aware.

From: Abbey, Lillian (NIH/NIAID) [E] (b) (6)

Sent: Wednesday, January 22, 2020 9:40 AM
To: Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Marston, Hilary (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Eisinger, Robert (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Mulach, Barbara (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA

I will reach out to Andrea in DEA to get this process started, and will work with Alan and his team on scientific content.
Lillian

From: Cassetti, Cristina (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 9:36 AM
To: Marston, Hilary (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Eisinger, Robert (NIH/NIAID) [E] (b) (6); Abbey, Lillian (NIH/NIAID) [E] (b) (6)
Subject: RE: Rapid FOA

Sure Hilary, will do. Copying Lillian who can coordinate internally with folks in DMID.
Thank you,
Cristina

From: Marston, Hilary (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 9:33 AM
To: Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6)
Cc: Eisinger, Robert (NIH/NIAID) [E] (b) (6)
Subject: FW: Rapid FOA
Importance: High

FYI we will run this by ASF today but could you guys send the description of need (I'm sorry to even ask) and get your review panel names?

From: Fenton, Matthew (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 9:31 AM
To: Marston, Hilary (NIH/NIAID) [E] (b) (6)
Cc: Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Gilles, Sharon (NIH/NIAID) [E] (b) (6); Harper, Jill (NIH/NIAID) [E] (b) (6); Eisinger, Robert (NIH/NIAID) [E] (b) (6); Lerner, Andrea (NIH/NIAID) [E] (b) (6); Wurster, Andrea (NIH/NIAID) [E] (b) (6); Old, Susan (NIH/NIAID) [E] (b) (6)

Subject: Re: Rapid FOA

Hillary - I'm out of the country this week, but essentially the process begins with requesting permission from OER to issue a urgent award NOSI (remember, these are supplements, but allow work outside of the scope of the parent grant), then we draft the NOSI and submit it for publication in the NIH Guide. Supplement requests will be reviewed by program staff, so DMID will need to assemble a "review panel" of Program Officers. Once approved, GMP will add the supplement funds to the parent awards.

Susan and Andrea Wurster (Ken Santora's successor) can provide more detail. I don't recall if these is a form that Tony needs to fill out to request permission from OER, but perhaps just an email with a description of the need and justification will do.

Matthew

From: Marston, Hilary (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, January 22, 2020 8:25 AM
To: Fenton, Matthew (NIH/NIAID) [E]
Cc: Auchincloss, Hugh (NIH/NIAID) [E]; Gilles, Sharon (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Eisinger, Robert (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]
Subject: Rapid FOA

Matthew, DMID wanted to explore activating the rapid FOA for the coronavirus outbreak. Before we ask ASF, can you remind us of the process?

Many thanks.

Row Labels	Count of Appl ID
AI	57
GM	**3**
HL	1
NS	1
OD	1
Grand Total	63

Project Number	Subproject ID	Appl ID	Project Title	Status Co	PI Name	PO Name	Admin IC	PCC	Extracted Text Link	RFA/PA Number	Institution/Organization	NIH Percentile	Priority Score	Total Cost
2 R01AI085089-11		10001115	Mechanisms of interferon antagonism in coronavirus replication and pathogenesis	PI	Baker, Susan C	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA19-056	Loyola University Chicago	[redacted]	(b) (5)	$425,526
1 R01AI148284-01A1		10050070	Mathematical and Statistical Methods for the Control of Global Infectious Disease Threats	PI	Longini, Ira M	Gezmu, Misrak; Ravichandran, Veerasamy	AI	M71 B	Extracted Text Link	PA19-056	University Of Florida			$805,313
1 R01AI148166-01A1		10049036	Role of Diabetes in MERS Coronavirus Pathogenesis	PI	Frieman, Matthew Bryan	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA19-056	University Of Maryland Baltimore			$621,748
4 R00AI123498-03		10046412	Structural Studies of the Coronavirus Life Cycle	A	Kirchdoerfer, Robert Nicholas	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA16-077	University Of Wisconsin-madison			$248,995
1 R21AI153993-01		10041805	Detection and genetic and biological characterization of bat influenza viruses in the Middle East	PI	Kayali, Ghazi	Hauguel, Teresa M	AI	M51B B	Extracted Text Link	PA19-053	Human Link			$215,720
1 R21AI153480-01		10038144	Broad Spectrum Anti-viral Compounds Targeting the SKI Complex	PI	Frieman, Matthew Bryan	Krafft, Amy	AI	M51F B	Extracted Text Link	PA19-053	University Of Maryland Baltimore			$231,750
1 R01AI153602-01		10034189	Identifying host and viral correlates for coronavirus pathogenesis	PI	Menachery, Vineet D	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA19-056	University Of Texas Med Br Galveston			$497,886
1 R01HL153609-01		10033610	Microbiome mechanisms controlling lung disease	PI	Lim, Efrem	Kalantari, Roya	HL	LLCHR	Extracted Text Link	PA18-784	Arizona State University-tempe Campus			$761,219
1 R01AI153007-01		10028537	Detrimental role of inflammatory monocyte-intrinsic TLR7 signaling in hCoV pathogenesis	PI	Channappanavar, Rudragouda	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA19-056	University Of Tennessee Health Sci Ctr			$490,856
1 DP1OD029543-01		10010238	A functional evolutionary genetic approach to combat viral infection	PI	Schoggins, John W.		OD		Extracted Text Link	RM19-005	Ut Southwestern Medical Center			$3,500,000
1 R21AI145400-01A1		10008171	The Host Genetics of Age-Dependent Susceptibility	PC	Menachery, Vineet D	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PAR18-181	University Of Texas Med Br Galveston			$155,614
1 R21AI145372-01A1		10009947	Identifying Genetic Regulators and New Models of Wild Type Coronavirus Pathogenesis	PC	Gralinski, Lisa	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PAR18-181	Univ Of North Carolina Chapel Hill			$123,000
5 U19AI100625-09	7727	10003843	Systems Immunogenetics of Emerging Coronavirus Infections in the Collaborative Cross [Parent Title: Systems Immunogenetics of Biodefense and Emerging Pathogens in the Collaborative Cross]	P	Baric, Ralph S		AI	I2C B	Extracted Text Link	AI16-050	Univ Of North Carolina Chapel Hill			
5 U19AI100625-09		10003924	Systems Immunogenetics of Biodefense and Emerging Pathogens in the Collaborative Cross	TP	Baric, Ralph S	Liu, Qian	AI	I2C B	Extracted Text Link	AI16-050	Univ Of North Carolina Chapel Hill			$2,332,322
5 R01AI141707-03		9996841	Prospectively characterizing the functionalized antigenic effects of mutations to viral entry proteins	TP	Bloom, Jesse D	Repik, Patricia M.	AI	M32B B	Extracted Text Link	PA18-484	Fred Hutchinson Cancer Research Center			$439,462
5 R01AI129269-05		9958825	Role of eicosanoids in pathogenic human CoV infections	TP	Perlman, Stanley	Barr, Robin; Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA13-302	University Of Iowa			$545,235
5 R01GM120553-05		9992973	Structural Studies of Coronavirus Fusion Proteins	TP	Veesler, David	Flicker, Paula F.; Vogt, Matthew J.	GM	B305PF	Extracted Text Link	PA13-302	University Of Washington			$294,397
5 R01AI135270-03		9989760	Structural and functional analysis of the coronavirus spike protein fusion peptide	TP	Whittaker, Gary R	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA16-160	Cornell University			$532,013
1 F31AI147560-01A1		9968590	Dissecting the role of the coronavirus proofreading exoribonuclease in RNA recombination	PA	Gribble, Jennifer	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA19-195	Vanderbilt University			
5 P01AI060699-14	6208	9988156	Adaptive MERS coronavirus cell entry pathways and their relevance to virulence and antiviral strategies [Parent Title: PPG: SARS-CoV-host cell interactions and vaccine development]	P	Gallagher, Thomas Miller		AI	M51C B	Extracted Text Link	PAR13-154	Loyola University Chicago			
5 P01AI060699-14	6207	9988155	Project 1 [Parent Title: PPG: SARS-CoV-host cell interactions and vaccine development]	P	Perlman, Stanley		AI	M51C B	Extracted Text Link	PAR13-154	University Of Iowa			
5 P01AI060699-14	6206	9988154	Animal/Virology Core [Parent Title: PPG: SARS-CoV-host cell interactions and vaccine development]	P	Perlman, Stanley		AI	M51C B	Extracted Text Link	PAR13-154	University Of Iowa			
5 P01AI060699-14	6205	9988153	Administrative Core [Parent Title: PPG: SARS-CoV-host cell interactions and vaccine development]	P	Perlman, Stanley		AI	M51C B	Extracted Text Link	PAR13-154	University Of Iowa			
5 P01AI060699-14		9988149	PPG: SARS-CoV host cell interactions and vaccine development	TP	Perlman, Stanley	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PAR13-154	University Of Iowa			$1,254,329
5 U01AI124260-05		9983589	Enhancing potency of the MERS vaccine by a novel ASP-1+alum adjuvant combination	TP	Lustigman, Sara	Lapham, Cheryl K.	AI	I2K B	Extracted Text Link	AI15-001	New York Blood Center			$526,550
5 R01AI110964-07		9962745	Understanding the Risk of Bat Coronavirus Emergence	TP	Daszak, Peter	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA18-484	Ecohealth Alliance, Inc.			$637,980
5 R01AI139761-03		9981276	Design and Analysis of Vaccine Trials for Emerging Infectious Disease Threats	TP	Dean, Natalie Exner	Repik, Patricia M.; Ravichandran, Veerasamy	AI	M32B B	Extracted Text Link	PA16-117	University Of Florida			$711,727
1 R21AI152076-01		9976480	Development of the ferret model for CV-D18 infection	PC	Mattapallil, Joseph John	Park, Eun-Chung	AI	M32A B	Extracted Text Link	PA19-053	Henry M Jackson Fdn For The Adv Mil Med			$175,000
5 R01AI132178-04		9977910	Broad-spectrum antiviral GS-5734 to treat MERS-CoV and related emerging CoV	TP	Baric, Ralph S	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	AI16-034	Univ Of North Carolina Chapel Hill			$1,166,670
5 R01AI124093-04		9977905	Balancing protection versus immunopathology by RSV-specific memory CD8 T cells	TP	Varga, Steven M	Kim, Sonnie	AI	M51D B	Extracted Text Link	PA16-160	University Of Iowa			$376,900
1 R01AI148881-01A1		9972953	Interplay between coronaviruses and nonsense-mediated mRNA decay pathway	PA	Makino, Shinji	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA18-484	University Of Texas Med Br Galveston			$358,318
1 U01AI151801-01		9968942	West African Center for Emerging Infectious Diseases	PC	Weaver, Scott C	Patterson, Jean Lois	AI	M32F B	Extracted Text Link	AI19-028	University Of Texas Med Br Galveston			$1,266,156
1 U01AI151799-01		9968931	Emerging Infectious Diseases Research Center - East and Central Africa	PC	Njenga, M Kariuki	Patterson, Jean Lois	AI	M32F B	Extracted Text Link	AI19-028	Washington State University			$1,163,482
1 U01AI151797-01		9968924	Understanding Risk of Zoonotic Virus Emergence in EID Hotspots of Southeast Asia	PC	Daszak, Peter	Patterson, Jean Lois	AI	M32F B	Extracted Text Link	AI19-028	Ecohealth Alliance, Inc.			$1,199,988
1 R21AI151185-01		9958780	Predictive Correlates of Human Immunity in a Genetically Diverse Mouse Model of Highly Pathogenic Influenza	PA	Rasmussen, Angela	Lane, Mary Chelsea	AI	M51I B	Extracted Text Link	PAR19-147	Columbia University Health Sciences			$180,962
1 R21AI151338-01		9954227	Targeting two-pore channels to block pathogen translocation through acidic Ca2+ stores	PC	Marchant, Jonathan S	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA19-053	Medical College Of Wisconsin			$150,000
1 K99AI151256-01		9953712	Identifying genetic barriers to animal virus replication in human cells: insights into zoonosis	PA	Warren, Cody Jay	Park, Eun-Chung	AI	M32A	Extracted Text Link	PA19-130	University Of Colorado			$92,593
5 R01AI141607-02		9948585	Development of a High-Throughput Microfluidics-Enabled Functional Assay for Rapidly Identifying Neutralizing Antibodies	TP	De Figueiredo, Paul	Lane, Mary Chelsea	AI	M51I B	Extracted Text Link	PA18-484	Texas A&m University			$719,651
5 R21AI146872-02		9942867	How MERS-CoV Regulates Innate Immunity in Primary Human Lung Cells	TP	Sims, Amy C	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA18-489	Univ Of North Carolina Chapel Hill			$194,375
5 R01AI089728-10		9930869	Receptor recognition and cell entry of coronaviruses	TP	Li, Fang	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA13-302	University Of Minnesota			$455,799
1 SC3GM132027-01A1		9934705	SARS-CoV Spike protein epitope mapping with RNA Q-beta displayed peptides: A vaccine candidate	PA	Bopda-Waffo, Alain	Krasnova, Irina N	GM	I330K	Extracted Text Link	PAR16-437	Alabama State University			$75,000
5 R01AI129822-04		9930107	Investigating seasonal drivers of viral zoonoses from Madagascar fruit bats	TP	Heraud, Jean-Michel	Park, Eun-Chung	AI	M32A B	Extracted Text Link	PAR14-085	Pasteur Institute From Madagascar			$124,877
5 R21AI137790-02		9920381	A novel and effective nanobody to prevent and treat Zika virus infection	TP	Du, Lanying	Davis, Mindy I.	AI	M55 B	Extracted Text Link	PA18-489	New York Blood Center			$267,000
5 R01AI130092-03		9918846	Small Molecule Protease Inhibitors against MERS-CoV	TP	Chang, Kyeong-Ok	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA16-160	Kansas State University			$732,873
5 U01AI149644-02		9918250	Respiratory Virus Vaccine and Adjuvant Exploration	TP	Baric, Ralph S	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	AI17-040	Univ Of North Carolina Chapel Hill			$1,000,000
5 R01AI140442-03		9915887	MERS coronavirus: antagonism of double-stranded RNA induced host response by accessory proteins	TP	Weiss, Susan R	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA16-160	University Of Pennsylvania			$447,595
5 R01AI139092-03		9914088	Structure-based design of coronavirus subunit vaccines	TP	Du, Lanying	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA16-160	New York Blood Center			$835,218
1 R13AI150022-01		9913043	3rd International Infectious Diseases of Bats Symposium	PA	Schountz, William A	Mulach, Barbara L.	AI	M74B B	Extracted Text Link	PA18-648	Colorado State University			$8,865
1 R21AI139738-01A1		9891962	Accelerating discovery of neutralizing paratopes with Functional Antibody Screening Technology	A	De Figueiredo, Paul	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA19-053	Texas A&m University			$225,750
5 R01GM123779-03		9889152	Electron Spin Relaxation in Model Membranes	TP	Freed, Jack H	Krepkiy, Dmitriy	GM	B26DBD	Extracted Text Link	PA16-160	Cornell University			$494,198
5 U19AI142759-02	7962	9888319	Project 1 - Coronavirus [Parent Title: Antiviral Drug Discovery and Development Center (AD3C)]	P	Denison, Mark R		AI	M65B B	Extracted Text Link	AI17-042	University Of Alabama At Birmingham			
5 U19AI142759-02		9888306	Antiviral Drug Discovery and Development Center (AD3C)	TP	Whitley, Richard J.	Beanan, Maureen J.	AI	M65B B	Extracted Text Link	AI17-042	University Of Alabama At Birmingham			$7,500,000
5 R01AI108197-08		9878740	Determinants of Coronavirus Fidelity in Replication and Pathogenesis	TP	Denison, Mark R	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA16-160	Vanderbilt University Medical Center			$672,084
1 R01AI149693-01		9864016	Genetic and virological determinants of coronavirus recombination	PA	Anthony, Simon J	Park, Eun-Chung	AI	M32A	Extracted Text Link	PA19-056	Columbia University Health Sciences			$516,096
5 R01AI137472-03		9864029	Rational design and evaluation of novel mRNA vaccines against MERS-CoV	A	Du, Lanying	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA16-160	New York Blood Center			$816,658
1 R01AI148284-01		9860262	Mathematical and Statistical Methods for the Control of Global Infectious Disease Threats	PA	Longini, Ira M	Gezmu, Misrak; Ravichandran, Veerasamy	AI	M71 B	Extracted Text Link	PAR17-167	University Of Florida			$635,029
5 R01AI127521-04		9858225	Structure, Function and Antigenicity of Coronavirus Spike Proteins	TP	Mclellan, Jason Scott	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA16-160	University Of Texas, Austin			$615,032
5 R01AI125215-04		9854789	Targeting TLR Signaling Pathways to Blunt Pathogen-mediated Acute Lung Injury	A	Vogel, Stefanie N.	Krafft, Amy	AI	M51F B	Extracted Text Link	PA16-160	University Of Maryland Baltimore			$533,953
5 F30AI129229-04		9843945	Roles of replication fidelity in viral RNA synthesis, population diversity, and overall fitness of coronaviruses	A	Graepel, Kevin Whittle	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PA14-150	Vanderbilt University			$37,762
5 R01NS104366-03		9840510	A TLR3-STAT1-miR-155 axis and astrocyte-myeloid crosstalk in viral encephalitis	A	Navas-Martin, Sonia	Wong, May; Vogt, Matthew J.	NS	WONGM NS	Extracted Text Link	PA16-160	Drexel University			$306,847
5 R01AI137011-03		9838150	Host genetic barriers to virus spillover	A	Sawyer, Sara	Janes, Daniel E; Mcdonald, David Joseph	AI	A26B	Extracted Text Link	PA16-160	University Of Colorado			$406,549
5 R21AI134993-02		9833488	Investigating How ADP-ribosylation Impacts Innate Immunity During Coronavirus Infection	A	Fehr, Anthony R	Stemmy, Erik J.	AI	M51C B	Extracted Text Link	PAR18-434	University Of Kansas Lawrence			$108,000
5 R03AI142046-02		9831393	Developing immune reagents to increase the preclinical value of the ferret model	A	Albrecht, Randy A.	Lane, Mary Chelsea	AI	M51I B	Extracted Text Link	PA18-488	Icahn School Of Medicine At Mount Sinai			$84,750

Created Date: Fri Jan 24 08:21:50 EST 2020
Category Name: CoV/MERS/SARS
Threshold: 0.20000
Category Definition FY: 2020
Thesaurus Version: RCDC Thesaurus Version 2020.04
* This concept currently exists in a child/grandchild (and so on) category

Concept Name
SARS coronavirus
Middle East Respiratory Syndrome Coronavirus
Severe Acute Respiratory Syndrome
Coronavirus
Coronavirus Infections
coronavirus receptor
coronavirus spike glycoprotein
Coronavirus spike protein
SARS Coronavirus Protease Pathway

From: Post, Diane (NIH/NIAID) [E]
To: RDBViral
Subject: Coronavirus response
Date: Sunday, January 26, 2020 6:06:05 PM
Attachments: 2019 nCoV Response Structure.pptx
Current Wuhan Pneumonia Update 1-8-2020[21].docx
2020-01-22 NIAID Draft Research Agenda.docx

Hi Everyone,

Thank you for meeting last week to talk about the coronavirus response. Attached is an updated response structure overview. Alan plans to implement next week. We can talk about it more on Tuesday. Also attached are some updates that have been put together so far regarding the research response.

Stephanie in BUGS is working on template language that can be used for responses to requests. Some of the requests you can send to Stephanie to answer (anything from the public making an inquiry for example), the others you can hopefully use the template language to answer quickly. I will send in a follow up email some examples of what they have used in the past that we can adapt.

NOTE – we have been directed that if any requests come to you from Dr. Fauci or Hilary Marston directly, please respond ASAP (regardless of deadline given). If you are not able to respond please send on to someone else to address.

Below are some links I've found helpful in keeping up with the situation:

https://www.cgtn.com/special/Battling-the-novel-coronavirus-What-we-know-so-far-.html
https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6
https://www.who.int/csr/don/en/
https://www.cdc.gov/coronavirus/2019-ncov/index.html
https://3g.dxy.cn/newh5/view/pneumonia?scene=2&clicktime=1579582238&enterid=1579582238&from=singlemessage&isappinstalled=0

Diane J. Post, Ph.D.
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2019 nCoV Response Structure

DMID POCAlan Embry*cc docs to Brooke Bozick*Rebecca Lampley meetings

DMID POC BackupDiane Post

DMID Deputy DirectorCristina Cassetti

Communications Brooke Bozick Stephanie CoomesBUGS

Proposal ReviewBrooke Bozick Chelsea Lane

AREA	RDB 1 SME	RDB 2 SME	DMID/DAIT SME
Basic	Erik Stemmy	Brooke Bozick	Eun-Chung Park, Liliana Brown, Alison Deckhut, Patrice Becker, Wolfgang Leitner
Vaccines	Erik Stemmy	Jenny Gordon	Kim Taylor, Paula Bryant, Jean Patterson
Therapeutics	Erik Stemmy	Amy Krafft	Rick Sciotti, Ann Eakin, Mindy Davis
Diagnostics	Amy Krafft	Erik Stemmy	Maureen Beanan
CEIRS	Marciela DeGrace	Rebecca Lampley	
Task Orders	Erik Stemmy	Chelsea Lane	Paula Bryant, Judy Hewitt
Reagents	Marciela DeGrace	Brooke Bozick	JoJo Stemple
Clinical	Chris Roberts	Sonnie Kim	John Beigel
Epidemiology	Michael Cooper		

RDB 1 SME – receive requests for group; responsible for group oversightRDB 2 SME – helps with operationalizing

Updated 1/8/2020

Information listed as "pers comm" reflects personal comments from investigators, and may not be verified from public health authorities.

Wuhan Pneumonia Update

Background

- In December 2019 the Wuhan Municipal Health Committee identified an outbreak of viral pneumonia cases of unknown cause.
- On December 31st the WHO China Country Office was notified of 44 patients with pneumonia of unknown etiology, 11 of which were severely ill.
- As of January 5th, 2020 there are 59 patients with a diagnosis of unknown viral pneumonia is Wuhan, 7 of which are severely ill. At least one patient is on ECMO (Peiris, pers comm 1/6/2020). The earliest case was reported December 12th, and the latest onset was December 29th. All patients are isolated and receiving treatment in Wuhan medical institutions. 163 close contacts have been identified for ongoing medical observation.
- Case-patients in the outbreak are reported to have fever, difficulty breathing, and bilateral lung infiltrates on chest radiography (CDC, http://bit.ly/36GxY3y).
- Hong Kong has added Wuhan Pneumonia to the list of notifiable diseases. As of January 7th, 2020 the Hong Kong Center for Health Protection has reports of 30 cases under enhanced surveillance with recent travel history to Wuhan. https://www.chp.gov.hk/files/pdf/enhanced_sur_pneumonia_wuhan_eng.pdf
- Epidemiological investigation showed that some patients operated businesses in the Wuhan South China Seafood City. As of January 1st, 2020 the market has been closed for environmental sanitation and disinfection.
- There is currently no clear evidence of human-to-human transmission, however one family cluster has been identified. No nosocomial transmission has been seen (Peiris, pers comm 1/6/2020).
- Fragments of coronavirus RNA with an 86% homology to SARS has been found in one patient (Peiris, pers comm 1/6/2020).
- News reports on 1/8/2020 the virus is a novel coronavirus, sequenced in one patient and identified in others.

Related Coronavirus Basic Research

- M51C CoV portfolio has 20 grants (13 basic, 2 Tx, 5 Vx).
- Peter Daszak (R01AI110964-06) is funded for work to understand how coronaviruses evolve and jump to human populations, with an emphasis on bat CoVs and high-risk populations at the human-animal interface. Main foreign sites are in China (including co-investigators at the Wuhan Institute of Virology). Main aims of the award are to characterize the diverse SARS-related CoVs in bat populations, conduct surveillance in human populations, and to characterize the spillover risk of novel CoVs.
    - Work under previous award has identified over 50 SARS-related CoVs, some of which can infect human cells and cause disease in humanized mouse models.
    - This group identified the Swine Acute Diarrheal Syndrome CoV (SADS-CoV), an alpha CoV that caused the death of >20,000 pigs in China.

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- Fang Li (R01AIAI089728-09) is funded to investigate the receptor recognition and cell entry in coronaviruses using structural approaches using spike proteins in complex with receptors. This award found the first evidence of a MERS-related CoV that uses the human receptor and provides evidence of a natural recombination event between bat CoVs.
- Stanley Perlman (P01AI060699-11) leads a team of investigators using mouse models of SARS and MERS to investigate CoV pathogenesis and develop vaccines and therapeutics. Projects focus on age-dependent differences in CoV pathogenesis, cell entry pathways as targets for antiviral strategies, and viral pathogenesis and lung disease.
- Animal Model development:
    - NIAID has directly supported several animal models of MERS-CoV, including adenovirus vector, transgenic human receptor knock-in, humanized mouse, and NHP.
    - Small animal models of MERS-CoV are widely used to understand viral pathogenesis and to test medical countermeasures. Mouse models are most common, particularly Crispr-Cas9 humanized and transgenic strains. Mouse models of MERS-CoV may also require use of a mouse-passaged strain to observe severe disease. Ongoing work by NIAID grantees continues to refine mouse models of MERS-CoV, including expanding to collaborative cross mice.
    - Three NHP species have been used as models of MERS-CoV: the rhesus macaque, common marmoset, and African Green Monkey. Generally, MERS-CoV infection results in viral replication and mild disease, and severity can vary by route of administration. The most severe disease is seen in marmosets.
    - NIAID has an IAA in place with USAMRIID for further development of the African Green Monkey model.
- CEIRS MERS Basic Research Projects:
    - MERS Surveillance (Egypt, Lebanon, Jordan, Tunisia, Algeria, Ethiopia). Ghazi Kayali & Richard Webby (St. Jude Children's Research Hospital); Mohamed Ali (National Research Centre, Egypt). Ongoing surveillance and genomic sequencing of virus from camels in 5 Middle Eastern countries including, Egypt, Tunisia, Algeria, Jordan, and Lebanon; as well as surveillance and sequencing of virus from bats in Lebanon and Ethiopia.
    - Development of methods and their application for the investigation of the animal sources of human infection with MERS CoV. Malik Peiris (University of Hong Kong); Richard Webby (St. Jude Children's Research Hospital). Longitudinal seroepdemiology studies of humans and animals in the Middle East and North Africa will investigate seasonality, routes of transmission, and geographic distribution or MERS-CoV.

Related Coronavirus Diagnostics:

- MERS diagnostics focus on serological evidence of infection and PCR sequencing of samples from patients.
- Developing advanced MERS diagnostics is a portfolio gap, and there is a need to focus on developing rapid, sensitive point-of-care diagnostics (PMCID: PMC6361340).

Related Coronavirus Medical Countermeasures:

Updated 1/8/2020

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- NIAID continues to support the preclinical and clinical development of MERS-CoV vaccines and therapeutics through both grant and contract mechanisms.
- NIAID has developed mouse models of MERS-CoV via both grant and contract mechanisms that can be used for efficacy studies of MERS-CoV MCMs.
- NIAID preclinical services can provide *in vitro* and *in* vivo screening of vaccines and therapeutics for MERS and SARS.

Vaccines. Work on vaccines has identified several candidates that produce a robust neutralizing antibody response. One vaccine candidate has completed a Phase I trial and three others are beginning Phase I or II trials.

- Vaccine candidates in Phase I trials: ChAdOx1 (NCT04170829, NCT03399578, Oxford Univ), MVA-MERS-S (NCT04119440, IDT), BVRS-GamVac (NCT04128059, Russian MoH).
- Vaccine Candidates in Phase II trials: GLS-5300 (Inovio), BVRS-GamVac (NCT04130594, Russian MoH).
- CEPI is supporting MERS vaccine development with candidates from Inovio (DNA Spike), Themis (measles vector), IDT (MVA vector), and Oxford University (ChAd vector).
- A Phase I clinical trial of a MERS DNA vaccine (Inovio) was conducted at WRAIR finding the vaccine was safe and well-tolerated.
- The VRC and collaborators have stabilized the MERS-CoV spike protein in its prefusion conformation. The stabilized spike protein is potently immunogenic and elicits protective antibodies to the receptor binding domain, n-terminal domain and other surfaces of the spike protein. The stabilized coronavirus spike protein, and mRNA expressing the spike protein through collaboration with Moderna Therapeutics, is currently being evaluated in the humanized DPP4 mouse model at UNC.
- Extramural grantees are developing MERS vaccine candidates including recombinant spike receptor binding domain protein (Lanying Du, NY Blood Center; Hotez, Baylor; Jason McLellan UT Austin), vaccine/adjuvant combinations (Ralph Baric, UNC), viral-like particles and live-attenuated MERS-CoV vaccines (Gallagher, Enjuanes; P01 to University of Iowa), Rabies virus vectored (Schnell, Frieman; Jefferson U, UMD)

Therapeutics. Currently no therapeutics approved. Overall candidates are in early stages along the drug development pipeline, however two antibody therapeutics have been tested in Phase I clinical trials.

- NIAID grants and contracts have supported efforts to develop a monoclonal antibody therapeutics for MERS-CoV (REGN3048 and REGN3051; PMC4507189). Efficacy studies were supported via DMID TO and NHP studies performed at RML (PMID: 29885377). A Phase I clinical trial was conducted at NIAID's Phase I Clinical Trial Units, and was completed in 2019 (NCT03301090).
- NIAID supported GLP toxicology and tissue cross reactivity studies for an IND for a human polyclonal antibody produced in transchromosomic cows (SAB 301). A Phase I trial was conducted at DCR (PMCID: PMC5871563). NIAID will hold the US IND for a Phase II/III trial to be conducted in the Kingdom of Saudi Arabia. Currently the protocol is under development and the trial is anticipated to start in Q3/Q4 2020.

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- A number of other therapeutic strategies have been tested (convalescent plasma, lopinavir/ritonavir, ribavirin, interferon), however small case numbers have made it difficult to assess their impact on morbidity and mortality in infected patients (PMID: 3023653).

Updated 1/8/2020

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Appendix 1: Currently funded M51C CoV Grants

PI Name	Title	Grant	Proj Start	Proj End	Abs	Objective
SIMS, AMY C	How MERS-CoV Regulates Innate Immunity in Primary Human Lung Cells	1 R21 AI146872-01	2019/06/05	2021/05/31	Abs	Basic
KIRCHDOERFER, ROBERT NICHOLAS	Structural Studies of the Coronavirus Life Cycle	4 R00 AI123498-03	2019/12/18	2021/11/30	Abs	Basic
GRAEPEL, KEVIN WHITTLE	Roles of replication fidelity in viral RNA synthesis, population diversity, and overall fitness of coronaviruses	5 F30 AI129229-03	2017/01/13	2020/10/12	Abs	Basic
FEHR, ANTHONY R	Investigating How ADP-ribosylation Impacts Innate Immunity During Coronavirus Infection	5 K22 AI134993-02	2018/12/07	2020/11/30	Abs	Basic
BAKER, SUSAN C	Mechanisms of viral proteases in coronavirus replication and pathogenesis	5 R01 AI085089-10	2010/07/01	2020/06/30	Abs	Basic
LI, FANG	Receptor recognition and cell entry of coronaviruses	5 R01 AI089728-09	2016/06/07	2021/05/31	Abs	Basic
BARIC, RALPH S	Determinants of Coronavirus Fidelity in Replication and Pathogenesis	5 R01 AI108197-07	2013/08/01	2023/02/28	Abs	Basic
BARIC, RALPH S	Mechanisms of MERS-CoV Entry, Cross-species Transmission and Pathogenesis	5 R01 AI110700-05	2015/04/20	2020/03/31	Abs	Basic
MAKINO, SHINJI	New Paradigm for Host and Viral Gene Regulation by MERS Coronavirus nsp1	5 R01 AI114657-05	2015/05/01	2020/04/30	Abs	Basic
PERLMAN, STANLEY	Role of eicosanoids in pathogenic human CoV infections	5 R01 AI129269-04	2016/09/23	2021/08/31	Abs	Basic
DANIEL, SUSAN	Structural and functional analysis of the coronavirus spike protein fusion peptide	5 R01 AI135270-02	2018/08/09	2022/07/31	Abs	Basic
WEISS, SUSAN R	MERS coronavirus: antagonism of double-stranded RNA induced host response by accessory proteins	5 R01 AI140442-02	2018/05/24	2023/04/30	Abs	Basic

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PERLMAN, STANLEY	PPG: SARS-CoV-host cell interactions and vaccine development	5 P01 AI060699-13	2004/07/01	2022/07/31	Abs	Basic/Vx
CHANG, KYEONG-OK	Small Molecule Protease Inhibitors against MERS-CoV	5 R01 AI130092-02	2018/05/15	2023/04/30	Abs	Tx
BARIC, RALPH S	Broad-spectrum antiviral GS-5734 to treat MERS-CoV and related emerging CoV	5 R01 AI132178-03	2017/08/09	2022/07/31	Abs	Tx
BARIC, RALPH S	Respiratory Virus Vaccine and Adjuvant Exploration	1 U01 AI149644-01	2019/04/19	2024/03/31	Abs	Vx
MCLELLAN, JASON SCOTT	Structure, Function and Antigenicity of Coronavirus Spike Proteins	5 R01 AI127521-03	2017/02/09	2022/01/31	Abs	Vx
DU, LANYING	Rational design and evaluation of novel mRNA vaccines against MERS-CoV	5 R01 AI137472-02	2018/02/13	2023/01/31	Abs	Vx
DU, LANYING	Structure-based design of coronavirus subunit vaccines	5 R01 AI139092-02	2018/05/21	2023/04/30	Abs	Vx
WHITTAKER, GARY R	Development of a subunit vaccine for MERS-CoV and other emerging coronaviruses	5 R21 AI135373-02	2018/06/06	2020/05/31	Abs	Vx

National Institute of Allergy and Infectious Diseases

NIAID Research Priorities for Wuhan Coronavirus

January 22, 2020

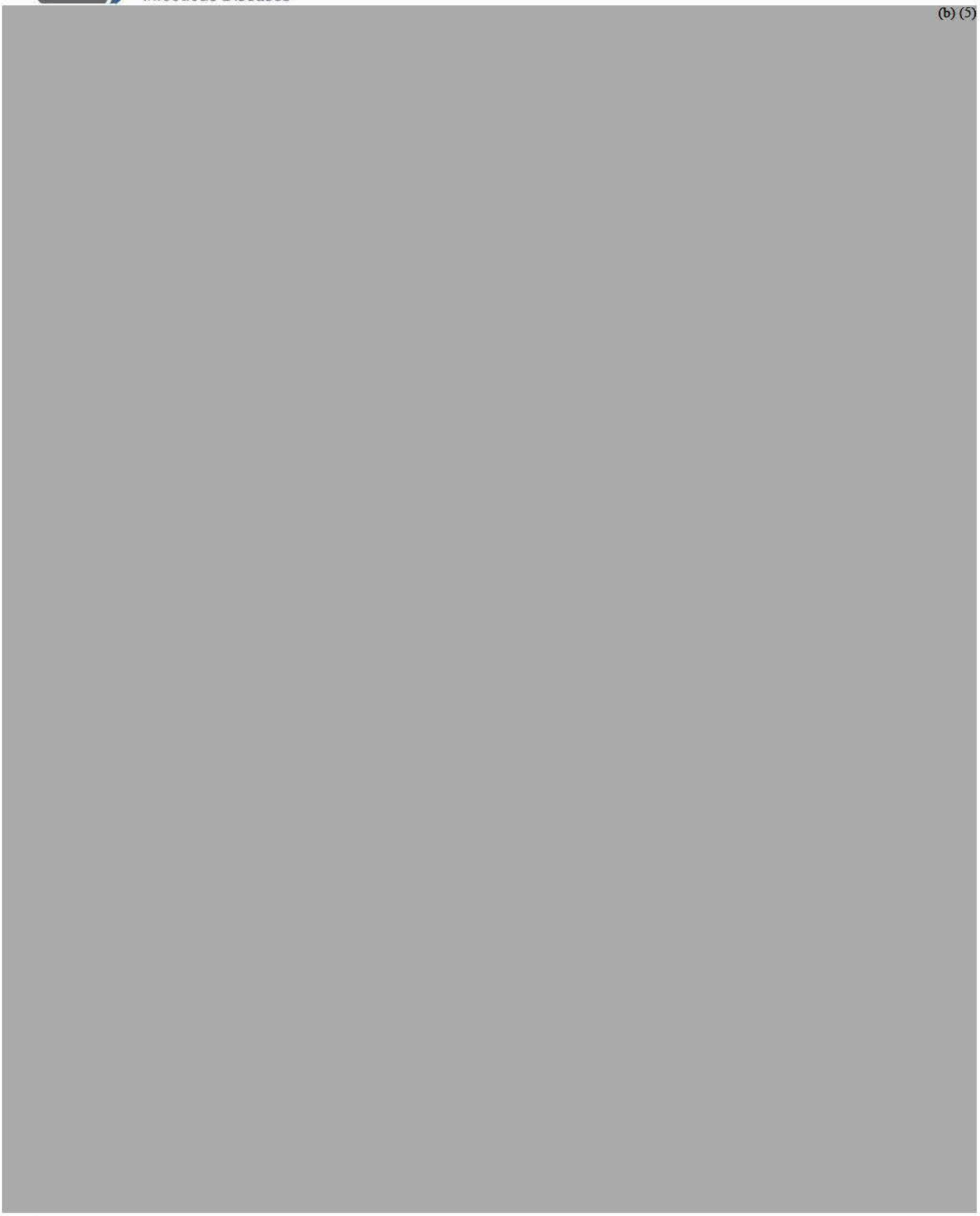
(b) (5)

[redacted]

(b) (5)

[redacted]

(b) (5)



From: Rojas, Cynthia (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Post, Diane (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Bozick, Brooke (NIH/NIAID) [E]; Schuster, Claire (NIH/NIAID) [E]; Lyon, Rickie (NIH/NIAID) [C]; NIAID BUGS
Subject: RE: (plz review) CoV / MERS NIAID web page
Date: Friday, January 24, 2020 4:38:05 PM
Attachments: Current Wuhan Pneumonia Update 1-8-2020[2].docx

Hi Erik,

Great, thank you! The only other items is clarifying what, if anything, from the current Wuhan summary can be shared publicly.

Thank you!!

Cynthia Rojas
Cynthia M. Rojas, MPH
Communications Health Specialist
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane, Room 7G74
Rockville, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 4:27 PM
To: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Cc: Post, Diane (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/OD) [E] (b) (6); Schuster, Claire (NIH/NIAID) [E] (b) (6); Lyon, Rickie (NIH/NIAID) [C] (b) (6); NIAID BUGS (b) (6)
Subject: RE: (plz review) CoV / MERS NIAID web page

Hi Cynthia,

See attached. I made some minor edits and added a bit to the intro about nCoV. Hopefully it's enough. Let me know if you need anything else.

Erik

From: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 2:06 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Post, Diane (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/OD) [E] (b) (6); Schuster, Claire (NIH/NIAID) [E] (b) (6); Lyon, Rickie (NIH/NIAID) [C] (b) (6)
Subject: RE: (plz review) CoV / MERS NIAID web page

Hi Erik,

Perfect, thank you! Please cc BUGS when you submit comments.

Thanks,

Cynthia

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Friday, January 24, 2020 2:04 PM

To: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Cc: Post, Diane (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/OD) [E] (b) (6); Schuster, Claire (NIH/NIAID) [E] (b) (6); Lyon, Rickie (NIH/NIAID) [C] (b) (6)
Subject: Re: (plz review) CoV / MERS NIAID web page

Hi Cynthia,

I have a call with WHO at 3 and plan to review this right after.

Erik

Sent from my iPhone

On Jan 24, 2020, at 1:57 PM, Rojas, Cynthia (NIH/NIAID) [E] (b) (6) wrote:

> Good Afternoon,
>
> I'm circling back on this. I know it's a very busy time right now.
>
> Thanks,
>
> Cynthia Rojas
>
> Cynthia M. Rojas, MPH
> Communications Health Specialist
> Office of Scientific Coordination and Program Operations
> Division of Microbiology and Infectious Diseases
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 5601 Fishers Lane, Room 7G74
> Rockville, MD 20892
> Phone: (b) (6)
> Email: (b) (6)
>
> **From:** Post, Diane (NIH/NIAID) [E] (b) (6)
> **Sent:** Wednesday, January 22, 2020 8:43 PM
> **To:** Rojas, Cynthia (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/OD) [E] (b) (6)
> **Cc:** Stemmy, Erik (NIH/NIAID) [E] (b) (6); Schuster, Claire (NIH/NIAID) [E] (b) (6); Lyon, Rickie (NIH/NIAID) [C] (b) (6)
> **Subject:** RE: (plz review) CoV / MERS NIAID web page
>
> Hi Cynthia,
>
> I know Erik is looking at this as well as others. We think we can make the Friday deadline.
>
> Diane
>
> **From:** Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
> **Sent:** Wednesday, January 22, 2020 3:01 PM
> **To:** Post, Diane (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Bozick, Brooke (NIH/OD) [E] (b) (6)
> **Cc:** Stemmy, Erik (NIH/NIAID) [E] (b) (6); Schuster, Claire (NIH/NIAID) [E] (b) (6); Lyon, Rickie (NIH/NIAID) [C] (b) (6)
> **Subject:** FW: (plz review) CoV / MERS NIAID web page
>
> Good Afternoon,
>
> We received Erik's out of office response. Attached is the drafted web page update for

MERS/SARS. They have also requested an update on the n2019CoV, if possible. OC predicts that the website will become a "coronavirus" page with MERS and SARS subsets. We provided them with the attached Wuhan Pneumonia Update that was crated for the front office a few weeks ago.

Please let us know if you have any comments, edits, or updates to the MERS/SARS 2019 web update content, and also which parts of the Wuhan summary can be shared publicly. Given the recent nCoV developments, OC is requesting our updates by Friday. Do you expect to be able to meet this deadline?

Thank you,

Cynthia M. Rojas, MPH
Communications Health Specialist
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From: "Rojas, Cynthia (NIH/NIAID) [E]" (b) (6)
Date: Wednesday, January 22, 2020 at 1:56 PM
To: "Stemmy, Erik (NIH/NIAID) [E]" (b) (6), "Beigel, John (NIH) [E]" (b) (6)
Cc: "Schuster, Claire (NIH/NIAID) [E]" (b) (6), "Lyon, Rickie (NIH/NIAID) [C]" (b) (6)
Subject: Re: (plz review) CoV / MERS NIAID web page

Good Afternoon John and Erik,

OC has also asked updates on the n2019CoV, if possible. Their full message is included below.

As much as possible, in reviewing this if you also could add what's happening presently with the n2019CoV that would be ideal (realizing that things are changing almost daily). Also, if you could get back to me on Friday with where things stand in the review that would be great. Thanks

We provided them with the attached summary that was crated for the front office a few weeks ago. Could you let us know what information from the attached, if any, can be shared publicly? Please also let us know if there are any further updates beyond the attached.

Thank you,

Cynthia M. Rojas, MPH
Communications Health Specialist
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Rockville, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: "Rojas, Cynthia (NIH/NIAID) [E]" (b) (6)
Date: Tuesday, January 21, 2020 at 4:48 PM
To: "Stemmy, Erik (NIH/NIAID) [E]" (b) (6), "Beigel, John (NIH) [E]" (b) (6)
Cc: "Schuster, Claire (NIH/NIAID) [E]" (b) (6), "Lyon, Rickie (NIH/NIAID) [C]" (b) (6)
Subject: FW: (plz review) CoV / MERS NIAID web page

Good Afternoon John and Erik,

Attached is the drafted web page update for MERS/SARS. Note that OC decided to (b) (5) and also predict that the website will become a "coronavirus" page with MERS and SARS subsets. Please let us know if you have any comments or edits by noon on Friday, January 24th.

Thank you!

Cynthia Rojas
Cynthia M. Rojas, MPH
Communications Health Specialist
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane, Room 7G74
Rockville, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Pekoc, Ken (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, January 21, 2020 3:28 PM
To: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: (plz review) CoV / MERS NIAID web page

I've attached a draft update for the NIAID web pages on MERS/SARS … all sections are pretty short. If your folks could review this week, that would be great. … anything inaccurate, or any significant projects missing?

We decided to (b) (5)

Note, I'm pretty sure this will become a "Coronavirus" page on the website, with MERS and SARS as subsets (and whatever happens with the new CoV in China, which we'll add).

Thanks

Updated 1/8/2020

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Wuhan Pneumonia Update

Background

- In December 2019 the Wuhan Municipal Health Committee identified an outbreak of viral pneumonia cases of unknown cause.
- On December 31st the WHO China Country Office was notified of 44 patients with pneumonia of unknown etiology, 11 of which were severely ill.
- As of January 5th, 2020 there are 59 patients with a diagnosis of unknown viral pneumonia is Wuhan, 7 of which are severely ill. At least one patient is on ECMO (Peiris, pers comm 1/6/2020). The earliest case was reported December 12th, and the latest onset was December 29th. All patients are isolated and receiving treatment in Wuhan medical institutions. 163 close contacts have been identified for ongoing medical observation.
- Case-patients in the outbreak are reported to have fever, difficulty breathing, and bilateral lung infiltrates on chest radiography (CDC, http://bit.ly/36GxY3y).
- Hong Kong has added Wuhan Pneumonia to the list of notifiable diseases. As of January 7th, 2020 the Hong Kong Center for Health Protection has reports of 30 cases under enhanced surveillance with recent travel history to Wuhan. https://www.chp.gov.hk/files/pdf/enhanced_sur_pneumonia_wuhan_eng.pdf
- Epidemiological investigation showed that some patients operated businesses in the Wuhan South China Seafood City. As of January 1st, 2020 the market has been closed for environmental sanitation and disinfection.
- There is currently no clear evidence of human-to-human transmission, however one family cluster has been identified. No nosocomial transmission has been seen (Peiris, pers comm 1/6/2020).
- Fragments of coronavirus RNA with an 86% homology to SARS has been found in one patient (Peiris, pers comm 1/6/2020).
- News reports on 1/8/2020 the virus is a novel coronavirus, sequenced in one patient and identified in others.

Related Coronavirus Basic Research

- M51C CoV portfolio has 20 grants (13 basic, 2 Tx, 5 Vx).
- Peter Daszak (R01AI110964-06) is funded for work to understand how coronaviruses evolve and jump to human populations, with an emphasis on bat CoVs and high-risk populations at the human-animal interface. Main foreign sites are in China (including co-investigators at the Wuhan Institute of Virology). Main aims of the award are to characterize the diverse SARS-related CoVs in bat populations, conduct surveillance in human populations, and to characterize the spillover risk of novel CoVs.
    - Work under previous award has identified over 50 SARS-related CoVs, some of which can infect human cells and cause disease in humanized mouse models.
    - This group identified the Swine Acute Diarrheal Syndrome CoV (SADS-CoV), an alpha CoV that caused the death of >20,000 pigs in China.

Updated 1/8/2020

Information listed as "pers comm" reflects personal comments from investigators, and may not be verified from public health authorities.

- Fang Li (R01AIAI089728-09) is funded to investigate the receptor recognition and cell entry in coronaviruses using structural approaches using spike proteins in complex with receptors. This award found the first evidence of a MERS-related CoV that uses the human receptor and provides evidence of a natural recombination event between bat CoVs.
- Stanley Perlman (P01AI060699-11) leads a team of investigators using mouse models of SARS and MERS to investigate CoV pathogenesis and develop vaccines and therapeutics. Projects focus on age-dependent differences in CoV pathogenesis, cell entry pathways as targets for antiviral strategies, and viral pathogenesis and lung disease.
- Animal Model development:
    - NIAID has directly supported several animal models of MERS-CoV, including adenovirus vector, transgenic human receptor knock-in, humanized mouse, and NHP.
    - Small animal models of MERS-CoV are widely used to understand viral pathogenesis and to test medical countermeasures. Mouse models are most common, particularly Crispr-Cas9 humanized and transgenic strains. Mouse models of MERS-CoV may also require use of a mouse-passaged strain to observe severe disease. Ongoing work by NIAID grantees continues to refine mouse models of MERS-CoV, including expanding to collaborative cross mice.
    - Three NHP species have been used as models of MERS-CoV: the rhesus macaque, common marmoset, and African Green Monkey. Generally, MERS-CoV infection results in viral replication and mild disease, and severity can vary by route of administration. The most severe disease is seen in marmosets.
    - NIAID has an IAA in place with USAMRIID for further development of the African Green Monkey model.
- CEIRS MERS Basic Research Projects:
    - MERS Surveillance (Egypt, Lebanon, Jordan, Tunisia, Algeria, Ethiopia). Ghazi Kayali & Richard Webby (St. Jude Children's Research Hospital); Mohamed Ali (National Research Centre, Egypt). Ongoing surveillance and genomic sequencing of virus from camels in 5 Middle Eastern countries including, Egypt, Tunisia, Algeria, Jordan, and Lebanon; as well as surveillance and sequencing of virus from bats in Lebanon and Ethiopia.
    - Development of methods and their application for the investigation of the animal sources of human infection with MERS CoV. Malik Peiris (University of Hong Kong); Richard Webby (St. Jude Children's Research Hospital). Longitudinal seroepdemiology studies of humans and animals in the Middle East and North Africa will investigate seasonality, routes of transmission, and geographic distribution or MERS-CoV.

Related Coronavirus Diagnostics:

- MERS diagnostics focus on serological evidence of infection and PCR sequencing of samples from patients.
- Developing advanced MERS diagnostics is a portfolio gap, and there is a need to focus on developing rapid, sensitive point-of-care diagnostics (PMCID: PMC6361340).

Related Coronavirus Medical Countermeasures:

Updated 1/8/2020

Information listed as "pers comm" reflects personal comments from investigators, and may not be verified from public health authorities.

- NIAID continues to support the preclinical and clinical development of MERS-CoV vaccines and therapeutics through both grant and contract mechanisms.
- NIAID has developed mouse models of MERS-CoV via both grant and contract mechanisms that can be used for efficacy studies of MERS-CoV MCMs.
- NIAID preclinical services can provide *in vitro* and *in* vivo screening of vaccines and therapeutics for MERS and SARS.

Vaccines. Work on vaccines has identified several candidates that produce a robust neutralizing antibody response. One vaccine candidate has completed a Phase I trial and three others are beginning Phase I or II trials.

- Vaccine candidates in Phase I trials: ChAdOx1 (NCT04170829, NCT03399578, Oxford Univ), MVA-MERS-S (NCT04119440, IDT), BVRS-GamVac (NCT04128059, Russian MoH).
- Vaccine Candidates in Phase II trials: GLS-5300 (Inovio), BVRS-GamVac (NCT04130594, Russian MoH).
- CEPI is supporting MERS vaccine development with candidates from Inovio (DNA Spike), Themis (measles vector), IDT (MVA vector), and Oxford University (ChAd vector).
- A Phase I clinical trial of a MERS DNA vaccine (Inovio) was conducted at WRAIR finding the vaccine was safe and well-tolerated.
- The VRC and collaborators have stabilized the MERS-CoV spike protein in its prefusion conformation. The stabilized spike protein is potently immunogenic and elicits protective antibodies to the receptor binding domain, n-terminal domain and other surfaces of the spike protein. The stabilized coronavirus spike protein, and mRNA expressing the spike protein through collaboration with Moderna Therapeutics, is currently being evaluated in the humanized DPP4 mouse model at UNC.
- Extramural grantees are developing MERS vaccine candidates including recombinant spike receptor binding domain protein (Lanying Du, NY Blood Center; Hotez, Baylor; Jason McLellan UT Austin), vaccine/adjuvant combinations (Ralph Baric, UNC), viral-like particles and live-attenuated MERS-CoV vaccines (Gallagher, Enjuanes; P01 to University of Iowa), Rabies virus vectored (Schnell, Frieman; Jefferson U, UMD)

Therapeutics. Currently no therapeutics approved. Overall candidates are in early stages along the drug development pipeline, however two antibody therapeutics have been tested in Phase I clinical trials.

- NIAID grants and contracts have supported efforts to develop a monoclonal antibody therapeutics for MERS-CoV (REGN3048 and REGN3051; PMC4507189). Efficacy studies were supported via DMID TO and NHP studies performed at RML (PMID: 29885377). A Phase I clinical trial was conducted at NIAID's Phase I Clinical Trial Units, and was completed in 2019 (NCT03301090).
- NIAID supported GLP toxicology and tissue cross reactivity studies for an IND for a human polyclonal antibody produced in transchromosomic cows (SAB 301). A Phase I trial was conducted at DCR (PMCID: PMC5871563). NIAID will hold the US IND for a Phase II/III trial to be conducted in the Kingdom of Saudi Arabia. Currently the protocol is under development and the trial is anticipated to start in Q3/Q4 2020.

Updated 1/8/2020

Information listed as "pers comm" reflects personal comments from investigators, and may not be verified from public health authorities.

- A number of other therapeutic strategies have been tested (convalescent plasma, lopinavir/ritonavir, ribavirin, interferon), however small case numbers have made it difficult to assess their impact on morbidity and mortality in infected patients (PMID: 3023653).

Updated 1/8/2020

Information listed as "pers comm" reflects personal comments from investigators, and may not be verified from public health authorities.

Appendix 1: Currently funded M51C CoV Grants

PI Name	Title	Grant	Proj Start	Proj End	Abs	Objective
SIMS, AMY C	How MERS-CoV Regulates Innate Immunity in Primary Human Lung Cells	1 R21 AI146872-01	2019/06/05	2021/05/31	Abs	Basic
KIRCHDOERFER, ROBERT NICHOLAS	Structural Studies of the Coronavirus Life Cycle	4 R00 AI123498-03	2019/12/18	2021/11/30	Abs	Basic
GRAEPEL, KEVIN WHITTLE	Roles of replication fidelity in viral RNA synthesis, population diversity, and overall fitness of coronaviruses	5 F30 AI129229-03	2017/01/13	2020/10/12	Abs	Basic
FEHR, ANTHONY R	Investigating How ADP-ribosylation Impacts Innate Immunity During Coronavirus Infection	5 K22 AI134993-02	2018/12/07	2020/11/30	Abs	Basic
BAKER, SUSAN C	Mechanisms of viral proteases in coronavirus replication and pathogenesis	5 R01 AI085089-10	2010/07/01	2020/06/30	Abs	Basic
LI, FANG	Receptor recognition and cell entry of coronaviruses	5 R01 AI089728-09	2016/06/07	2021/05/31	Abs	Basic
BARIC, RALPH S	Determinants of Coronavirus Fidelity in Replication and Pathogenesis	5 R01 AI108197-07	2013/08/01	2023/02/28	Abs	Basic
BARIC, RALPH S	Mechanisms of MERS-CoV Entry, Cross-species Transmission and Pathogenesis	5 R01 AI110700-05	2015/04/20	2020/03/31	Abs	Basic
MAKINO, SHINJI	New Paradigm for Host and Viral Gene Regulation by MERS Coronavirus nsp1	5 R01 AI114657-05	2015/05/01	2020/04/30	Abs	Basic
PERLMAN, STANLEY	Role of eicosanoids in pathogenic human CoV infections	5 R01 AI129269-04	2016/09/23	2021/08/31	Abs	Basic
DANIEL, SUSAN	Structural and functional analysis of the coronavirus spike protein fusion peptide	5 R01 AI135270-02	2018/08/09	2022/07/31	Abs	Basic
WEISS, SUSAN R	MERS coronavirus: antagonism of double-stranded RNA induced host response by accessory proteins	5 R01 AI140442-02	2018/05/24	2023/04/30	Abs	Basic

Updated 1/8/2020

Information listed as "pers comm" reflects personal comments from investigators, and may not be verified from public health authorities.

PERLMAN, STANLEY	PPG: SARS-CoV-host cell interactions and vaccine development	5 P01 AI060699-13	2004/07/01	2022/07/31	Abs	Basic/Vx
CHANG, KYEONG-OK	Small Molecule Protease Inhibitors against MERS-CoV	5 R01 AI130092-02	2018/05/15	2023/04/30	Abs	Tx
BARIC, RALPH S	Broad-spectrum antiviral GS-5734 to treat MERS-CoV and related emerging CoV	5 R01 AI132178-03	2017/08/09	2022/07/31	Abs	Tx
BARIC, RALPH S	Respiratory Virus Vaccine and Adjuvant Exploration	1 U01 AI149644-01	2019/04/19	2024/03/31	Abs	Vx
MCLELLAN, JASON SCOTT	Structure, Function and Antigenicity of Coronavirus Spike Proteins	5 R01 AI127521-03	2017/02/09	2022/01/31	Abs	Vx
DU, LANYING	Rational design and evaluation of novel mRNA vaccines against MERS-CoV	5 R01 AI137472-02	2018/02/13	2023/01/31	Abs	Vx
DU, LANYING	Structure-based design of coronavirus subunit vaccines	5 R01 AI139092-02	2018/05/21	2023/04/30	Abs	Vx
WHITTAKER, GARY R	Development of a subunit vaccine for MERS-CoV and other emerging coronaviruses	5 R21 AI135373-02	2018/06/06	2020/05/31	Abs	Vx

From: Haskins, Melinda (NIH/NIAID) [E]
To: Mulach, Barbara (NIH/NIAID) [E]
Cc: NIAID OCGR Leg; NIAID BUGS; Handley, Gray (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]
Subject: Re: Urgent for Dr. Fauci: China"s lab for studying SARS and Ebola is in Wuhan, the outbreak"s center
Date: Thursday, January 23, 2020 9:30:36 PM

Thank you!

Sent from my iPhone

On Jan 23, 2020, at 9:29 PM, Mulach, Barbara (NIH/NIAID) [E] (b) (6) wrote:

Quick update from Ping Chen:
The two institutes are not connected administratively. Wuhan Institute of Virology is an Institute under the Chinese Academy of Sciences (CAS).
The Virology department in Wuhan University is known as one of the best Virology department among Chinese universities.

From: Haskins, Melinda (NIH/NIAID) [E] (b) (6)
Sent: Thursday, January 23, 2020 9:29 PM
To: Mulach, Barbara (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>; NIAID BUGS <BUGS@niaid.nih.gov>; Handley, Gray (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6); Cassetti, Cristina (NIH/NIAID) [E] (b) (6); Embry, Alan (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: Re: Urgent for Dr. Fauci: China's lab for studying SARS and Ebola is in Wuhan, the outbreak's center
Thank you very much.

Sent from my iPhone

On Jan 23, 2020, at 9:26 PM, Mulach, Barbara (NIH/NIAID) [E] (b) (6) wrote:

HI Melinda,

We've identified one grant with a sub-contract to Wuhan Institute of Virology (thanks for the lead) and one primary award to Wuhan University. We are trying to get clarification regarding whether or not the two organizations are related so we know if the second application is relevant to the request or not.

Grant: R01 AI119064-06
PI: Peter Daszak
Title: Understanding the Risk of Bat Coronavirus Emergence
Institution: ECOHEALTH ALLIANCE, INC.
Sub-award to Wuhan Institute of Virology
In the interest of time, I'm sending you two documents providing additional details regarding the role of Wuhan Institute of Virology. If you would like a shorter summary or a different format, just let us know.
Grant: R01 AI116442-05
PI: LAN, KE
Title: Versatile functions of LANA in KSHV pathogenesis
Institution: WUHAN UNIVERSITY
There is no reference in the application to BSL facilities or biocontainment, so this is probably not relevant for the current exercise. Let us know if you would like additional information on this.
I hope this is helpful. Let us know what else we can do to help.
Barbara
-----Original Message-----
From: Haskins, Melinda (NIH/NIAID) [E] (b) (6)
Sent: Thursday, January 23, 2020 8:18 PM
To: NIAID BUGS <BUGS@niaid.nih.gov>; Handley, Gray (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6)
Cc: NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: Urgent for Dr. Fauci: China's lab for studying SARS and Ebola is in Wuhan, the outbreak's center
https://www.dailymail.co.uk/health/article-7922379/Chinas-lab-studying-SARS-Ebola-Wuhan-outbreaks-center.html
Colleagues,
Dr. Fauci will be brief multiple Senators tomorrow morning on our novel coronavirus response at the request of Senator Lamar Alexander, who has an interest in public health matters and China. Would you please confirm the exact nature or our support to the Wuhan Institute of Virology/Biosafety Lab. You'll want to read the Daily Mail article above.
Thanks for the quick response!
Melinda
Sent from my iPhone
<R01AI110964 Renewal FACTS clearance.docx>
<Daszak Wuhan Exceprts.docx>

From: Rojas, Cynthia (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: summary of MERS and SARS projects
Date: Wednesday, November 20, 2019 4:20:54 PM

Hi Erik,
Thank you so much for your thorough review! We're sending this forward to OC and will request a final copy for you and Alan to review before it's posted.
Thank you!!
Cynthia Rojas

Cynthia M. Rojas, MPH
Communications Health Specialist
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane, Room 7G74
Rockville, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, November 19, 2019 8:05 AM
To: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Subject: RE: summary of MERS and SARS projects
Hi Cynthia,
Great job! Sorry it took me so long to get back to you. I wanted to think about the additional text a bit. I ultimately decided that (b) (5) Will leave it up to you/BUGS to decide if it's better to include specifics.
Let me know if you have any other questions or need anything else from me.
Erik

From: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Sent: Thursday, November 14, 2019 3:30 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: RE: summary of MERS and SARS projects
Hi Erik,
I've attached the drafted response. The only new material is the middle paragraph which (b) (5) It was difficult to put this into layman's terms, so if there are any terms that we could further clarify, let me know. The first paragraph is from the language that you and Amanda drafted I April, and the final paragraph is from the MERS vaccine page update that you worked on with Sarah earlier this year. I also spoke to GrantOps and the final count of MERS/SARS projects for FY19 won't be available until early next year, which is why I didn't list any values in the summary. I'm going to let OC know that the figures are not available, but that we could circle back early next year to update the site with the number of NIAID supported

projects, if needed.
Let me know what you think.
Thanks!
Cynthia

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, November 14, 2019 12:18 PM
To: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Subject: RE: summary of MERS and SARS projects

Hi Cynthia,
The NCT number for the Regeneron study should be: NCT03301090. The AIMS trial does not yet have one, as it's too early in development. I've attached the paper from the Phase I from DCR, and the current **draft** study protocol. Note that the details of the protocol are likely to change, so I don't recommend including much for that until we have it finalized.
Let me know if you need anything else!
Erik

From: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Sent: Thursday, November 14, 2019 12:09 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: RE: summary of MERS and SARS projects

Hi Erik,
I apologize for not responding sooner. Thank you so much for this list! I'm working on the summaries now. Could you send me the clinicaltrials.gov link or a reference for the two trials highlighted below?
Thank you!
Cynthia

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, November 12, 2019 12:44 PM
To: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: RE: summary of MERS and SARS projects

Sounds good. I've put a list of some interesting projects below. These were all active in 2019. Let me know if you need more or if you want me to come up with any other text!
Erik

- AIMS Trial – **A**nt**I**body against **M**ER**S** Trial. Phase II/III trial in Saudi Arabia of SAB-301, a polyclonal Ab therapeutic produced in transchromasomic cows. The trial is supported and executed in Saudi Arabia, but DMID will hold the US IND and contribute regulator support. DCR conducted the Phase I of the trial at the clinical center
- Phase I trial of Regeneron MERS Antibodies performed by DMID Phase I Units
- Basic Science/Emergence/Pathogenesis projects: R01AI110964, R01AI089728, R01AI110700, R01AI085089
- Therapeutic Projects: R01AI132178, R01AI130092,
- Vaccine Projects: P01AI060699 , R01AI127521, U01AI149644, R01AI139092, R01AI137472

From: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Sent: Thursday, November 07, 2019 3:50 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)

Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: RE: summary of MERS and SARS projects
Hi Erik,
Thank you so much for your feedback. I think you make some excellent points, and we had some similar concerns. I think we can start with the second portion of the request with language surrounding project highlights or specific projects for 2019. (b) (5) This would be a good place to start, let me know what you think.
Thank you,
Cynthia Rojas
Cynthia M. Rojas, MPH
Communications Health Specialist
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane, Room 7G74
Rockville, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, November 7, 2019 3:25 PM
To: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: RE: summary of MERS and SARS projects
Hi Cynthia,
Sure, I'll be happy to get the information. This seems like a bit of a change for the website, though. In the past they haven't wanted in include specific numbers for things because of how quickly they get outdated. (b) (5)
Let me know what you think and I'll put something together.
Erik

From: Rojas, Cynthia (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, November 06, 2019 2:27 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: FW: summary of MERS and SARS projects
Good Afternoon Erik,
I hope you're having a good week. Could you send me a list of active MERS and SARS projects (including project numbers) that you think should be highlighted on the NIAID website? See e-mail below, OC is working on updating the MERS and SARS webpages on the NIAID site and have asked for our help drafting a bit of the content. We referred Ken to Martin Johnson for the funding information because MERS and SARS are not searchable sections in NIH RePORTER. I'm working on drafting language on some MERS and SARS projects for your review, but would benefit greatly from a list of projects to highlight. I have included some summary language that we have on file from

previous requests below.

In June 2012, a novel coronavirus, subsequently named the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), was identified in a patient in the Kingdom of Saudi Arabia. Leveraging knowledge and expertise from related viruses, NIAID rapidly built a robust research program on this previously unknown virus. Key areas of investigation included basic research on where MERS-CoV comes from and how it causes disease, the development of animal models to study the virus, and the development of treatments and vaccines. NIAID continues to support the development vaccines and therapeutics, including antibodies used as treatments for MERS-CoV. RDB also works closely with other federal government and international partners such as CDC, WHO, and Coalition for Epidemic Preparedness Innovations (CEPI) to coordinate the global response to MERS-CoV. The branch remains poised to respond to emerging respiratory infections, and MERS-CoV represents just one example of the additional responsibilities the Branch Chief manages during and after an outbreak situation.

Scientists have learned that for MERS-CoV to infect a person, the virus enters cells using a protein known as the spike, or S protein. After entering the cell, the virus delays the normal immune system response, allowing the infection to gain a foothold in the body. By the time the immune system recovers, the infection has progressed and become much harder to fight off. NIAID-funded scientists are exploring MERS-CoV vaccines that would block the S protein or the delay of the immune system. Other grantees are working to develop a live, attenuated MERS-CoV vaccine, which is a type of vaccine that contains a version of the living microbe that has been weakened in the lab, so it cannot cause disease. Investigators at the NIAID Vaccine Research Center are using techniques learned from SARS-CoV vaccine development to create a MERS-CoV DNA vaccine with plans to test in mice.

Thank you in advance for your help addressing this inquiry.

Kind Regards,

Cynthia Rojas
Cynthia M. Rojas, MPH
Communications Health Specialist
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane, Room 7G74
Rockville, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Pekoc, Ken (NIH/NIAID) [E] (b) (6)
Sent: Monday, November 4, 2019 3:04 PM
To: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: summary of MERS and SARS projects

Hi … I'm updating the MERS and SARS webpages on the NIAID site and am hoping you'll be able to send me a brief overview of NIAID-funded projects … if possible a tally showing the most recent number of projects under way on each disease with a funding total, and then a one-paragraph synopsis of 1 or 2 of the more interesting projects. … by Nov 15? Later?

For example: In fiscal 2019 NIAID funded X SARS research projects totaling $XX

million and Y MERS research projects totaling $YY million. Those projects included a SARS immune study at ZZZZ university … and a MERS vaccine study at QQQQ university. The immune study aims to … while the vaccine study …
Let me know if you have Qs or concerns
Thanks

From: Rodriguez, Elizabeth (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: DMID GrantOps
Subject: RE: Award Error for R01AI110964-06 PI Daszak
Date: Friday, July 26, 2019 11:09:21 AM
Attachments: NIAID COV 2019 Budget Letter 2R01AI110964-06.pdf

---

Dear Dr. Erik Stemmy,

It appears that figures from the corrected budget letter that accompanied the ARA submitted on 11/14/18 (see attached) may not have been taken into account when calculating the award. We recommend working with the GMS to get this sorted out. Please let us know if we can be of further assistance.

Thank You,

Liz

Elizabeth Rodriguez, MS
Health Specialist, DMID Grant Ops
OSCPO/DMID/NIAID/NIH
5601 Fishers Lane, Room 7G46
Rockville, MD 20852
Phone: (b) (6)
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, July 25, 2019 12:31 PM
To: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: Award Error for R01AI110964-06 PI Daszak

Hi GrantOps,

The NoA for the award above just went out this week, and the dollar amount was very wrong. Originally, the application came in last year mistakenly over the $500k cap and we did an ARA with the PI saying they would reduce the budget to be within the cap (see attached email thread and letter). It looks like the NoA was issued for an amount that even exceeds the original budget request ($593,362 vs $515,358). Should I work with the GMS on this or is this something you can help with?

Thanks!

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: (b) (6)
Email: (b) (6)

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

****

EcoHealth Alliance

14 November 2018

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Budget Error in Renewal Proposal 2R01AI110964-06

To Whom It May Concern:

This letter pertains to our renewal proposal (2R01AI110964-06) with the title "Understanding the Risk of Bat Coronavirus Emergence" for consideration under the NIH Research Grant Program (R01, PA-18-484). Our submitted renewal proposal budget was in error. If our application receives a fundable score, we will reduce our budget to below the $500,000 per year cap in all 5 years of the award.

Our total budget should be **$3,225,898** including indirect costs. Without indirect costs our total direct cost budget should be **$2,499,944** and annually detailed as follows:

Year	Direct Cost	Indirect Cost	Total
1	$499,989	$164,835	$664,824
2	$499,989	$140,280	$640,269
3	$499,989	$140,280	$640,269
4	$499,989	$140,280	$640,269
5	$499,989	$140,280	$640,269

Please contact us, if there are any questions or further details required. Thank you very much for your consideration.

Sincerely,

(b) (6)

Dr. Peter Daszak, PI
President, EcoHealth Alliance
460 West 34th Street, Ste 1701
New York, NY 10001, USA
(b) (6)
(b) (6)

(b) (6)

Dr. Aleksei Chmura
AOR and Chief of Staff, EcoHealth Alliance
460 West 34th Street, Ste 1701
New York, NY 10001, USA
(b) (6)
(b) (6)

From: Girma, Tseday (NIH/NIAID) [E]
To: Aleksei Chmura
Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER
Date: Monday, July 8, 2019 7:58:50 AM
Attachments: image001.png

Thanks for sending me this. I will look into why its showing as none on my screen.
Thanks,
Tseday

From: Aleksei Chmura (b) (6)
Sent: Monday, July 8, 2019 7:39 AM
To: Girma, Tseday (NIH/NIAID) [E] (b) (6)
Cc: Peter Daszak (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER
Tseday,
This is via our current, active R01AI110964 - 05 award IRB with Hummingbird (IRB00009289).
Please see attached screen shot from OHRP. Should I get them to email you to confirm?
Cheers!
-Aleksei

Aleksei Chmura, PhD
Chief of Staff

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

(b) (6) (office)
(mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

On Jul 8, 2019, at 07:33, Girma, Tseday (NIH/NIAID) [E] (b) (6) wrote:
Good morning,
No – I couldn't find any record associated with that FWA in OHRP website. Please follow up with them and let me know the status.
Thanks,
Tseday

From: Aleksei Chmura (b) (6)
Sent: Monday, July 8, 2019 7:23 AM
To: Girma, Tseday (NIH/NIAID) [E] (b) (6)
Cc: Peter Daszak (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER
Dear Tseday,
Can you find our number as follows: FWA00022431?

Cheers!

-Aleksei

On Jul 8, 2019, at 07:21, Girma, Tseday (NIH/NIAID) [E] (b) (6) wrote:
Good morning,
Thank you for submitting the IIA document for North Carolina performance site. While reviewing your application, I noticed that you entered 'None' in eRA commons for Human subjects Federal Wide Assurance (FWA). Per policy, "institutions that are awarded funds for human subjects research are considered to be engaged in human subjects research and must have an approved FWA even if another institution performs the human subjects activities through a subaward." For the full list of certification and assurance requirements, go to the Human Subjects Research Requirements SOP. I also check the OHRP website, I wasn't able to look up your FWA info.
Please let us know if you established FWA with OHRP, if not, you will have to do it ASAP. We are not able to issue an award without an FWA.
Thank you,

Tseday Girma
Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E24
Rockville, MD 20852
Phone (b) (6)
Email (b) (6)
NIAID, National Institutes of Health, DHHS
Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

New Search

Return to: Search

Office for Human Research Protections Database (Current Data)

Find Assurance in table below and click the corresponding name to view details:

Total Records: 1 **Total Pages:** 1

Results per page: 20 Go

Assurance	Institution	City	Type	Status
FWA00022431	EcoHealth Alliance	New York	FWA	Active

From: era-notify@mail.nih.gov
To: Girma, Tseday (NIH/NIAID) [E]; NIAID GM I2 Notifications; Stemmy, Erik (NIH/NIAID) [E]
Subject: Just in Time Submitted by NIH Commons for Grant Application: R01AI110964-06 .
Date: Monday, May 6, 2019 11:02:15 PM

A Just in Time Submission was submitted by Signing Official: Chmura, Aleksei to the NIH for grant application: R01AI110964-06 associated with Principal Investigator DASZAK, PETER using the NIH Commons.

The Just In Time information submitted to NIH is available for review in the Grant Folder within IMPACII.
If you have any questions about this email, please contact Aleksei Chmura at (b) (6), who initiated this action.

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact. Please access Commons at http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

From: DMID GrantOps
To: NIAID DMSRO
Cc: DMID GrantOps
Subject: FW: Release of DMID R01 EOID- Expedited Council
Date: Tuesday, April 23, 2019 11:26:37 AM

Dear All-
Good news! The following R01payline applications from 201905 expedited Council have been released for funding.
ATTN POs:

- Alert DMID GrantOps if a grant below involves one or more of the 15 Select Agents listed in the USG Policy for Oversight of Life Sciences **Dual Use Research of Concern** (unless previously reported).
- Confirm whether biological agent(s) or toxin(s) used in the research appear on the revised list of HHS Select Agents (details: http://www.selectagents.gov/SelectAgentsandToxinsList.html) before completing the program checklist.
- Answer "YES" to the Biosafety program checklist question for all grants coded as Biodefense.
- Resolve bars and administrative issues, and complete checklists as soon as possible.
- For grants that fall under the NIH Genomic Data Sharing (GDS) policy: answer "YES" to Genomic Data Sharing PO checklist questions. Contact your Branch ICO coordinator to adjust the Genomic Data Sharing flag in IMPAC, if needed. For human genomic data, confirm receipt of Institutional Certification; for the NIAID GDSSOP, see here.
- Foreign grants:
  - Foreign applications MUST go to Council as a special score or they cannot be funded.
  - Both foreign grants and domestic grants with foreign components require entry into the FTS.
- Please confirm your FCC **(including the BioD/AMR codes)** and request corrections ASAP. Coding errors have budget implications.

For DMID grant-related issues, please send your initial email to "DMID GrantOps".
Thanks,
Trish
Patricia M. Strickler-Dinglasan, PhD (C)
Phone: (b) (6)

From: Pontier, Trisha (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 23, 2019 11:14 AM
To: Pontier, Trisha (NIH/NIAID) [E]; Catalay, Sally (NIH/NIAID) [E] <scatalay@niaid.nih.gov>; NIAID DMIDFunding<DMIDFunding@niaid.nih.gov>; NIAID GMP STAFF <NIAIDGMPSTAFF@niaid.nih.gov>
Subject: Release of DMID R01 EOID- Expedited Council

BFMB approves the following grants.

To view these grants in the NPARS application, please click here.

Grant Number	GMS Name	PI Name	Institution	Title	PI ReqAmt	DIV RecAmount	GMS RecAmount	GMO RecAmount	Release Amount	CAN/ Ponicode	DIV Rank	RFA/PA	PCC	Percentile/ Score	Council-NPARS	NPARS Program Req Number of Years	Batch Number
1 R01AI146835-01	Wall, Cheryl	LIEN, EGIL	UNIV OF MASSACHUSETTS MED SCH WORCESTER	Caspase-8 as a focal hub in effector-triggered immunity	$584,061	$584,061	$0	$0	$584,061	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M46B B	(b) (5)	201905	5	5569
1 R01AI145687-01A1	Silvombeg, Elizabeth	DE FIGUEIREDO, PAUL	TEXAS A&M UNIVERSITY	Development of a High-Throughput Microfluidics-Enabled Functional Assay for Rapidly Identifying Neutralizing Antibodies	$702,284	$702,284	$0	$0	$702,284	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M51I B		201905	5	5569
1 R01AI143257-01A1	Smith, Philip	SUN, REN	UNIVERSITY OF CALIFORNIA LOS ANGELES	Mechanism for anti-interferon functions of influenza virus	$390,060	$390,060	$0	$0	$390,060	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M51I B		201905	5	5569
1 R01AI143360-01A1	Briggs, Jenna	BRUNO, VINCENT	UNIVERSITY OF MARYLAND BALTIMORE	Therapeutic targeting of growth factor receptors to treat Mucormycosis	$527,987	$527,987	$0	$0	$527,987	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M30D B		201905	5	5569
2 R01AI036525-20	Rojas, Cynthia	SZTEIN, MARCELO	UNIVERSITY OF MARYLAND BALTIMORE	Immune Mechanisms of Protection in S. Typhi Infection and Vaccination in Humans	$567,403	$567,403	$0	$0	$567,403	8472364(8472364)/PAYLINE/NIAID OD		PA18-345	M64D B		201905	5	5569
2 R01AI038897-25	Madoo, David	SCHNEEWIND, OLAF	UNIVERSITY OF CHICAGO	Surface Proteins of Gram-Positive Bacteria	$405,000	$405,000	$0	$0	$405,000	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M38A BR		201905	5	5569
2 R01AI040996-20	Briggs, Jenna	KLEIN, BRUCE	UNIVERSITY OF WISCONSIN-MADISON	Mechanisms of anti-fungal Vaccine immunity	$553,347	$553,347	$0	$0	$553,347	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M31 B		201905	5	5569
1 R01AI141560-01A1	Landgren, Jason	CATANZARO, ANTONINO	UNIVERSITY OF CALIFORNIA, SAN DIEGO	An Antigen-Detection Blood Test for Pulmonary Tuberculosis	$757,863	$757,863	$0	$0	$757,863	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M35C B		201905	5	5569
1 R01AI141536-01A1	Fan, Michael	ZOLKIEWSKI, MICHAL	KANSAS STATE UNIVERSITY	Discovery of Hsp100-selective inhibitors for targeting multiple microbial pathogens	$514,035	$514,035	$0	$0	$514,035	8472364(8472364)/PAYLINE/NIAID OD		PAR17-438	M64F B		201905	4	5569
2 R01AI110964-06	Girma, Tsoday	DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	Understanding the Risk of Bat Coronavirus Emergence	$736,996	$736,996	$0	$0	$736,996	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M51C B		201905	5	5569
1 R01AI146210-01	Diallo, MARIAMA	HUANG, XUEFEI	MICHIGAN STATE UNIVERSITY	Synthetic glycan conjugates with bacteriophage Qbeta for broad spectrum anti-salmonella vaccines	$424,323	$424,323	$0	$0	$424,323	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M64D B		201905	5	5569
1 R01AI141390-01A1	Alford, Trevor	HORWITZ, MARCUS	UNIVERSITY OF CALIFORNIA LOS ANGELES	Development of a Safe and Potent Vaccine Against Melioidosis using the LVS dupB Vector Platform	$789,812	$789,812	$0	$0	$789,812	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M46D B		201905	5	5569
1 R01AI146133-01	Girma, Tsoday	KIRKMAN, LAURA	WEILL MEDICAL COLL OF CORNELL UNIV	Role of Translesional Polymerases in Genome Diversification of the Malaria Parasite	$715,154	$715,154	$0	$0	$715,154	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M93 BR		201905	5	5569
2 R01AI033108-24A1	Walcott, Roberta	STRAND, MICHAEL	UNIVERSITY OF GEORGIA	Endocrinology of Mosquito Reproduction	$355,000	$355,000	$0	$0	$355,000	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M43 B		201905	5	5569
2 R01AI102922-06	Kindhom, Jordan	DUNLOP, MARY	BOSTON UNIVERSITY (CHARLES RIVER CAMPUS)	Cell-to-cell heterogeneity and the emergence of antibiotic resistance	$428,450	$428,450	$0	$0	$428,450	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M36 BR		201905	5	5569
1 R01AI141522-01A1	Sadat, SAYED	RICE, LOUIS	RHODE ISLAND HOSPITAL	Mechanism and activity of beta-lactam resistant enzymes in E. faecium and E. faecalis	$777,570	$777,570	$0	$0	$777,570	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M38A BR		201905	5	5569
2 R01AI102584-06A1	Alford, Trevor	YILDIZ, HAVVA	UNIVERSITY OF CALIFORNIA SANTA CRUZ	Vibrio cholerae c-diGMP signaling: Motile to biofilm transition and transmission	$757,971	$757,971	$0	$0	$757,971	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M64D B		201905	5	5569
1 R01AI146584-01	Sadat, SAYED	TOWNSEND, JEFFREY	YALE UNIVERSITY	Evolutionary multispecies transcriptomics to reveal genes that govern fungal spore germination and pathogenesis	$838,298	$838,298	$0	$0	$838,298	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M31 B		201905	5	5569
1 R01AI143534-01A1	Khurana, Vandhana	SULLIVAN, SHEENA	UNIVERSITY OF MELBOURNE	Does repeated influenza vaccination constrain influenza immune responses and protection?	$774,124	$774,124	$0	$0	$774,124	8472364(8472364)/PAYLINE/NIAID OD		PA18-484	M51J B		201905	5	5569
1 R01AI145870-01	Girma, Tsoday	RAVETCH, JEFFREY	ROCKEFELLER UNIVERSITY	Development of vaccination strategies to elicit broadly protective immunity against influenza	$864,833	$864,833	$0	$0	$864,833	8472364(8472364)/PAYLINE/NIAID OD		PA18-859	M51A B		201905	5	5569
1 R01AI141511-01A1	Alford, Trevor	STONE, VICTORIA	UNIVERSITY OF CALIFORNIA SANTA CRUZ	Development of validated probes for the bacterial type III secretion system	$762,559	$762,559	$0	$0	$762,559	8472364(8472364)/PAYLINE/NIAID OD		PAR13-438	M58A B		201905	4	5569
1 R01AI149747-01	Madoo, David	COBEY, SARAH	UNIVERSITY OF CHICAGO	Longitudinal dynamics of protection after influenza infection and vaccination	$505,191	$505,191	$0	$0	$505,191	8472364(8472364)/PAYLINE/NIAID OD		PAR17-267	M51J B		201901	5	5569
2				Inflammatory Suppression													

R01AI110452-06	Sadat, SAYED	BUCALA, RICHARD	YALE UNIVERSITY	of Adaptive Immunity by Plasmodium MIF	$418,750	$418,750	$0	$0	$418750	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M44 B	(b) (5)	201905	5	5569
1 R01AI146342-01	Liang, Shan	TANG, HENGLI	FLORIDA STATE UNIVERSITY	Perturbation of Host DNA Replication and Cell Cycle Progression by Zika Virus	$378,998	$378,998	$0	$0	$378998	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M52C B		201905	5	5569
1 R01AI145883-01	Girma, Tsedey	YANG, WAN	COLUMBIA UNIVERSITY HEALTH SCIENCES	Disease Persistence and Population Dynamics Modeling Measles under Mass Vaccination	$507,841	$507,841	$0	$0	$507,841	8472364/8472364)/PAYLINE/NIAID OD		PAR17-267	M52A B		201905	5	5569
1 R01AI146078-01	Lundgren, Jason	BAYER, ARNOLD	LA BIOMED RES INST/HARBOR UCLA MED CTR	Bicarbonate-Mediated Enhancement of Beta-Lactam-MRSA Killing: Mechanisms and Clinical Translatability	$300,838	$300,838	$0	$0	$300,838	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M38A BR		201905	5	5569
1 R01AI130307-01A1	Carlisle, Tina	FARKAS, TIBOR	LOUISIANA STATE UNIV A&M COL BATON ROUGE	Determinants of Enteric Calicivirus Infection.	$370,000	$370,000	$0	$0	$370,000	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M64E B		201905	5	5569
1 R01AI147628-01	Mpuja, Bora	MANCIA, FILIPPO	COLUMBIA UNIVERSITY HEALTH SCIENCES	Leveraging PCRT Structure to Discern Function and Predict Emergence of Drug-Resistant Mabria	$421,253	$421,253	$0	$0	$421253	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M91 BR		201905	5	5569
1 R01AI141953-01A1	Smith, Philip	BALIGA, NITIN	INSTITUTE FOR SYSTEMS BIOLOGY	A systems approach to manipulate microbial adaptation to structured environments	$930,885	$930,885	$0	$0	$930885	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M63 BR		201905	5	5569
1 R01AI140400-01A1	Graton, Shaun	BACHMANN, BRIAN	VANDERBILT UNIVERSITY	Biosynthesis and Synthetic Biology of Antibiotic Oligosaccharides	$474,925	$474,925	$0	$0	$474925	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M30C BR		201905	4	5569
2 R01AI091594-06A1	Briggs, Jenna	PATEL, ROBIN	MAYO CLINIC ROCHESTER	Novel Electrochemical Bandage for Treatment of Wound Infections	$581,092	$581,092	$0	$0	$581,092	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M38A B		201905	5	5569
1 R01AI147681-01	Madoo, David	DOWDY, DAVID	JOHNS HOPKINS UNIVERSITY	Innovative contact tracing strategies for detecting TB in mobile rural and urban South African populations	$653,813	$653,813	$0	$0	$653,813	8472364/8472364)/PAYLINE/NIAID OD		PA18-345	M33E B		201905	5	5569
1 R01AI143709-01A1	Fain, Michael	YANG, ZHILONG	KANSAS STATE UNIVERSITY	Mechanisms regulating poxvirus post-replicative protein synthesis	$375,906	$375,906	$0	$0	$375,906	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M34A B		201905	5	5569
1 R01AI147128-01	Pont, Laura	RUBINSTEIN, FERNANDO	INSTITUTO DE EFECTIVIDAD CLINICA Y SANIT	TB-TST (TB treatment support tools) Refinement and evaluation of an interactive mobile app and direct adherence monitoring or TB treatment outcomes	$396,560	$396,560	$0	$0	$396,560	8472364/8472364)/PAYLINE/NIAID OD		PA18-722	M33E B		201905	5	5569
1 R01AI141626-01A1	Smith, Philip	VISWANATHAN, V	UNIVERSITY OF ARIZONA	Host-cell mitochondral alterations play a central role in EPEC pathogenesis	$352,489	$352,489	$0	$0	$352,489	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M64A B		201905	5	5569
2 R01AI101047-06A1	Wolcott, Roberta	WANG, BAOZHONG	GEORGIA STATE UNIVERSITY	Novel Influenza nano vaccines for broad cross protection	$763,035	$763,035	$0	$0	$763,035	8472364/8472364)/PAYLINE/NIAID OD		PA18-859	M31A B		201905	5	5569
1 R01AI146241-01	Diallo, MARIAMA	RAO, GAURI	UNIV OF NORTH CAROLINA CHAPEL HILL	Pharmacology of intrathecal/intraventricular polymyxins: A systems-based approach	$597,848	$597,848	$0	$0	$597,848	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M30C BR		201905	5	5569
1 R01AI143265-01A1	Pont, Laura	ADAMS WALDORF, KRISTINA	UNIVERSITY OF WASHINGTON	JAK-STAT Control of Zika Virus-Induced Fetal Injury	$919,949	$919,949	$0	$0	$919,949	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M52C B		201905	5	5569
1 R01AI146914-01	Lundgren, Jason	RALSTON, KATHERINE	UNIVERSITY OF CALIFORNIA AT DAVIS	The role of Entamoeba histolytica trogocytosis (trogo- nibble) in the pathogenesis of amoebiasis	$372,773	$372,773	$0	$0	$372,773	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M64 B		201905	5	5569
1 R01AI147325-01	Smith, Philip	WANG, JUN	UNIVERSITY OF ARIZONA	High Throughput Screening of Inhibitors Targeting the Enterovirus A71 and D68 2A Proteases	$537,177	$537,177	$0	$0	$537,177	8472364/8472364)/PAYLINE/NIAID OD		PAR17-438	M55 B		201905	4	5569
1 R01AI143656-01A1	Heath, Kevin	BELISLE, JOHN	COLORADO STATE UNIVERSITY	Host Metabolic Biosignatures for the Diagnosis of Lyme Disease	$781,156	$781,156	$0	$0	$781,156	8472364/8472364)/PAYLINE/NIAID OD		PA16-243	M55 B		201905	5	5569
1 R01AI143850-01A1	Mpuja, Bora	RAMAGE, HOLLY	UNIVERSITY OF PENNSYLVANIA	Defining the Role of West Nile Virus-Host Protein Interactions in Evading Antiviral Immunity	$402,500	$402,500	$0	$0	$402,500	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M52C B		201905	5	5569
2 R01AI019641-33A1	Saeed, Sufiyan	MURPHY, TIMOTHY	STATE UNIVERSITY OF NEW YORK AT BUFFALO	Genome Evolution During Bacterial Persistence in the Human Airways in COPD	$648,435	$648,435	$0	$0	$648,435	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M54A BR		201905	5	5569
2 R01AI094623-07A1	Graton, Shaun	KALODIMOS, CHARALAMPOS	ST. JUDE CHILDREN'S RESEARCH HOSPITAL	Structural insight into novel mechanisms of type III secretion	$448,750	$448,750	$0	$0	$448750	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M64A B		201905	5	5569
1 R01AI141633-01A1	Girma, Tsedey	THANASSI, DAVID	STATE UNIVERSITY NEW YORK STONY BROOK	Modulation of Host Cell Responses by Francisella tularensis	$549,471	$549,471	$0	$0	$549471	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M46B B		201905	5	5569
1 R01AI145960-01	Powell, Tama	BALDWIN, MICHAEL	UNIVERSITY OF MISSOURI-COLUMBIA	Mechanism of botulinum neurotoxin transport across membranes	$358,900	$358,900	$0	$0	$358900	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M44C B		201905	5	5569
2 R01AI027655-31A1	Alford, Trevor	PORTNOY, DANIEL	UNIVERSITY OF CALIFORNIA BERKELEY	How Listeria senses and responds to different host environments	$370,714	$370,714	$0	$0	$370714	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M64A B		201905	5	5569
1 R01AI140766-01A1	Graton, Shaun	SCHULTZ-CHERRY, STACEY	ST. JUDE CHILDREN'S RESEARCH HOSPITAL	Effects of obesity on the dynamics of Influenza transmission	$769,323	$769,323	$0	$0	$769,323	8472364/8472364)/PAYLINE/NIAID OD		PA18-859	M51B B		201905	5	5569
1 R01AI146172-01	Hernandez, Raul	OGINO, TOMOAKI	CASE WESTERN RESERVE UNIVERSITY	Dissecting catalytic and regulatory functions of nonsegmented negative strand RNA viral polymerases	$360,000	$360,000	$0	$0	$360,000	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M52A B		201905	5	5569
1 R01AI147646-01	Kitsoulis, Regina	WAN, XIUFENG	MISSISSIPPI STATE UNIVERSITY	Use of Clinical Samples to Identify Influenza Virus Antigenic Variants	$530,007	$530,007	$0	$0	$530,007	8472364/8472364)/PAYLINE/NIAID OD		PA18-859	M51B B		201905	5	5569
1 R01AI146160-01	Nee, Mable	ZHOU, QI	PURDUE UNIVERSITY	Advancing innovative therapies against pandrug-resistant Gram-negative superbugs	$673,485	$673,485	$0	$0	$673,485	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M38A BR		201905	5	5569
1 R01AI141671-01A1	Kitsoulis, Regina	BARRIER, MARIETTE	WEST VIRGINIA UNIVERSITY	Vaccine Development Against Bacterial Pathogens Based on iron Acquisition Proteins	$524,949	$524,949	$0	$0	$524,949	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M38A B		201905	5	5569
1 R01AI146199-01	Carlisle, Tina	SCARAFFIA, PATRICIA	TULANE UNIVERSITY OF LOUISIANA	Mechanistic regulation of ammonia metabolism in Aedes aegypti mosquitoes	$391,993	$391,993	$0	$0	$391,993	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M63 B		201905	5	5569
1 R01AI139267-01A1	Heath, Kevin	PETERSEN, CHRISTINE	UNIVERSITY OF IOWA	Field trial and modeling of transmission blocking vaccine to prevent Lyme disease	$728,991	$728,991	$0	$0	$728991	8472364/8472364)/PAYLINE/NIAID OD		PA16-243	M55 B		201905	5	5569

														(b) (5)			
1 R01AI145954-01	Pone, Laura	MOUGOUS, JOSEPH	UNIVERSITY OF WASHINGTON	Identity, function and control of Francisella effectors encoded outside its pathogenicity island	$719,446	$719,446	$0	$0	$719,446	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M46B		201905	5	5569
1 R01AI146063-01	Rojas, Cynthia	ZHU, XIAOPING	UNIV OF MARYLAND, COLLEGE PARK	FcRn-Targeted Mucosal Vaccination Against Influenza Infections	$599,064	$599,064	$0	$0	$599,064	8472364/8472364)/PAYLINE/NIAID OD		PA18-859	M51A		201905	5	5569
1 R01AI146329-01	Saeed, Sufiyan	ACHKAR, JACQUELINE	ALBERT EINSTEIN COLLEGE OF MEDICINE, INC	Characteristics and protective efficacy of human antibodies against M. tuberculosis	$788,818	$788,818	$0	$0	$788,818	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M53A		201905	5	5569
1 R01AI146123-01	Powell, Tamia	KORPE, POONUM	JOHNS HOPKINS UNIVERSITY	Household Transmission of Cryptosporidium	$769,094	$769,094	$0	$0	$769,094	8472364/8472364)/PAYLINE/NIAID OD		PA18-484	M90		201905	5	5569
1 R01AI146101-01	Mpinja, Bora	PARDI, NORBERT	UNIVERSITY OF PENNSYLVANIA	Development of Universal Influenza Virus Vaccines Using Nucleoside-Modified Messenger RNA	$641,792	$641,792	$0	$0	$641,792	8472364/8472364)/PAYLINE/NIAID OD		PA18-859	M51A		201905	5	5569

Let me know if you have any Questions,
Thank you,

From: Ortiz, Omar (NIH/NIAID) [E]
To: NIAID RDB
Cc: Marcus, Lardyn (NIH/NIAID) [E]
Subject: PMT 10- Day Review
Date: Wednesday, January 2, 2019 8:50:04 AM

	PI Name	Grant #	Title	%	PS	HS	RFA/PA	Comm	Council	Dual	Stat	PCC_OK	Dlg
	M33AB	SESHADRI, CHETAN	1 R01AI146072-01	The Role of Lipid-specific T cells in Mediating Protection Against M. tuberculosis			10	PA18-484	No	201905	P	17	Yes
	M33AB	VENKETARAMAN, VISHWANATH	1 R01AI146585-01	Granulomatous Responses against M.tb			20	PA18-484	No	201905	P	17	Yes
	M33AB	GONZALEZ-JUARRERO, MERCEDES	1 R01AI146195-01	Host directed therapy targeting STAT3 pathway and TB chemotherapy			10	PA18-484	No	201905	P	17	Yes
	M33AB	SALGAME, PADMINI	1 R01AI146146-01	TLR2 regulation of immunopathology in TB.			10	PA18-484	No	201905	P	17	Yes
	M33AB	JAGANNATH, CHINNASWAMY	1 R01AI146244-01	NOVEL AUTOPHAGY-INDUCING BOVINE ADENOVIRAL VACCINES FOR TUBERCULOSIS			10	PA18-484	No	201905	P	17	Yes
	M33AB	ACHKAR, JACQUELINE	1 R01AI146329-01	Characteristics and protective efficacy of human antibodies against M. tuberculosis			20	PA18-484	No	201905	P	17	Yes
	M33AB	MATTILA, JOSHUA	1 R21AI146300-01	Systems biology-based identification of neutrophil-regulated immunosuppressive mechanisms in tuberculous granulomas			10	PA18-489	No	201905	P	17	Yes
	M33AB	DUTTA, NOTON	1 R03AI146505-01	Exploring sex-based differences in response to host-directed therapy for TB			10	PA18-488	No	201905	P	17	Yes
	M33AB	BAI, GUANGCHUN	1 R21AI146617-01	A novel c-di-AMP-based recombinant BCG vaccine			10	PA18-489	No	201905	P	17	Yes
	M33AB	BARCZAK, AMY	1 R21AI146813-01	Targeting MT1-MMP to inhibit pathologic inflammation in TB			10	PA18-489	No	201905	P	17	Yes
	M33AB	IZZO, ANGELO	1 R21AI146442-01	Cytomegalovirus as a risk factor for exacerbation of Mycobacterium tuberculosis infection			10	PA18-489	No	201905	P	17	Yes
	M33AB	SHI, LANBO	1 R01AI146730-01	Modulation of host cell metabolism in tuberculosis			10	PA18-484	No	201905	P	17	Yes
	M33AB	GRAYFER, LEON	1 R01AI141466-01A1	An amphibian model of macrophage susceptibility and resistance to mycobacteria			10	PA18-484	No	201905	P	17	Yes
	M33AB	QUINN, FREDERICK	1 R01AI132632-01A1	Ferret or Guinea Pig TB Transmission and Disease Model			10	PA18-484	No	201905	P	17	Yes
	M33AB	GILMAN, ROBERT	1 R21AI142419-01A1	Investigating platelets in the innate immune response to tuberculosis			20	PA18-489	No	201905	P	17	Yes
	M33AB	TSUJI, MORIYA	1 R21AI142215-01A1	Features of group 1 CD1-restricted human T cells during M. tuberculosis infection in CD1-transgenic human immune system mice			10	PA18-489	No	201905	P	17	Yes
	M33AB	CHATTERJEE, SOUMYA	1 R21AI137533-	Study of responses to CD44 targeted			10	PA18-489	No	201905	P	17	Yes

		01A1	nanovectors to design a novel adjunctive anti-tuberculosis host-directed therapy									
M33ABR	RAJARAM, MURUGESAN	1 R21AI142430-01A1	Role of the macrophage P-glycoprotein in enhancing emergence of antibiotic resistant Mycobacterium tuberculosis		20	PA18-489	No	201905	P	17	Yes	
M33D	BISHAI, WILLIAM	1 R21AI143298-01A1	CONTRIBUTION OF RIP1 KINASE TO TUBERCULOSIS SUSCEPTIBILITY, PROGRESSION, AND IMMUNOPATHOLOGY		10	PA18-489	No	201905	P	17	Yes	
M33DB	YU, EDWARD	1 R01AI147455-01	Structural and functional characterization of the Mycobacterial MmpL3 transporter		10	PA18-484	No	201905	P	17	Yes	
M33EB	RUBINSTEIN, FERNANDO	1 R01AI147129-01	TB-TST (TB treatment support tools): Refinement and evaluation of an interactive mobile app and direct adherence monitoring on TB treatment outcomes		20	PA18-722	No	201905	P	17	Yes	
M33EB	MENZIES, NICOLAS	1 R01AI146555-01	Optimal targeting for individual and population-level TB prevention		10	PAR17-267	No	201905	P	17	Yes	
M33EB	SLOOT, ROSA	1 R03AI146903-01	Novel approaches to establish the relationship between poverty and the tuberculosis epidemic in South Africa		10	PA18-488	No	201905	P	17	Yes	
M33EB	JENKINS, HELEN	1 R21AI146493-01	Quantifying the Pediatric Tuberculosis Infection Burden in Ukraine		20	PA18-489	No	201905	P	17	Yes	
M33EB	CHAISSON, RICHARD	1 R21AI146955-01	Tuberculosis Transmission in Children and Adolescents in Tibetan Boarding Schools		E2	PA18-489	No	201905	P	17	Yes	
M33EB	GOLUB, JONATHAN	2 R01AI097494-06A1	Assessing mortality in Diabetes associated Tuberculosis		20	PA18-484	No	201905	P	17	Yes	
M33EB	MODONGO, CHAWANGWA	1 R01AI141506-01A1	A new model for TB case finding and care delivery: The same-day community-based TB care cascade		20	PAR18-007	No	201905	P	17	Yes	
M33EB	STEIN, CATHERINE	1 R21AI147294-01	Resistance to M. tuberculosis infection in Guinea-Bissau		20	PA18-489	No	201905	P	17	Yes	
M33EB	HORNE, DAVID	1 R01AI147289-01	Aerobiology, immunology, and control of community and household Mycobacterium tuberculosis transmission		20	AI18-037	No	201905	P	17	Yes	
M33EB	DOWDY, DAVID	1 R01AI147344-01	Innovative approaches to understanding and halting tuberculosis transmission in rural, semi-urban, and urban Nepal		20	AI18-037	No	201905	P	17	Yes	
M33EBR	FRANKE, MOLLY	1 R01AI146095-01	Strengthening evidence on optimal multidrug-resistant tuberculosis treatment regimens through improved epidemiologic methods		20	PA18-484	No	201905	P	17	Yes	
M33EBR	GAO, QIAN	1 R01AI147323-	Population-based genomic epidemiology		20	AI18-037	No	201905	P	17	Yes	

		01	to identify the key drivers for recent transmission of tuberculosis in rural China									
M33EBR	FARHAT, MAHA	1 R01AI147342-01	Frontiers in TB transmission: a biosocial and genetic inquiry into treatment failure and drug resistance in Pune, India		20	AI18-037	No	201905	P	17	Yes	
M33H	BREWER, WILLIAM	1 F31AI147507-01	Cyclopropanation of the mycobacterial lipid trehalose dimycolate as a driver of host angiogenesis		10	PA18-671	No	201905	P	17	Yes	
M33HB	TOMASI, FRANCESCA	1 F31AI147479-01	Functional characterization of TacAT, a novel toxin-antitoxin system in Mycobacterium tuberculosis		10	PA18-671	No	201905	P	17	Yes	
M33HB	PACL, HAYDEN	1 F30AI147473-01	Myeloid Lactate Dehydrogenase A in TB Immunity		E4	PA18-668	No	201905	P	17	Yes	
M33HB	MORGUN, EVGUENIA	1 F30AI147449-01	Efficacy and memory response of Mycobacterial lipid specific CD1-restricted T cell elicited by nanoparticle vaccine		10	PA18-668	No	201905	P	17	Yes	
M33HB	LOJEK, LISA	1 F32AI147508-01	The role of immunity in shaping Mycobacterium tuberculosis metabolism		10	PA18-670	No	201905	P	17	Yes	
M33HB	HERRERA, NADIA	1 F32AI147553-01	Investigating the role of ESX-1 in Cell-Cell communication of Mycobacterium tuberculosis		10	PA18-670	No	201905	P	17	Yes	
M33HB	LAUGHLIN, ZANE	1 F31AI143133-01A1	Mechanism of Bacterial Ribosome 30S and 50S Subunit Recognition and Modification by M. tuberculosis TlyA		10	PA18-671	No	201905	P	17	Yes	
M33HBR	LEVINE, CARLY	1 F31AI147453-01	The role of glycerol kinase in small colony variant formation and the induction of phenotypic drug tolerance in Mycobacterium tuberculosis		10	PA18-671	No	201905	P	17	Yes	
M51AB	PARSONS, ANDREA	1 F31AI147467-01	Immunogenicity of exosome-targeted influenza virus hemagglutinins using non-replicating, rare species adenoviral vectors		10	PA18-671	No	201905	P	17	Yes	
M51AB	AINSLIE, KRISTY	1 R01AI147497-01	Optimizing a Universal Influenza Subunit Nano/Microparticulate Vaccine		10	PA18-859	No	201905	P	17	Yes	
M51AB	WAN, XIUFENG	1 R01AI145299-01A1	Impact of repeated vaccination on the effectiveness of seasonal influenza vaccines		10	PA18-859	No	201905	P	17	Yes	
M51BB	BEAVER, EMILY	1 F30AI147559-01	Virulence Determinants of Potentially Zoonotic Influenza Viruses		10	PA18-673	No	201905	P	17	Yes	
M51BB	FONTOURA, BEATRIZ	1 R01AI147495-01	Virulence Factor at the Interface of Viral mRNA Nuclear Export and Host RNA Processing		10	PA18-484	No	201905	P	17	Yes	
M51C	DASZAK, PETER	2 R01AI110964-	Understanding the Risk of Bat Coronavirus		20	PA18-484	No	201905	P	17	Yes	

		06	Emergence									
M51C	RACANIELLO, VINCENT	1 R21AI142657-01A1	Ex vivo modeling of enterovirus D68 and human rhinovirus respiratory pathogenesis			48	PA18-489	No	201905	P	17	Yes
M51C B	FOXMAN, ELLEN	1 R01AI146117-01	Tradeoffs in host defense during rhinovirus infection			10	PA18-484	No	201905	P	17	Yes
M51C B	NJENGA, M	1 R01AI146144-01	Epidemiology of MERS-CoV Circulating in East Africa			20	PA18-484	No	201905	P	17	Yes
M51C B	MENACHERY, VINEET	1 R01AI146332-01	Using a novel MERS-like coronavirus to probe barriers to zoonotic emergence			10	PA18-484	No	201905	P	17	Yes
M51C B	SIMS, AMY	1 R21AI146872-01	How MERS-CoV Regulates Innate Immunity in Primary Human Lung Cells			10	PA18-489	No	201905	P	17	Yes
M51C B	GRIBBLE, JENNIFER	1 F31AI147560-01	Dissecting the role of the coronavirus proofreading exoribonuclease in RNA recombination			10	PA18-671	No	201905	P	17	Yes
M51C B	JOHNSON, BRYAN	1 F32AI143134-01A1	Microbial interference with coronavirus infection			10	PA18-670	No	201905	P	17	Yes
M51C B	CHU, HONG	1 R01AI142713-01A1	Immunoproteasome in airway defense against rhinovirus infection			10	PA18-484	No	201905	P	17	Yes
M51D	GUERRERO-PLATA, MARIA	1 R21AI147204-01	Regulation of the antiviral response by microrna expression in pneumovirus infection.			10	AI18-025	No	201905	P	17	Yes
M51D	SEVERSON, WILLIAM	1 R03AI142065-01A1	In vivo assessment of quinazolinediones for the treatment of respiratory syncytial virus			10	PA18-488	No	201905	P	17	Yes
M51D	FELT, SEBASTIEN	1 F32AI147352-01	The impact of the host innate immune pressure on the evolution of respiratory syncytial virus and its defective viral genomes			10	PA18-670	No	201905	P	17	Yes
M51D	SUN, JIE	1 R21AI147368-01	A novel model of acute and chronic pathogenesis of RSV infection in pre-term infants			10	PA18-489	No	201905	P	17	Yes
M51D	WALDSTEIN, KODY	1 F31AI147465-01	Determing the Role of RSV F Protein in Modulating Inflammasome Activation			10	PA18-671	No	201905	P	17	Yes
M51D	SLAUGHTER, KERRI	1 F31AI147459-01	Direct cell-to-cell spread of human metapneumovirus infection			10	PA18-671	No	201905	P	17	Yes
M51D	MOUSA, JARROD	1 R01AI143865-01A1	Structural and mechanistic insights into antibody neutralization of human metapneumovirus			20	PA18-484	No	201905	P	17	Yes
M51D	WAGNER, NICOLE	1 F32AI147582-01	A Targeted and Synergistic Approach Incorporating Mass Spectrometric Methods to Develop Novel Biotherapeutics Against Respiratory Syncytial Viral Proteins			10	PA18-670	No	201905	P	17	Yes
M51D B	BAO, XIAOYONG	1 R21AI147179-01	Targeting Strategy of tRNA-derived RNA Fragments			10	AI18-025	No	201905	P	17	Yes
M51D B	TRIPP, RALPH	1 R21AI147199-	Determining the functional role of			10	AI18-025	No	201905	P	17	Yes

		01	microRNAs (miRs) and transfer RNA fragments (tRFs) in normal human bronchoepithelial (NHBE) cells infected with RSV or influenza									
M51DB	TABATADZE, DAVID	1 R43AI142719-01A1	Development of Killed Whole RSV Vaccine With Preserved Antigenic Epitopes by Using Novel Inactivator Selectively Targeting Pathogens Genomic Molecules		10	PA18-574	No	201905	P	17	Yes	
M51FB	ALFENITO, MARK	1 R21AI146290-01	Generation and Testing of an Anti-M1 Epitope Therapeutic Antibody Universally Targeting Type A Influenzas		10	PA18-858	No	201905	P	17	Yes	
M51FB	HAJIPOURAN BENAM, KAMBEZ	1 R21AI146656-01	Host Activation of Influenza Viruses, and Its Modulation		10	PA18-489	No	201905	P	17	Yes	
M51FB	LIU, LIN	1 R21AI146834-01	Role of Axin 1 in Influenza Virus Infection		48	PA18-489	Yes	201905	P	17	Yes	
M51FB	LUTHRA, PRIYA	1 R21AI146441-01	PACT and Influenza A Virus: At Crossroads of Antiviral Responses and Virus Replication		10	PA18-489	No	201905	P	17	Yes	
M51FB	WILSON, IAN	1 R01AI141518-01A1	Antivirals against influenza hemagglutinin		10	PA18-484	No	201905	P	17	Yes	
M51FBR	LIAO, JIAYU	1 R01AI146847-01	Targeting Host Factors-SUMO E3 ligase for broad-spectrum: Anti-influenza viruses and drug resistant strains		10	PAR17-438	No	201905	P	17	Yes	
M51GB	POURMAND, NADER	1 R21AI146883-01	Handheld Bioelectronic Microbial Detection: The Microbe Meter		10	PA18-489	No	201905	P	17	Yes	
M51GB	STORCH, GREGORY	1 R21AI146999-01	New test for the diagnosis of acute respiratory infection that detects viruses and evaluates host gene expression in a nasal sample		20	PA18-489	Yes	201905	P	17	Yes	
M51HB	KOBIE, JAMES	1 R01AI145332-01A1	Dynamics of the protective vaccine-induced human influenza neuraminidase B cell response		20	PA18-484	No	201905	P	17	Yes	
M51IB	MCAULEY, JULIE	1 R21AI146968-01	Understanding viral and host factors that contribute to influenza disease severity		10	PA18-858	No	201905	P	17	Yes	
M51IB	JENSEN, LISELOTTE	1 R21AI147282-01	Functional roles of IL-36 regulated non-coding RNAs in innate antiviral immunity in barrier epithelial cells		10	AI18-025	No	201905	P	17	Yes	
M51IB	SANGESLAND, MAYA	1 F31AI147360-01	A genetic template for generating universally protective responses to influenza		10	PA18-671	No	201905	P	17	Yes	
M51IB	SANT, ANDREA	1 R21AI145269-01A1	Potentiating broadly protective local immunity to influenza virus		10	PA18-858	No	201905	P	17	Yes	
M51IB	SUN, REN	1 R01AI143287-01A1	Mechanism for anti-interferon functions of influenza virus		10	PA18-484	No	201905	P	17	Yes	
M51JB	ZIMMERMAN, RICHARD	1 R01AI146085-01	Informing optimal influenza vaccine policy using complementary computational		10	PA18-484	No	201905	P	17	Yes	

			modeling strategies									
M51JB	BUTLER, ANNE	1 R01AI146148-01	Evaluating Influenza Vaccine Effectiveness and Safety by Vaccine Formulation in Diverse Populations			20	PA18-484	No	201905	P	17	Yes
M51JB	SCOTCH, MATTHEW	1 R01AI142398-01A1	Phylogeography of Cocirculating Subtypes of Influenza A in the United States			X4	PA18-484	No	201905	P	17	Yes
M54B	RATNER, ADAM	1 R21AI147511-01	Genome-wide assessment of Group B Streptococcus fitness and virulence			10	PA18-489	No	201905	P	17	Yes
M54B	HARVILL, ERIC	1 R01AI140764-01A1	The combined action of antibiotics and the immune system in the treatment of respiratory infections			10	PA18-484	No	201905	P	17	Yes
M54BB	COOK, LAURA	1 R21AI147502-01	Transcriptomic and Genetic Differences of Group A Streptococcus in Humans: Acute Infection versus Carriage			20	PA18-489	No	201905	P	17	Yes
M54C	EISENMESSER, ELAN	1 R21AI144333-01A1	Identifying the molecular roles of Streptococcus Pneumoniae G5 domains in cellular adherence.			10	PA18-489	No	201905	P	17	Yes
M58A	KERSCHNER, JOSEPH	1 R21AI147607-01	Develop novel trans-tympanic drug delivery formulas to treat otitis media			10	PA18-489	No	201905	P	17	Yes
M58A	MCIVER, KEVIN	2 R01AI047928-16	PRD-containing Virulence Regulators of Pathogenic Streptococci			20	PA18-484	No	201905	P	17	Yes
M58B	CHANDERRAJ, RISHI	1 F32AI147468-01	Novel molecular indices of infection in the diagnosis of pneumonia			20	PA18-670	No	201905	P	17	Yes
M59	JASPAN, HEATHER	1 R01AI147622-01	Factors influencing Group B Streptococcus colonization in South African pregnant women			20	PA18-484	No	201905	P	17	Yes
M59B	SCHROEDER, HARRY	1 R01AI145331-01A1	Derivation and functional attributes of opsonophagocytic antibodies elicited by pneumococcal vaccination in aged individuals			20	PA18-484	No	201905	P	17	Yes

From: Ortiz, Oscar (NIH/NIAID) [E]
To: NIAID ROB
Cc: Marcus, Landon (NIH/NIAID) [E]
Subject: PMT-10 Day Review
Date: Monday, December 17, 2018 8:20:13 AM
Attachments: image001.png

PCC	PI Name	Grant #	Title	%	PS	HS	RFA/PA	Comm	Council	Dual	Stat	PCC_OK	Dia
[illegible]	SESHADRI, CHETAN	1 R01AI146072-01	[illegible]			(b)(5) [redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	VENKETARAMAN, VISHWANATH	1 R01AI146585-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	GONZALEZ-JUARRERO, MERCEDES	1 R01AI146195-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	SALGAME, PADMINI	1 R01AI146145-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	JAGANNATH, CHINNASWAMY	1 R01AI146244-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	ACHKAR, JACQUELINE	1 R01AI146329-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	MATTILA, JOSHUA	1 R21AI146909-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	DUTTA, NOTON	1 R03AI146505-01	[illegible]			[redacted]	PA18-488	No	201905	P	17	Yes	
[illegible]	BAI, GUANGCHUN	1 R21AI146617-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	BARCZAK, AMY	1 R21AI146813-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	IZZO, ANGELO	1 R21AI146642-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	SHI, LANBO	1 R01AI146730-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	GRAYFER, LEON	1 R01AI141486-01A1	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	QUINN, FREDERICK	1 R01AI132632-01A1	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	GILMAN, ROBERT	1 R21AI142419-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	TSUJI, MORIYA	1 R21AI142215-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	CHATTERJEE, SOUMYA	1 R21AI137813-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	RAJARAM, MURUGESAN	1 R21AI142430-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	MURRAY, MEGAN	1 R01AI147316-01	[illegible]			[redacted]	AI18-037	No	201905	P	17	Yes	
[illegible]	DHEDA, KEERTAN	1 R01AI147346-01	[illegible]			[redacted]	AI18-037	No	201905	P	17	Yes	
[illegible]	RHEE, KYU	1 R01AI147341-01	[illegible]			[redacted]	AI18-037	No	201905	P	17	Yes	
[illegible]	KANA, BAVESH	1 R01AI147348-01	[illegible]			[redacted]	AI18-037	No	201905	P	17	Yes	
[illegible]	RUBINSTEIN, FERNANDO	1 R01AI147129-01	[illegible]			[redacted]	PA18-723	No	201905	P	17	Yes	
[illegible]	MENZIES, NICOLAS	1 R01AI146555-01	[illegible]			[redacted]	PAR17-267	No	201905	P	17	Yes	
[illegible]	SLOOT, ROSA	1 R03AI146903-01	[illegible]			[redacted]	PA18-488	No	201905	P	17	Yes	
[illegible]	JENKINS, HELEN	1 R21AI146465-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	CHAISSON, RICHARD	1 R21AI146655-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	GOLUB, JONATHAN	2 R01AI097494-05A1	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	MODONGO, CHAWANGWA	1 R01AI141509-01A1	[illegible]			[redacted]	PAR18-007	No	201905	P	17	Yes	
[illegible]	STEIN, CATHERINE	1 R21AI147294-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	HORNE, DAVID	1 R01AI147289-01	[illegible]			[redacted]	AI18-037	No	201905	P	17	Yes	
[illegible]	DOWDY, DAVID	1 R01AI147344-01	[illegible]			[redacted]	AI18-037	No	201905	P	17	Yes	
[illegible]	FRANKE, MOLLY	1 R01AI146695-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	GAO, QIAN	1 R01AI147323-01	[illegible]			[redacted]	AI18-037	No	201905	P	17	Yes	
[illegible]	FARHAT, MAHA	1 R01AI147342-01	[illegible]			[redacted]	AI18-037	No	201905	P	17	Yes	
[illegible]	JACKSON, MARY	1 R21AI147329-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	LAMICHHANE, GYANU	1 R21AI140049-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	TUCKER, ELIZABETH	1 K08AI139371-01A1	[illegible]			[redacted]	PA18-373	No	201905	P	17	Yes	
[illegible]	DINARDO, ANDREW	1 K23AI141681-01A1	[illegible]			[redacted]	PA18-375	No	201905	P	17	Yes	
[illegible]	HUGHES, TRAVIS	1 F30AI143160-01A1	[illegible]			[redacted]	PA18-668	No	201905	P	17	Yes	
[illegible]	OLSON, GREGORY	1 F30AI142848-01A1	[illegible]			[redacted]	PA18-668	No	201905	P	17	Yes	
[illegible]	ZHENG, ALLEN	1 F30AI143243-01A1	[illegible]			[redacted]	PA18-668	No	201905	P	17	Yes	
[illegible]	BROOKE, CHRISTOPHER	1 R01AI146974-01	[illegible]			[redacted]	PA18-859	No	201905	P	17	Yes	
[illegible]	MILLER, CHRISTOPHER	1 R01AI146973-01	[illegible]			[redacted]	PA18-859	No	201905	P	17	Yes	
[illegible]	MCAULEY, JULIE	1 R21AI146968-01	[illegible]			[redacted]	PA18-858	No	201905	P	17	Yes	
[illegible]	ATIANAND, MANINJAY	1 R21AI146981-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	GAGLIARDI, TALITA	1 R03AI147126-01	[illegible]			[redacted]	PA18-488	No	201905	P	17	Yes	
[illegible]	WU, NICHOLAS	1 K99AI138465-01A1	[illegible]			[redacted]	PA18-398	No	201905	P	17	Yes	
[illegible]	ORTIGOZA, MILA	1 K08AI141759-01A1	[illegible]			[redacted]	PA18-373	No	201905	P	17	Yes	
[illegible]	PETIT, CHAD	1 R21AI147271-01	[illegible]			[redacted]	PA18-858	No	201905	P	17	Yes	
[illegible]	TE VELTHUIS, AARTJAN	1 R21AI147172-01	[illegible]			[redacted]	AI18-025	No	201905	P	17	Yes	
[illegible]	SULLIVAN, CHRISTOPHER	1 R21AI147176-01	[illegible]			[redacted]	AI18-025	No	201905	P	17	Yes	
[illegible]	TENOEVER, BENJAMIN	1 R21AI147180-01	[illegible]			[redacted]	AI18-025	No	201905	P	17	Yes	
[illegible]	WHITTAKER, GARY	1 R21AI142571-01A1	[illegible]			[redacted]	PA18-858	No	201905	P	17	Yes	
[illegible]	FORST, CHRISTIAN	1 R21AI142326-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	PARRISH, COLIN	1 R21AI142297-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	JENSEN, LISELOTTE	1 R21AI147382-01	[illegible]			[redacted]	AI18-025	No	201905	P	17	Yes	
[illegible]	LIU, JIN	1 R21AI147284-01	[illegible]			[redacted]	AI18-025	No	201905	P	17	Yes	
[illegible]	CHANG, EUGENE	1 R01AI146721-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	DASZAK, PETER	2 R01AI110964-06	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	RACANIELLO, VINCENT	1 R21AI143657-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	FOXMAN, ELLEN	1 R01AI146117-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	NJENGA, M	1 R01AI146144-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	MENACHERY, VINEET	1 R01AI146332-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	SIMS, AMY	1 R21AI146872-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	GUERRERO-PLATA, MARIA	1 R21AI147204-01	[illegible]			[redacted]	AI18-025	No	201905	P	17	Yes	
[illegible]	SEVERSON, WILLIAM	1 R03AI142665-01A1	[illegible]			[redacted]	PA18-488	No	201905	P	17	Yes	
[illegible]	FELT, SEBASTIEN	1 F32AI147350-01	[illegible]			[redacted]	PA18-670	No	201905	P	17	Yes	
[illegible]	BAO, XIAOYONG	1 R21AI147179-01	[illegible]			[redacted]	AI18-025	No	201905	P	17	Yes	
[illegible]	TRIPP, RALPH	1 R21AI147199-01	[illegible]			[redacted]	AI18-025	No	201905	P	17	Yes	
[illegible]	ALFENITO, MARK	1 R21AI146290-01	[illegible]			[redacted]	PA18-858	No	201905	P	17	Yes	
[illegible]	HAJPOURANBENAM, KAMBEZ	1 R21AI146656-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	LIU, JIN	1 R21AI146834-01	[illegible]			[redacted]	PA18-489	Yes	201905	P	17	Yes	
[illegible]	LUTHRA, PRIYA	1 R21AI146441-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	WILSON, IAN	1 R01AI141518-01A1	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	LIAO, JIAYU	1 R01AI146847-01	[illegible]			[redacted]	PAR17-436	No	201905	P	17	Yes	
[illegible]	POURMAND, NADER	1 R21AI146883-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	STORCH, GREGORY	1 R21AI146898-01	[illegible]			[redacted]	PA18-489	Yes	201905	P	17	Yes	
[illegible]	SANGESLAND, MAYA	1 F31AI147360-01	[illegible]			[redacted]	PA18-671	No	201905	P	17	Yes	
[illegible]	ZIMMERMAN, RICHARD	1 R01AI146085-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	BUTLER, ANNE	1 R01AI146146-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	QUINN, ROBERT	1 R01AI145925-01	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	CHO, DO-YEON	1 K08AI146220-01	[illegible]			[redacted]	PA18-373	No	201905	P	17	Yes	
[illegible]	GANTNER, BENJAMIN	1 R01AI139156-01A1	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	
[illegible]	MUSSER, JAMES	1 R21AI145771-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	ZOU, XIAOQIN	1 R03AI146452-01	[illegible]			[redacted]	PA18-488	No	201905	P	17	Yes	
[illegible]	SWORDS, WILLIAM	1 R21AI146905-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	KOROTKOVA, NATALIA	1 R21AI146945-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	CHO, KYU HONG	1 R15AI140204-01A1	DISSECTING THE ROLE OF THE SECOND MESSENGER c-di-AMP IN THE GROWTH AND VIRULENCE OF [illegible]			[redacted]	PA18-504	No	201905	P	17	Yes	
[illegible]	SCANLON, KAREN	1 R21AI140032-01A1	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	CHAUSSEE, MICHAEL	1 R03AI142535-01A1	[illegible]			[redacted]	PA18-488	No	201905	P	17	Yes	
[illegible]	HARVILL, ERIC	1 R21AI147356-01	BACTERIAL AND HOST FACTORS IN OTITIS MEDIA			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	BESSEN, DEBRA	1 R21AI146370-01	[illegible]			[redacted]	PA18-489	No	201905	P	17	Yes	
[illegible]	MOE, GREGORY	2 R01AI046464-18	[illegible]			[redacted]	PA18-484	No	201905	P	17	Yes	

PCC	PI Name	Grant #	Title	%	PS	HS	RFA/PA	Comm	Council	Dual	Stat	PCC_OK	Dig
[illegible]	GONZALEZ, DAVID	1 R01AI141869-01A1	[illegible]			[redacted] (b)(5)	PA18-484	No	201905	P	17	Yes	
[illegible]	HUGHES, KELLY	1 R01AI146570-01	Antibacterial agents from pathogenic [illegible]				PA18-484	No	201905	P	17	Yes	
[illegible]	HARHILL, ERIC	1 R21AI147355-01	[illegible]				PA18-489	No	201905	P	17	Yes	
[illegible]	STONE, VICTORIA	1 R01AI141511-01A1	[illegible]				PAR17-438	No	201905	P	17	Yes	
[illegible]	BARBIER, MARIETTE	1 R01AI141671-01A1	Vaccine Development Against Bacterial Pathogens Based on [illegible]				PA18-484	No	201905	P	17	Yes	
[illegible]	ROTHSTEIN, THOMAS	1 R01AI148251-01	[illegible]				PA18-484	No	201905	P	17	Yes	

1 2

Sort

PCC	PI Name	Grant #	Title	%	PS	HS	RFA/PA	Comm	Council	Dual	Stat	PCC_OK	Dig
MSS	CAMPO, JOSEPH	1 R21AI146628-01	Paraproteome-wide characterization of the antibody response to live genetically attenuated Streptococcus pneumoniae immunization			[redacted] (b)(5)	PA18-344	No	201905	P	17	Yes	
MSS	YEAGER, MICHAEL	1 R01AI141662-01A1	Persistent Post-Viral State of Bacterial Pneumonia Susceptibility and Severity in Down Syndrome				PA18-484	No	201905	P	17	Yes	

1 2

From: Aleksei Chmura
To: Graham, Adam (NIH/OD) [E]
Cc: Stemmy, Erik (NIH/NIAID) [E]; 李泓萤; Dr. Peter Daszak
Subject: IRB Question from Grant Number: 5R01AI110964 - 05 PI Name: DASZAK , PETER
Date: Wednesday, October 3, 2018 9:47:25 AM
Attachments: image001.png
R01AI110964 - Daszak 6-25-18.pdf

Dear Adam,

We have an online, anonymous survey we would like to conduct with individuals at the wildlife-domestic animal interface in southern China under our award. We are teasing out the different risk and motivating factors for Coronavirus and bat exposure as per our specific aim 2 in our proposal. The IRB of our Chinese/local partner the Wuhan School of Public Health has reviewed our proposed study and approved it. Both the Wuhan School of Public Health and EcoHealth Alliance (our institution) have active FWAs. This proposed online, anonymous survey is not part of our current, approved IRB protocol under our award.

Our understanding is that we will also need USA IRB approval (as we have had with all our other human research) and that having a China-only IRB approval will not be sufficient for our proposed online survey. We wanted to confirm with you before proceeding with a new US IRB approval. This will affect our participant enrollment numbers too. How would we proceed with this - just forward to you our US and China IRB approval notifications or is this done via Research.gov? If it will be easier, both Hongying Li and I are available for a phone call anytime tomorrow or Friday.

Many thanks,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff

EcoHealth Alliance
460 West 34th Street
Ste. 1701
New York, NY 10001

(b) (6) (direct)
(b) (6) (mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

Begin forwarded message:

From: "Graham, Adam (NIH/NIAID) [E]" (b) (6)

Subject: Grant Number: 5R01AI110964 - 05 PI Name: DASZAK , PETER
Date: July 5, 2018 at 15:25:16 EDT
To: (b) (6), "Stemmy, Erik (NIH/NIAID) [E]" (b) (6), (b) (6)
Cc: "Linde, Emily (NIH/NIAID) [E]" (b) (6), "Glowinski, Irene (NIH/NIAID) [E]" (b) (6), "Erbelding, Emily (NIH/NIAID) [E]" (b) (6), "Ford, Andrew (NIH/NIAID) [E]" (b) (6), "Khurana, Dhana (NIH/NIAID) [E]" (b) (6)

Good afternoon,
Attached is a letter notifying you that the GoF Research Funding Pause has been lifted via the HHS P3CO Framework and that the GoF term-of-award was removed when the next last Type 5 notice-of-award was issued.
Please let us know if you have any questions.

Adam Graham
Grants Management Specialist
DHHS, NIH, NIAID, GMP
Room 4E40, MSC 9833
5601 Fishers Lane
Bethesda, MD 20892
(b) (6)
(b) (6)

***Effective January 1, 2017**, NIH closeout policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.*

National Institute of Allergy and Infectious Diseases

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 05, 2018

Mr. Aleksei Chmura
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-05

Dear Mr. Chmura:

On December 19, 2017, the U.S. Department of Health and Human Services (DHHS) issued the *Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) (https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf). The HHS P3CO Framework is responsive to and in accordance with the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (Recommended Policy Guidance) (https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf) issued by the White House Office of Science and Technology Policy on January 9, 2017. Additionally, and as noted in the Recommended Policy Guidance, adoption of the HHS P3CO Framework satisfies the requirement for lifting the Research Funding Pause on certain gain-of-function (GoF) research.

The HHS P3CO Framework guides DHHS funding decisions on research that is reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (PPPs). A PPP is a pathogen that satisfies both of the following:

- It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and
- It is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

In accordance with the HHS P3CO Framework, research involving an enhanced PPP is subject to additional HHS department-level review. NIAID re-reviewed the grant application and other information provided by you, and made the following assessment:

> The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO Framework. The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and

Grants Management Specialist immediately and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

Please remember that the institution must comply in full with all terms and conditions placed on this grant.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Adam Graham
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Emily Linde
Dr. Emily Erbelding
Dr. Irene Glowinski
Dr. Andrew Ford

National Institute of Allergy and Infectious Diseases

From: Ford, Andrew (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Strickler-Dinglasan, Patricia (NIH/NIAID) [C]; Ford, Andrew (NIH/NIAID) [E]
Subject: FW: 5R01AI110964-05 GoF-P3CO Replacement Term
Date: Thursday, June 21, 2018 2:45:30 PM
Attachments: R01AI110964 - Daszak.docx

Hey Erik,
Have you had a chance to review the attached letter? If so, do you have any edits that need to be incorporated?
Thanks,
Andrew

From: Ford, Andrew (NIH/NIAID) [E]
Sent: Thursday, June 14, 2018 9:12 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Khurana, Dhana (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6); Strickler-Dinglasan, Patricia (NIH/NIAID) [C] (b) (6)
Subject: 5R01AI110964-05 GoF-P3CO Replacement Term
Dear Erik and Dhana,
Attached is a draft letter to the EcoHealth Alliance noting that NIAID re-reviewed the proposed research in accordance with the HHS P3CO Framework and revised the terms and conditions of the award to reflect that should certain growth parameters be met, the NIAID Program Officer and Grants Management Specialist are to be notified immediately and that further research may require review by DHHS in accordance with the HHS P3CO Framework.
Approximately 99% of the letter is the same as the other letters that were sent upon release of the HHS P3CO Framework in December. However, could you please review the language noted by comment boxes:

- Erik – that the science is accurately portrayed. I adapted the letter to Li, therefore, your signature already appears in the letter.
- Dhana – that the reference to the revised term is accurate/acceptable. Please note, the (b) (5)

After your review we can proceed to have the letter signed and sent.
I would be happy to discuss any questions.
Thanks,
Andrew

Andrew Q. Ford, Ph.D.
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane Room 7G64
Rockville, MD 20892
(b) (6)
(b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

(b) (5)

[redacted]

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 7, 2018 6:01:55 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI089728-08	Li	2018-06-01	2018-04-13	Y	35	Encarnacao
R01AI110964-05	DASZAK	2018-06-01	2018-04-13	Y	35	Graham
K99AI123498-02	Kirchdoerfer	2018-07-01	2018-05-02	Y	35	Kindbom
R01AI085089-09	Baker	2018-07-01	Not Recvd	N	35	Madoo

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 30, 2018 6:01:13 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI089728-08	Li	2018-06-01	2018-04-13	Y	35	Encarnacao
R01AI110964-05	DASZAK	2018-06-01	2018-04-13	Y	35	Graham

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 23, 2018 6:01:35 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-05	DASZAK	2018-06-01	2018-04-13	Y	35	Graham
R01AI089728-08	Li	2018-06-01	2018-04-13	Y	35	Encarnacao

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 16, 2018 6:01:33 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-05	DASZAK	2018-06-01	2018-04-13	Y	35	Graham
R01AI089728-08	Li	2018-06-01	2018-04-13	Y	35	Encarnacao

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]; Graham, Adam (NIH/OD) [E]; NIAID GM I2 Notifications
Subject: eRA Commons: RPPR for Grant R01AI110964-05 Received by Agency
Date: Friday, April 13, 2018 5:55:36 PM

RPPR for grant R01AI110964-05 associated with Program Director/Principal Investigator PETER DASZAK has been received electronically through the eRA Commons. You may view the progress report through one of the IMPAC II modules by going to the Grant Folder and selecting the e-Application.

Program Class Code:	M51C
Program Officer:	Stemmy, Erik J.
Grants Management Specialist:	Graham, Adam

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact. Please access Commons at http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 9, 2018 6:02:31 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

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Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI114657-04	Makino	2018-05-01	2018-02-23	Y	35	Briggs
R01AI089728-08	Li	2018-06-01	Not Recvd	N	35	Encarnacao
R01AI110964-05	DASZAK	2018-06-01	Not Recvd	N	35	Graham

From: Folkers, Greg (NIH/NIAID) [E]
Subject: NIAID: New coronavirus emerges from bats in China, devastates young swine http://bit.ly/2Gz4dZM
Date: Wednesday, April 4, 2018 6:08:34 PM

: 4-Apr-2018

New coronavirus emerges from bats in China, devastates young swine

Identified in same region, from same bats, as SARS coronavirus
NIH/National Institute of Allergy and Infectious Diseases

IMAGE: This is a horseshoe bat. view more
Credit: EcoHealth Alliance

WHAT:

A newly identified coronavirus that killed nearly 25,000 piglets in 2016-17 in China emerged from horseshoe bats near the origin of the severe acute respiratory syndrome coronavirus (SARS-CoV), which emerged in 2002 in the same bat species. The new virus is named swine acute diarrhea syndrome coronavirus (SADS-CoV). It does not appear to infect people, unlike SARS-CoV which infected more than 8,000 people and killed 774. No SARS-CoV cases have been identified since 2004. The study investigators identified SADS-CoV on four pig farms in China's Guangdong Province. The work was a collaboration among scientists from EcoHealth Alliance, Duke-NUS Medical School, Wuhan Institute of Virology and other organizations, and was funded by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health. The research is published in the journal *Nature*.

The researchers say the finding is an important reminder that identifying new viruses in animals and quickly determining their potential to infect people is a key way to reduce global health threats. SADS-CoV began killing piglets on a farm near Foshan in Guangdong Province in late October 2016. Investigators initially suspected porcine epidemic diarrhea virus (PEDV) as the cause. PEDV is a type

of coronavirus common to swine that had been identified at the Foshan farm. Detection of PEDV ceased by mid-January 2017, yet piglets continued to die, suggesting a different cause. Scientists say separating sick sows and piglets from the rest of the herd helped stop the outbreak of SADS-CoV by May 2017.

Investigators confirmed the connection of SADS-CoV to bats by identifying the new virus in the small intestine of piglets from the outbreak. They then determined that the genetic sequence of SADS-CoV is similar to that of a bat coronavirus discovered in 2007 and looked for evidence of SADS-CoV in bat specimens collected from 2013 to 2016 in Guangdong Province. The new virus appeared in 71 of 596 specimens (11.9 percent).

The researchers also tested 35 farm workers who had close contact with sick pigs, none of whom tested positive for SADS-CoV.

Currently six coronaviruses are known to cause disease in people, but so far only two of them--SARS-CoV and Middle East Respiratory Syndrome coronavirus--have caused large outbreaks of fatal illness in people.

###

This research was supported by NIAID award R01AI110964.

ARTICLE:

P Zhou, *et al*. Fatal swine acute diarrhea syndrome caused by an HKU2-related coronavirus of bat origin. *Nature*. DOI: 10.1038/s41586-018-0010-9 (2018).

WHO:

NIAID's Erik Stemmy, Ph.D., Human Coronavirus Research Program Officer, is available for comment.

CONTACT:

To schedule interviews, please contact Ken Pekoc, (b) (6).

NIAID conducts and supports research--at NIH, throughout the United States, and worldwide--to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID website.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit http://www.nih.gov/.

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Media Contact

Ken Pekoc
(b) (6)
(b) (6)

@NIAIDNews
http://www.niaid.nih.gov

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 2, 2018 6:02:43 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

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R01AI089728-08	Li	2018-06-01	Not Recvd	N	35	Encarnacao
R01AI110964-05	DASZAK	2018-06-01	Not Recvd	N	35	Graham

From: Pekoc, Ken (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Coleman, Amanda (NIH/NIAID) [C]; NIAID BUGS
Subject: (April 4) RE: SADS-CoV for review / NIAID news item (Nature)
Date: Thursday, March 29, 2018 2:14:29 PM
Attachments: 2018 Nature Daszak new CoV MA6.docx

FYI, just learned from Peter and *Nature* that the study will be posted online April 4, 1 p.m. Eastern. Our news release is at HHS being reviewed, so we should be fine on timing.
Most recent version is attached.

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thursday, March 01, 2018 5:28 AM
To: Peter Daszak (b) (6); Pekoc, Ken (NIH/NIAID) [E] (b) (6)
Cc: Aleksei Chmura (b) (6); Coleman, Amanda (NIH/NIAID) [C] (b) (6); Anthony Ramos (b) (6); Robert Kessler (b) (6); Hongying Li (b) (6)
Subject: RE: SADS-CoV for review / NIAID news item (Nature)

Thanks Peter! (b) (5). Looking forward to the final publication of the paper.
Erik

From: Peter Daszak (b) (6)
Sent: Wednesday, February 28, 2018 3:11 PM
To: Pekoc, Ken (NIH/NIAID) [E] (b) (6)
Cc: Aleksei Chmura (b) (6); Coleman, Amanda (NIH/NIAID) [C] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Anthony Ramos (b) (6); Robert Kessler (b) (6); Hongying Li (b) (6)
Subject: RE: SADS-CoV for review / NIAID news item (Nature)
Importance: High

Hi Ken,
I've attached the draft with some edits on there. Great draft and I've only made a few suggested edits. (b) (5) I've suggested some alternative language...
We'll let you know as soon as we hear from Nature about the publication date and embargo details...
Cheers,
Peter

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www.ecohealthalliance.org

@PeterDaszak
@EcoHealthNYC
EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

From: Peter Daszak
Sent: Wednesday, February 28, 2018 2:11 PM
To: 'Pekoc, Ken (NIH/NIAID) [E]'
Cc: Aleksei Chmura; 'Coleman, Amanda (NIH/NIAID) [C]'; 'Stemmy, Erik (NIH/NIAID) [E]'; Anthony Ramos; Robert Kessler (b) (6); Hongying Li
Subject: RE: SADS-CoV for review / NIAID news item (Nature)
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That means that we're probably 2-4 weeks away from publication (March 15th, 22nd or 29th issue probably). The next step will be them sending round edited text for our final corrections, and then probably 2 weeks after that for a publication date.

I've got your text for press and we'll get that back with any corrections/edits etc. within a couple of days from now.

We're planning a coordinated press release among EHA-Duke NUS-Wuhan Institute of Virology and probably other orgs involved in the study (in China). We're the only US or Western organization. I'm a corresponding author so that should help ensure that journalists come to me as well as the other (4!) corresponding authors who are in Singapore and China. I also expect Nature will do a short piece on the paper when they send round their weekly briefer to journalists and my experience is that this will generate a lot of the publicity.

I'm cc'ing our Communications Director, Anthony Ramos, and his staff member Robert Kessler. We'll probably pitch the story to a couple of journalists at high quality US outlets who have done work with us before so we can get some high profile publicity. We'll keep you informed about how this goes, of course.

Look forward to working with you all on this and to coordinating our efforts to get good coverage on this paper!

Cheers,

Peter

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wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

From: Pekoc, Ken (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, February 6, 2018 5:27 PM
To: Peter Daszak
Cc: Aleksei Chmura; Coleman, Amanda (NIH/NIAID) [C]
Subject: SADS-CoV for review / NIAID news item (Nature)

Greetings Dr. Daszak from NIAID's Rocky Mountain Laboratories.
I have drafted a news release for your upcoming study in Nature regarding the identification of SADS-CoV. If you could review the draft for scientific accuracy, then I'll route it to our communications staff for adherence to NIAID style.
If you have any information on the publication date, that would be helpful as well.
… recall that we had communicated briefly in fall 2012 when you were scheduled for a talk at our facility via Vincent Munster … but a storm and flooding in NYC waylaid your travel plans.
Best,

Ken Pekoc
Public Affairs Officer
Rocky Mountain Laboratories
NIAID Office of Communications and Government Relations
(b) (6)

DRAFT

FOR IMMEDIATE RELEASE
Wednesday, April 4, 2018
1 p.m. Eastern Time

New Coronavirus Emerges from Bats in China, Devastates Young Swine
Identified in Same Region, from Same Bats, as SARS Coronavirus

WHAT:
A newly identified coronavirus that killed nearly 25,000 piglets in 2016-17 in China emerged from horseshoe bats near the origin of the severe acute respiratory syndrome coronavirus (SARS-CoV), which emerged in 2002 in the same bat species. The new virus is named swine acute diarrhea syndrome coronavirus (SADS-CoV). It does not appear to infect people, unlike SARS-CoV which infected more than 8,000 people and killed 774. No SARS-CoV cases have been identified since 2004. The study investigators identified SADS-CoV on four pig farms in China's Guangdong Province. The work was a collaboration among scientists from EcoHealth Alliance, Duke-NUS Medical School, Wuhan Institute of Virology and other organizations, and was funded by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health. The research is published in the journal *Nature*.

The researchers say the finding is an important reminder that identifying new viruses in animals and quickly determining their potential to infect people is a key way to reduce global health threats.

SADS-CoV began killing piglets on a farm near Foshan in Guangdong Province in late October 2016. Investigators initially suspected porcine epidemic diarrhea virus (PEDV) as the cause. PEDV is a type of coronavirus common to swine that had been identified at the Foshan farm. Detection of PEDV ceased by mid-January 2017, yet piglets continued to die, suggesting a different cause. Scientists say separating sick sows and piglets from the rest of the herd helped stop the outbreak of SADS-CoV by May 2017.

Investigators confirmed the connection of SADS-CoV to bats by identifying the new virus in the small intestine of piglets from the outbreak. They then determined that the genetic sequence of SADS-CoV is similar to that of a bat coronavirus discovered in 2007 and looked for evidence of SADS-CoV in bat specimens collected from 2013 to 2016 in Guangdong Province. The new virus appeared in 71 of 596 specimens (11.9 percent).

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Currently six coronaviruses are known to cause disease in people, but so far only two of them – SARS-CoV and Middle East Respiratory Syndrome coronavirus – have caused large outbreaks of fatal illness in people.

ARTICLE:

P Zhou, *et al*. Fatal Swine Acute Diarrhea Syndrome caused by an HKU2-related Coronavirus of Bat Origin. *Nature*. DOI: 10.1038/s41586-018-0010-9 (2018).

WHO:
NIAID's Erik Stemmy, Ph.D., Human Coronavirus Research Program Officer, is available for comment.

CONTACT:
To schedule interviews, please contact Ken Pekoc, (b) (6)

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About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit http://www.nih.gov/.

###

NIH...Turning Discovery Into Health®

Horseshoe bat (EcoHealth Alliance)

Researchers preparing to locate bats in a Chinese cave. (EcoHealth Alliance)

From:	Peter Daszak
To:	Pekoc, Ken (NIH/NIAID) [E]
Cc:	Aleksei Chmura; Coleman, Amanda (NIH/NIAID) [C]; Stemmy, Erik (NIH/NIAID) [E]; Anthony Ramos; Robert Kessler; Hongying Li
Subject:	RE: SADS-CoV for review / NIAID news item (Nature)
Date:	Wednesday, February 28, 2018 3:12:12 PM
Attachments:	2018 Nature Daszak new CoV MA1 NIAID PD edits.docx

Hi Ken,

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EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

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Cc: Aleksei Chmura; 'Coleman, Amanda (NIH/NIAID) [C]'; 'Stemmy, Erik (NIH/NIAID) [E]'; Anthony Ramos; Robert Kessler [redacted] (b) (6); Hongying Li
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… recall that we had communicated briefly in fall 2012 when you were scheduled for a talk at our facility via Vincent Munster … but a storm and flooding in NYC waylaid your travel plans.

Best,

Ken Pekoc
Public Affairs Officer
Rocky Mountain Laboratories
NIAID Office of Communications and Government Relations
(b) (6)

Please note that I am not a spokesperson for NIAID.

statements made that are the sender's own and not expressly made on behalf of NIAID by one of its representatives.

DRAFT
FOR IMMEDIATE RELEASE
Day, XXXXXX, 2018
XXXX Eastern Time

(b) (5)

[redacted]

From: Peter Daszak
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Hongying Li; Aleksei Chmura; Alison Andre; Anthony Ramos
Subject: Update - A new bat-origin coronavirus emerging in pigs in China discovered under our NIAID R01
Date: Wednesday, January 24, 2018 1:31:05 PM
Attachments: Nature-2017-05-06890-Main text-180117.docx
Figure 1-180117-120mm.pdf
Figure 3-180117-89mm.pdf
Figure 2-180117-183mm.pdf

Great news Erik – the paper has now been accepted in principle by Nature.
I've attached a copy of the final version here. Nature will likely edit it, and may have other changes before final acceptance, but things usually move fairly quickly at this point so I want you to be aware ahead of time.
EcoHealth Alliance will be putting out a press release in the USA in conjunction with our Chinese partners. I've cc'd our head of communications, Anthony Ramos, who will keep you in the loop on what we're drafting. Nature will also probably put out a release, but because I'm corresponding author, we should get direct publicity from that.
I'll share our draft press release with you so that you can coordinate with your colleagues at NIAID. I'll also let Tony Fauci know, cc'ing you of course Erik.
Cheers,
Peter

Peter Daszak
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From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, November 9, 2017 4:50 PM
To: Peter Daszak
Subject: Automatic reply: Confidential - A new bat-origin coronavirus emerging in pigs in China discovered under our NIAID R01
Thanks for your message. I am out of the office on international travel from November 3rd through the 9th. November 10th is a Federal Holiday. I expect to have limited access to email during this time. If you need urgent assistance, please contact Sonnie Kim (b) (6) Thank you.

Title: **Fatal Swine Acute Diarrhea Syndrome caused by an HKU2-related Coronavirus of Bat Origin**

Authors: Peng Zhou[1]*, Hang Fan[2]*, Tian Lan[3]*, Xing-Lou Yang[1], Wei-Feng Shi[4], Wei Zhang[1], Yan Zhu[1], Ya-Wei Zhang[2], Qing-Mei Xie[3], Shailendra Mani[5], Xiao-Shuang Zheng[1], Bei Li[1], Jin-Man Li[2], Hua Guo[1], Guang-Qian Pei[2], Xiao-Ping An[2], Jun-Wei Chen[3], Ling Zhou[3], Kai-Jie Mai[3], Zi-Xian Wu[3], Di Li[3], Danielle E. Anderson[5], Li-Biao Zhang[6], Shi-Yue Li[7], Zhi-Qiang Mi[2], Tong-Tong He[2], Feng Cong[8], Peng-Ju Guo[8], Ren Huang[8], Yun Luo[1], Xiang-Ling Liu[1], Jing Chen[1], Yong Huang[2], Qiang Sun[2], Xiang-Li-Lan Zhang[2], Yuan-Yuan Wang[2], Shao-Zhen Xing[2], Yan-Shan Chen[3], Yuan Sun[3], Juan Li[4], Peter Daszak[9]†, Lin-Fa Wang[5]†, Zheng-Li Shi[1]†, Yi-Gang Tong[2,10]†, Jing-Yun Ma[3]†

Affiliations:

[1]CAS Key Laboratory of Special Pathogens and Biosafety, Wuhan Institute of Virology, Chinese Academy of Sciences, Wuhan 430071, China

[2]Beijing Institute of Microbiology and Epidemiology, No. 20 Dongda Street, Fengtai District, Beijing 100071, China

[3]College of Animal Science, South China Agricultural University & Key Laboratory of Animal Health Aquaculture and Environmental Control, Guangdong, Guangzhou 510642, China

[4]Shandong Universities Key Laboratory of Etiology and Epidemiology of Emerging Infectious Diseases, Taishan Medical College, Taian 271000, China

[5]Programme in Emerging Infectious Diseases, Duke-NUS Medical School, Singapore 169857, Singapore

[6]Guangdong Key Laboratory of Animal Conservation and Resource Utilization, Guangdong Public Laboratory of Wild Animal Conservation and Utilization, Guangdong Institute of Applied Biological Resources, Guangzhou 510260, China

[7]School of Public Health, Wuhan University, 430072, China

[8]Guangdong Key Laboratory of Laboratory Animals, Guangdong Laboratory Animals Monitoring Institute, Guangzhou 510640, China

[9]EcoHealth Alliance, New York, USA

[10]School of Life Sciences, North China University of Science and Technology, Tangshan, Hebei 063000, China

*These authors contributed equally to this work

†To whom correspondence should be addressed: daszak@ecohealthalliance.org; linfa.wang@duke-nus.edu.sg; tong.yigang@gmail.com; majy2400@scau.edu.cn; zlshi@wh.iov.cn

Cross-species transmission of viruses from wildlife animal reservoirs poses a significant threat to human and animal health. Bats have been recognized as one of the most important reservoirs for emerging viruses and the jump of a bat-origin coronavirus into humans via intermediate hosts was responsible for the high-impact emerging zoonosis, severe acute respiratory syndrome (SARS). Here, we report virological, epidemiological, evolutionary and experimental infection evidence that a novel HKU2-related bat coronavirus, Swine Acute Diarrhea Syndrome coronavirus (SADS-CoV), is the etiological agent responsible for a large scale outbreak of fatal disease in pigs in China that caused the death of 24,693 piglets across four farms. Significantly, the outbreak began in Guangdong Province in the vicinity of the origin of the SARS pandemic. Furthermore, we identified SADS-related CoVs with 96-98% sequence identity in 11.9% (71/596) of anal swabs collected from bats in Guangdong Province during 2013-16, predominantly in *Rhinolophus* spp. horseshoe bats that are known reservoirs of SARS-related CoVs. Our results demonstrated striking similarities between the SADS and SARS outbreaks in geographic, temporal, ecological and etiological settings. This study highlights the importance in identifying coronavirus diversity and distribution in bats to mitigate future outbreaks that threaten livestock, public health and economic growth.

The emergence of severe acute respiratory syndrome (SARS) in southern China in 2002, which was caused by a previously unknown coronavirus (SARS-CoV)[1-5] and led to more than 8,000 human infections and 774 deaths

[http://www.who.int/csr/sars/en/], heralded two new frontiers in emerging infectious diseases. Firstly, it demonstrated that coronaviruses are capable of causing fatal diseases in humans. Secondly, the identification of bats as the reservoir for SARS-related coronaviruses, and likely origin of SARS-CoV[6-8] firmly established bats as an important source of highly lethal zoonotic viruses that include Hendra, Nipah, Ebola and Marburg viruses[9].

Here we report a series of fatal swine disease outbreaks in Guangdong Province, China, approximately 100 km from the location of the purported index case of SARS. Most strikingly, we found that the causative agent of this swine acute diarrhea syndrome (SADS) is a novel HKU2-related coronavirus 98.48% identical in genome sequence to a bat coronavirus we detected in 2016 from a bat cave in the vicinity of the index pig farm. This new virus (SADS-CoV) originated from the same genus of horseshoe bats (*Rhinolophus*) as SARS-CoV.

From 28 October 2016, fatal swine disease outbreaks were observed in a pig farm in Qingyuan, Guangdong Province, China, very close to the location of the first known index case of SARS which occurred in 2002 in Foshan (Extended Data Fig. 1a). Porcine epidemic diarrhea virus (PEDV, a coronavirus) had caused prior outbreaks at this farm, and was detected in the intestine of deceased piglets at the start of the outbreak. However, PEDV could no longer be detected in deceased piglets after 12th January 2017, despite accelerating mortality (Fig. 1a) and extensive testing for other common swine viruses yielded negative results (Extended Data Table 1). These findings suggested an outbreak of a novel disease. Clinical signs are similar to those

caused by other known swine enteric coronaviruses[10,11] and include severe and acute diarrhea, and acute vomiting, leading to death due to rapid weight loss in newborn piglets less than five days of age. Infected piglets died 2-6 days following disease onset, while infected sows suffered only mild diarrhea and most recovered in two days. The disease caused no signs of febrile illness in piglets or sows. The mortality rate reached as high as 90% for piglets five days or younger, while for piglets older than eight days the mortality dropped to 5%. Subsequently, SADS-related outbreaks were found in three additional pig farms within 20-150 km of the index farm (Extended Data Fig. 1a) and, by 2nd May 2017, had resulted in the death of 24,693 piglets from four farms (Fig. 1a). In Farm A alone, 64% (4,659/7,268) of all piglets born in February died. The outbreak has abated, and measures taken to control SADS have included separation of sick sows and piglets from the rest of the herd. A qPCR test described below was used as the main diagnostic tool to confirm SADS-CoV infection.

A sample collected from the small intestine of a diseased piglet was subjected to metagenomics analysis by next generation sequencing (NGS) to identify potential etiologic agents. Of the 15,256,565 total reads obtained, 4,225 matched sequences of the bat CoV HKU2, which was first detected in Chinese horseshoe bats in Hong Kong and Guangdong Province, China[12]. By *de novo* assembly and targeted PCR we obtained a 27,173-bp CoV genome that shared 95% sequence identity to HKU2-CoV (Genbank accession number NC009988.1). Thirty-three full genome sequences of SADS-CoV were subsequently obtained (8 from farm A, 5 farm B, 11 farm C and 9

105 farm D), and they are 99.9% identical to each other (Supplementary Information
106 Table 1).

107 Using qPCR targeting the nucleocapsid gene (Supplementary Information
108 Table 2), we detected SADS-CoV in acutely sick piglets and sows, but not in
109 recovered or healthy pigs on the four farms, nor in nearby farms that showed no
110 evidence of SADS. The virus replicated to higher titers in piglets than in sows (Fig.
111 1b). SADS-CoV displayed tissue tropism for small intestine (Fig.1c), as observed for
112 other swine enteric coronaviruses[13]. Retrospective PCR analysis revealed that SADS-
113 CoV was present on Farm A during the PEDV epidemic, where the first strongly
114 positive SADS-CoV sample was detected on 6 December 2016. From mid-January
115 onwards, SADS-CoV was the dominant viral agent detected in diseased animals
116 (Extended Data Fig.1b). It is possible that the presence of PEDV early in the SADS-
117 CoV outbreak may have somehow facilitated or enhanced spillover and amplification
118 of SADS. However the fact that the vast majority of piglet mortality occurred after
119 PEDV infection had become undetectable suggests that SADS-CoV itself causes a
120 lethal infection in pigs that was responsible for these large-scale outbreaks, and that
121 PEDV does not directly contribute to its severity in individual pigs. This was
122 supported by the absence of PEDV and other known swine diarrhea viruses during the
123 peak and later phases of the SADS outbreaks in the four farms (Extended Data Table
124 1).

125 We rapidly developed an antibody assay based on the S1 domain of the spike
126 (S) protein using the Luciferase Immunoprecipitation System (LIPS)[14]. As SADS is

127 acute with rapid onset in piglets, serological investigation was conducted only in
128 sows. Among 46 recovered sows tested, 12 were seropositive for SADS-CoV within
129 three weeks of infection (Fig. 1d). To investigate possible zoonotic transmission,
130 serum samples from 35 farm workers who had close contact with sick pigs were
131 subjected to the same LIPS test and none were positive for SADS-CoV.

132 While the overall genome identity of SADS-CoV and HKU2-CoV is 95%, the
133 S gene sequence identity is only 86%, suggesting that previously reported HKU2-
134 CoV is not the direct progenitor of SADS-CoV, but that they may have originated
135 from a common ancestor. To test the hypothesis, we developed a SADS-CoV specific
136 qPCR assay based on its RNA dependent RNA polymerase (RdRp) gene
137 (Supplementary Information Table 2) and screened 596 bat anal swabs collected
138 during 2013-2016 from seven different locations in Guangdong Province (Extended
139 Data Fig. 1a). A total of 71 samples (11.9%) tested positive (Extended Data Table 2),
140 the majority (94.3%) were from *Rhinolophus* spp. bats which are also the natural
141 reservoir hosts of SARS-related coronaviruses[6-8, 15-18]. Four complete genome
142 sequences with the highest RdRp PCR fragment sequence identity to that of SADS-
143 CoV were determined by NGS. They are very similar in size (27.2 kb) to SADS-CoV
144 (Fig. 2a) and we tentatively nominate them SADS related coronaviruses (SADSr-
145 CoV). Overall sequence identity between SADSr-CoV and SADS-CoV ranges from
146 96-98%. Most importantly, the S protein of SADS-CoV shared more than 98%
147 sequence identity with those of the two SADSr-CoVs (162149 and 141388),
148 compared to 86% with HKU2-CoV. The major sequence differences among the four

149 SADSr-CoV genomes lie in the predicted coding regions of the S and NS7a and NS7b
150 genes (Fig. 2a). In addition, the coding region of the S protein N-terminal (S1) domain
151 was determined from 19 bat SADSr-CoVs to aid more detailed phylogenetic analysis.
152 The phylogeny of S1 and full-length genome revealed a high genetic diversity
153 of alpha coronaviruses among bats and strong coevolutionary relationships to their
154 hosts (Fig. 2b and Extended Data Fig. 2), with SADS-CoVs more closely related to
155 SADSr-CoVs from *Rhinolophus affinis* than from *Rhinolophus sinicus* in which
156 HKU2-CoV was found. Both phylogenetic and haplotype network analyses
157 demonstrated that viruses from the four farms likely originated from their reservoir
158 hosts independently (Extended Data Fig. 3), and a few viruses might have undergone
159 further genetic recombination (Extended Data Fig. 4). However, molecular clock
160 analysis of the 33 SADS-CoV genome sequences failed to establish a positive
161 association between sequence divergence and sampling date. Therefore, we speculate
162 that either the virus was introduced into pigs from bats multiple times, or the virus
163 was introduced into pigs once, but subsequent genetic recombination disturbed the
164 molecular clock.
165 For viral isolation, we tried to culture the virus in a variety of cell lines (see
166 Methods for detail) using intestinal tissue homogenate as starting material.
167 Cytopathic effect was observed in Vero cells only after five passages (Extended Data
168 Fig. 5a &b). The identity of SADS-CoV was verified in Vero cells by
169 immunofluorescent staining (Extended Data Fig. 5c & d) and by whole genome

sequencing (GenBank accession number MG557844). Similar results were obtained by other groups[19, 20].

Known coronavirus host cell receptors include angiotensin-converting enzyme 2 (ACE2) for SARS-related CoV, aminopeptidase N (APN) for certain alphacoronavirus like HCoV-229E, and dipeptidyl peptidase 4 (DPP4) for MERS-CoV[21-23]. To investigate the receptor usage of SADS-CoV, we tested live or pseudotyped SADS-CoV infection on HeLa cells expressing each of the three molecules, respectively. While the positive control worked for SL-CoV and MERS-CoV pseudoviruses, we found no evidence of enhanced infection or entry for SADS-CoV, suggesting that none of them is a functional receptor of SADS-CoV (Extended Data Table 3).

To fulfill Koch's postulates for SADS-CoV, two different types of animal challenge experiments were conducted (see Method for details). The first challenge experiment was conducted with SPF piglets infected with a tissue homogenate of SADS-CoV positive intestine. Two days after infection, 3/7 animals died in the challenge group whereas 4/5 survived in the control group. Incidentally, the one piglet that died in the control group was the only individual that didn't receive colostrum due to a shortage of supply. It is thus highly likely that lack of nursing and inability to access colostrum was responsible for the death (Extended Data Table 4). For the second challenge, healthy piglets were acquired from a farm in Guangdong that had been free of diarrheal disease for a number of weeks prior to the experiment, and were infected with the cultured isolate of SADS-CoV or tissue culture medium as control.

Of those inoculated with SADS-CoV, 50% (3/6) died between 2-4 days post infection, while all control animals survived (Extended Data Table 5). All animals in the infected group suffered watery diarrhea, rapid weight loss and intestinal lesions (determined after euthanasia upon experiment termination, Extended Data Table 4 & 5). Histopathological examination revealed significant villus atrophy only in SADS-CoV inoculated farm piglets 4-days after inoculation but not in control piglets (Fig. 3a and 3b) and viral N protein-specific staining was observed mainly in small intestine epithelial cells (Fig. 3c and 3d).

The current study highlights the value of proactive viral discovery in wildlife, and targeted surveillance in response to an emerging infectious disease event, as well as the disproportionate importance of bats as reservoirs of viruses that threaten veterinary and public health[24]. It also demonstrates that by using modern technological platforms such as NGS, LIPS serology and phylogenic analysis, key experiments that traditionally rely on isolation of live virus can be performed rapidly prior to virus isolation.

Online Content Methods, along with any additional Extended Data display items and Source Data, are available in the online version of the paper, references unique to these sections appear only in the online paper.

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245
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Supplementary Information is available in the online version of the paper.

Main Figure Legend

Figure 1 | Detection of SADS-CoV infection in pigs in Guangdong, China. a, Records of daily death toll on the four farms from 28 October 2016 to 2 May 2017. **b**, Detection of SADS-CoV by qPCR. Sample size: 12 sick piglets, 5 sick sows, 16 recovered sows, and 10 healthy piglets. **c**, Tissue distribution of SADS-CoV in diseased pigs (n=3). Centre values are average while bars indicate standard deviations. **d**, Detection of SADS-CoV antibodies. Sample size: 46 first bleed sera taken in the first three weeks of the outbreak, 8 second bleed sera taken >1 month post outbreak onset, 8 healthy pig control sera, 35 human sera from pig farmers.

Figure 2 | Genome and phylogenetic analysis of SADS-CoV and SADSr-CoV. a, Genome organization and comparison. Color-coding for different genomic regions: Green- nonstructural polyproteins ORF1a and 1b; Yellow- structural proteins S, E, M and N; Blue- accessory proteins NS3a, NS7a and Ns7b; Orange- UTRs. The level of sequence identity of SADSr-CoV to SADS-CoV is illustrated by different patterns of boxes: Open- highly similar; Dotted- moderately similar; Dash lined- least similar. **b**, Phylogenetic analysis of 57 S1 sequences (33 from SADS-CoV and 24 from SADSr-CoV). Different colors represent different host species as shown on the left. Scale bar indicates nucleotide substitutions per site.

322 **Figure 3 | Immunohistopathology of SADS-CoV infected tissues.** Sections of
323 Jejunum tissue from control (**a**, **c**) and infected farm piglets (**b**, **d**) 4-day after
324 inoculation, respectively, were stained with hematoxylin and eosin in **a** & **b** (bar =
325 200 μm) or with rabbit anti- SADSr-CoV N serum (red), DAPI (blue) and mouse
326 antibodies for epithelial cell marker cytokeratin 8, 18 and19 (green) in **c** & **d** (bar = 50
327 μm). SADS-CoV N protein is evident in epithelial cells and deeper in the tissue of
328 infected piglets, which exhibit villus shortening. The experiment was conducted three
329 times independently with similar results.

330

331 **METHODS**

332 **Sample collection.** Bats were captured and sampled in their natural habitat in
333 Guangdong Province (Extended Data Fig. 1) as described previously[6]. Fecal swab
334 samples were collected in viral transport medium (VTM) composed of Hank's
335 balanced salt solution at pH7.4 containing BSA (1%), amphotericin (15 μg/ml),
336 penicillin G (100 units/ml), and streptomycin (50 μg/ml). Stool samples from sick
337 pigs were collected in VTM. When appropriate and feasible, intestinal samples were
338 also taken from deceased animals. Samples were aliquoted and stored at -80 ^{0}C until
339 use. Blood samples were collected from recovered sows and farm workers who had
340 close contact with sick pigs. Serum was separated by centrifugation at 3,000 *g* for 15
341 min within 24 h of collection and preserved at 4 ^{0}C. Human serum collection was
342 approved by the Medical Ethics Committee of the Wuhan School of Public Health,

Wuhan University and Hummingbird IRB. Human, pigs and bats were sampled without gender or age preference unless where indicated (e.g. piglets or sows).

Virus isolation. The following cells were used for virus isolation in this study: Vero (cultured in DMEM +10% FBS); *Rhinolophus sinicus* primary or immortalized cells generated by our laboratory (all cultured in DMEM/F12 +15% FBS): kidney primary RsKi9409, lung primary RsLu4323, lung immortalized RsLuT, brain immortalized RsBrT and heart immortalized RsHeT; and swine cell lines: two intestinal porcine enterocytes IPEC (RPMI1640+10% FBS) and SIEC (DMEM+10% FBS), three kidney PK15, LLC-PK1 (DMEM+10% FBS for all) and IBRS (MEM+10% FBS), and one pig testes cells ST (DMEM+10% FBS). All cell lines were tested free of mycoplasma contamination, applied to species identification and authenticated by microscopic morphologic evaluation. None of cell lines was on the list of commonly misidentified cell lines (by ICLAC).

Cultured cell monolayers were maintained in their respective medium. PCR-positive pig fecal or supernatant from homogenized pig intestine (in 200 µl VTM) spin at 8,000g for 15 min, filtered and diluted 1:2 with DMEM supplied with 16 µg/ml trypsin before adding to cells. After incubation at 37 ^{0}C for 1 h, the inoculum was removed and replaced with fresh culture medium containing antibiotics (below) and 16 µg/ml trypsin. The cells were incubated at 37 ^{0}C and observed daily for cytopathic effect (CPE). Four blind passages (three-day interval between every passage) were performed for each sample. After each passage, both the culture supernatant and cell pellet were examined for presence of virus by RT-PCR using the

SADS-CoV primers listed in Supplementary Information Table 2. Penicillin (100 units/ml) and streptomycin (15 μg/ml) were included in all tissue culture media.

RNA extraction, S1 gene amplification and qPCR. Whenever commercial kits were used, manufacturer's instructions were followed without modification. RNA was extracted from 200 μl of swab samples (bat), feces or homogenized intestine (pig) with the High Pure Viral RNA Kit (Roche). RNA was eluted in 50 μl of elution buffer and used as the template for RT-PCR. Reverse transcription was performed using the SuperScript III kit (Thermo Fisher Scientific).

To amplify S1 genes from bat samples, nested PCR was performed with primers designed based on HKU2-CoV (Genbank accession number NC009988.1)[12] (Supplementary Information Table 2). The 25 μl first-round PCR mixture contained 2.5 μl 10×PCR reaction buffer, 5 pmol of each primer, 50 mM MgCl2, 0.5 mM dNTP, 0.1 μl Platinum Taq Enzyme (Thermo Fisher Scientific) and 1 μl cDNA. The 50 μl second-round PCR mixture was identical to the first-round PCR mixture except for primers. Amplification of both rounds was performed as follows: 94 ^{0}C for 5 min followed by 60 cycles consisting of 94 ^{0}C for 30 s, 50 ^{0}C for 40 s, 72 ^{0}C for 2.5 min, and a final extension of 72 ^{0}C for 10 min. PCR products were gel purified and sequenced.

For qPCR analysis, primers based on SADS-CoV RdRp and NP genes were used (Supplementary Information Table 2). RNA extracted from above was reverse-transcribed using PrimeScript RT Master Mix (Takara). The 10 μl qPCR reaction mix contained 5 μl 2×SYBR premix Ex Taq II (Takara), 0.4 μM of each primer and 1 μl

cDNA. Amplification was performed as follows: 95 ^{0}C for 30 s followed by 40 cycles consisting of 95 ^{0}C for 5 s, 60 ^{0}C for 30 s, and a melting curve step.

Luciferase Immunoprecipitation System (LIPS) assay. The SADS-CoV S1 gene was codon optimized for eukaryotic expression, synthesized (GenScript) and cloned in frame with the Renilla luciferase gene (Rluc) and a FLAG tag in the **pREN2** vector[14]. **pREN2**-S1 plasmids were transfected into Cos-1 cells using Lipofectamine 2000 (Thermo Fisher Scientific). At 48 h post-transfection, cells were harvested, lysed and a luciferase assay was performed to determine Rluc expression for both the empty vector (**pREN2**) and the **pREN2**-S1 construct. For testing of unknown pig or human serum samples, 1 µl of serum was incubated with 10 million units of Rluc alone (vector) or Rluc-S1, respectively, together with 3.5 µl of a 30% protein A/G ultralink bead suspension (Thermo Fisher Scientific). After extensive washing to remove unbounded luciferase-tagged antigen, captured luciferase amount was determined using the commercial luciferase substrate kit (Promega). The ratio of Rluc-S1/Rluc (Vector) was used to determine the specific S1 reactivity of pig and human sera. Commercial FLAG antibody (Thermo Fisher Scientific) was used as the positive control, and various pig sera (from uninfected animals in China or Singapore; or pigs infected with PEDV, TGEV or Nipah virus) were used as a negative control.

Protein expression and antibody production. The N gene from SADSr-CoV 3755 (GenBank accession number MF094702), which shared a 98% aa sequence identity to the SADS-CoV N gene, was inserted into **pET-28a+** (Novagen) for prokaryotic expression. Transformed *E. coli* were grown at 37 ^{0}C for 12-18 h in media containing

409 1 mM IPTG. Bacteria were collected by centrifugation and resuspended in 30 ml of 5
410 mM imidazole and lysed by sonication. The lysate, from which N protein expression
411 was confirmed with an anti-HIS-tag antibody, was applied to the Ni^{2+} resin (Thermo
412 Fisher Scientific). The purified N protein, at a concentration of 400 μg/ml, was used
413 to immunize rabbits for antibody production following published methods[25]. After
414 immunization and two boosts, rabbits were euthanized and sera were collected. Rabbit
415 anti-N protein serum was used 1:10,000 for subsequent Western blots.
416 **Amplification, cloning and expression of human and swine genes.** Construction of
417 expression clones for human ACE2 in **pcDNA3.1** has been described previously[8, 26].
418 Human DPP4 was amplified from human cell lines. Human APN gene was
419 commercially synthesized. Swine APN, DPP4 and ACE2 genes were amplified from
420 piglet intestine. Full-length gene fragments were amplified using specific primers
421 (provided upon request). The human ACE2 gene was cloned into **pCDNA3.1** fused
422 with HIS tag. Human APN, DPP4, Swine APN, DPP4 and ACE2 genes were cloned
423 into **pCAGGS** fused with S tag. Purified plasmids were transfected to HeLa cells.
424 After 24 h, HeLa cells expressing human or swine genes were confirmed by
425 immunofluorescence assay (IFA) using mouse anti-HIS tag or mouse anti-S tag
426 monoclonal antibodies (produced in house) followed by cyanin 3-labeled goat anti-
427 mouse/rabbit IgG (Proteintech Group).
428 **Pseudovirus preparation.** The codon-humanized S protein genes of SADS-CoV or
429 MERS-CoV cloned into **pcDNA3.1** were used for pseudovirus construction as
430 described previously[8, 26]. Briefly, 15 μg of each pHIV-Luc (**pNL4.3.Luc.R^-E^-Luc**)

and the S protein expressing plasmids (or empty vector control) were co-transfected into 4×10^6 293T cells using Lipofectamine 3000 (Thermo Fisher Scientific). After 4 h, the medium was replaced with fresh medium. Supernatants were harvested at 48 h post transfection and clarified by centrifugation at 3,000g, then passed through a 0.45μm filter (Millipore). The filtered supernatants were stored at -80°C in aliquots until use. To evaluate the incorporation of S proteins into the core of HIV virions, pseudoviruses in supernatant (20 ml) were concentrated by ultracentrifugation through a 20% sucrose cushion (5ml) at 80,000g for 90 min using a SW41 rotor (Beckman). Pelleted pseudoviruses were dissolved in 50μl phosphate-buffered saline (PBS) and examined by electron microscopy (EM).

Pseudovirus infection. HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared using Lipofectamine 2000 (Thermo Fisher Scientific). Pseudoviruses prepared above were added to APN, ACE2 or DPP4 overexpressed HeLa cells at 24h post transfection. The unabsorbed viruses were removed and replaced with fresh medium at 3 hpi. The infection was monitored by measuring the luciferase activity conferred by the reporter gene carried by the pseudovirus, using the Luciferase Assay System (Promega) as follows: cells were lysed at 48 hpi, and 20 μl of the lysates was taken for determining luciferase activity by the addition of 50 μl of luciferase substrate.

Examination of known CoV receptors for SADS-CoV entry/infection. HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared by a lipofectamine 2000 system (Thermo Fisher Scientific) in 96-well plate, with mock-transfected cells as

453 controls. SADS-CoV grown from Vero cells was used to infect Hela cells transiently
454 expressing APN, ACE2 or DPP4. The inoculum was removed after 1h absorption and
455 washed twice with PBS and supplemented with medium. SARS-related-CoV
456 WIV16[18] and MERS-CoV HIV-pseudovirus were used as positive control for
457 human/swine ACE2 or human/swine DPP4, respectively. At 24 hpi, cells were
458 washed with PBS and fixed with 4% formaldehyde in PBS (pH 7.4) for 20 min at
459 room temperature. SL-CoV WIV16 replication was detected using rabbit antibody
460 against the SL-CoV Rp3 nucleocapsid protein (made in house, 1:100) followed by
461 cyanin 3-conjugated goat anti-rabbit IgG (1:50, Proteintech)[18]. SADS-CoV replication
462 was monitored using rabbit antibody against the SADSr-CoV 3755 N protein (made
463 in house, 1:50) followed by FITC-conjugated goat anti-rabbit IgG (1:50, Proteintech).
464 Nucleus was stained with DAPI (Beyotime). Staining patterns were examined using
465 the FV1200 confocal microscopy (Olympus). Infection of MERS-CoV HIV-
466 pseudovirus was monitored by luciferase at 48 hpi.
467 **High throughput sequencing, pathogen screening and genome assembly.** Tissue
468 from the small intestine of deceased pigs was homogenized and filtered through 0.45
469 μm filters before nucleic acid was extracted and ribosomal RNA were depleted using
470 NEBNext rRNA Depletion Kit (New England Biolabs). Metagenomics analysis of
471 both RNA and DNA viruses was performed. For the RNA virus screening, the
472 sequencing library was constructed using Ion Total RNA-Seq Kit v2 (Thermo Fisher
473 Scientific). For the DNA virus screening, NEBNext Fast DNA Fragmentation &
474 Library Prep Set for Ion Torrent (New England Biolabs) was used for library

475 preparation. Both libraries were sequenced on an Ion S5 sequencer (Thermo Fisher
476 Scientific). An analysis pipeline was applied on the sequencing data which perform
477 the following analysis steps: 1) raw data quality filtering, 2) host genomic sequence
478 filtering, 3) blastn against virus nucleotide database using BLAST, 4) blastx against
479 virus protein database using DIAMOND v0.9.0; 5) contig assembling and blastx
480 against virus protein database. For whole viral genome sequencing, amplicon primers
481 (To be provided upon request) were designed using the Thermo Fisher Scientific
482 online tool with HKU2-CoV and SADS-CoV Farm A genome as reference, and the
483 sequencing libraries were constructed using NEBNext Ultra II DNA Library Prep Kit
484 for Illumina and sequenced on an MiSeq sequencer. PCR and Sanger sequencing was
485 performed to fill gaps in the genome. Genome sequences were assembled using CLC
486 Genomic Workbench v9.0. 5'-RACE was performed to determine the 5'-end of the
487 genomes using SMARTer RACE 5'/3' Kit (Takara). Genomes were annotated using
488 Clone Manager Professional Suite 8 (Sci-Ed Software).
489 **Phylogenetic analysis.** SADS-CoV genome sequences and other representative
490 coronavirus sequences (obtained from GenBank) were aligned using MAFFT v7.221.
491 Phylogenetic analyses with full-length genome, S gene and RdRp were performed
492 using MrBayes v3.2. Twenty million to fifty million steps were run, with GTR+G+I
493 model (General Time Reversible model of nucleotide substitution with a proportion of
494 invariant sites and γ-distributed rates among sites). The first 10% were removed as
495 burn-in. The association between phylogenies and phenotypes (e.g. host species and
496 farms) was assessed by BaTS beta-build2, with the trees obtained in the previous step

497 used as input. For SADS-CoVs, a median-joining network analysis was performed
498 using PopART v1.7, with $\varepsilon = 0$. Phylogenetic analysis of the 33 full-length SADS-
499 CoV genome sequences was performed using RAxML v8.2.11, with GTRGAMMA
500 as the nucleotide substitution model and 1,000 bootstrap replicates. The maximum
501 likelihood tree was used to test the molecular clock by TempEst v1.5. Potential
502 genetic recombination events in our datasets were detected using RDP v4.72.
503 **Animal infection studies.** Experiments were carried out strictly in accordance with
504 the recommendations of the Guide for the Care and Use of Laboratory Animals of the
505 National Institutes of Health. The use of animals in this study was approved by the
506 South China Agricultural University Committee of Animal Experiments (approval ID:
507 201004152).
508 Two different animal challenge experiments were conducted. Pigs were used
509 without gender preference. In the first experiment, which was conducted before the
510 virus was isolated, we used 3-day old specific pathogen free (SPF) piglets of the same
511 breeding line, cared at a specific pathogen free (SPF) facility, supplied by colostrum
512 (except one). These are bred and reared to be free of PEDV, CSFV, SIV, PCV2 and
513 PPV, and are routinely tested using PCR. We also conducted NGS to further confirm
514 this before the animal experiment, and to demonstrate freedom from SADS-CoV
515 infection. The intestinal tissue samples from diseased and healthy animals,
516 respectively (intestinal samples excised from euthanized piglets, then ground to make
517 slurry for the inoculum. NGS was performed to confirm no other pig pathogens exist),
518 were used to feed two groups of 5 (as control) and 7 (infection) animals, respectively.

519 For the second experiment, isolated SADS-CoV was used to infect healthy piglets
520 from a farm in Guangdong which had been free of diarrheal disease for a number of
521 weeks previously. These piglets were from the same breed as those on SADS-affected
522 farms, to eliminate potential host factor differences and to more accurately reproduce
523 the conditions that occurred during the outbreak in the region. Both groups of piglets
524 were cared at a known pig disease free facility. Again, qPCR and NGS were used to
525 make sure that there was no other known swine diarrhea virus present in the virus
526 inoculum or any of the experimental animals. Two groups (6 for each group) of 3-day
527 old piglets were inoculated with SADS-CoV culture supernatant or normal cell culture
528 medium as control. NGS and qPCR was used to confirm that there were no other
529 known swine pathogens in the inoculum.

530 For both experiments, animals were recorded daily for signs of diseases, such
531 as diarrhea, weight loss and death. Fecal swabs were collected daily from all animals
532 and screened for known swine diarrhea viruses by qPCR. Weight loss was calculated
533 as >5% loss from original weight at day 0. It is important to point out that piglets at
534 three days old tend to suffer from diarrhea and weight loss when they are taken away
535 from sows and the natural breast-feeding environment without infection. At
536 experimental endpoints, piglets were humanely euthanized and necropsies performed.
537 Pictures were taken to record gross pathological changes to the intestines. Ileal,
538 jejunal and duodenal tissues were taken from selected animals and stored at -80 ^{0}C for
539 further analysis.

Hematoxylin and eosin (H&E) and immunohistochemistry (IHC) analysis. Frozen (-80 ^{0}C) small intestinal tissues including duodenum, jejunum, and ileum taken from the above experimentally infected pigs were pre-frozen at -20 ^{0}C for 10 min. Tissues were then embedded in optimal cutting temperature compound and cut into 8-μm sections using the Cryotome FSE machine (Thermo Fisher Scientific). Mounted microscope slides were fixed with paraformaldehyde and stained with H&E for histopathological examination.

For IHC analysis, the rabbit antibody raised against the SADSr-CoV 3755 N protein was used for specific staining of SADS-CoV antigen. Slides were blocked by incubating with 10% goat serum (Beyotime) at 37 ^{0}C for 30 min, followed by overnight incubation at 4 ^{0}C with the rabbit anti-3755 N protein serum (1:1000) and mouse anti-Cytokeratin 8+18+19 mAb (Abcam) 1:100 diluted in PBST buffer containing 5% goat serum. After washing, slides were then incubated for 50 min at room temperature with Cy3 conjugated goat-anti-rabbit IgG (Proteintech) and FITC conjugated goat-anti-mouse IgG (Proteintech) diluted 1:100 in PBST buffer containing 5% goat serum. Slides were stained with DAPI (Beyotime) and observed under fluorescence microscope (Nikon).

Data Availability statement. Sequence data that support the findings of this study have been deposited in GenBank with the accession codes listed: MF094681-MF094688, MF769416-MF769444, MF094697-MF094701, MF769406-MF769415, and MG557844 (e.g. http://www.ncbi.nlm.nih.gov/nuccore/MF094861). Raw sequencing data that support the findings of this study have been deposited in

562 Sequence Read Achieve (SRA) with the accession codes listed: SRR5991652,
563 SRR5991654, SRR5991649, SRR5991656, SRR5991651, SRR5995595,
564 SRR5991657, SRR5991648, SRR5991650, SRR5991658, SRR5991657 and
565 SRR5991655（e.g. https://www.ncbi.nlm.nih.gov/sra/?term=SRR5991652).

566 25. E. Harlow, D. Lane, Antibodies: A Laboratory Manual. (Cold Spring Harbor
567 Laboratory Press, New York, 1988).
568 26. Ren, W. et al. Difference in receptor usage between severe acute respiratory
569 syndrome (SARS) coronavirus and SARS-like coronavirus of bat origin. J
570 Virol 82, 1899-1907 (2008).

571

572 **EXTENDED DATA LEGEND**

573 **Extended Data Figure 1 | Map of outbreak locations and sampling sites in**
574 **Guangdong Province, China (a) and the co-circulation of PEDV and SADS-CoV**
575 **during the initial outbreak on Farm A (b). a,** SADS-affected farms are labeled A to
576 D with blue swine symbols following the temporal sequence of the outbreaks. Bat
577 sampling sites are indicated by black bat symbols. The bat SADSr-CoV that is most
578 closely related to SADS-CoV (sample 162140) originated in Conghua. The red flag
579 marks Foshan city, site of the SARS index case. **b**, Pooled intestinal samples (n=5 or
580 more biological independent samples) were collected at dates given on the x-axis
581 from deceased piglets and analyzed by qPCR. The viral load for each piglet is shown
582 as copy number per milligram of intestine tissue (y-axis).

583 **Extended Data Figure 2 | Bayesian phylogenetic tree of the full-length genome (a)**
584 **or ORF1ab sequences (b) of SADS-CoV and related coronaviruses.** Trees were
585 constructed using MrBayes with the average standard deviation of split frequencies
586 under 0.01. The host of each sequence is represented pictorially. Newly sequenced
587 SADS-CoVs are highlighted in red, bat SADSr-CoVs in blue and previously
588 published sequences in black. Scale bar indicates nucleotide substitutions per site.

589 **Extended Data Figure 3 | Phylogeny and haplotype network analyses of the 33**
590 **SADS-CoV strains from the four farms**. **a**, phylogenetic tree constructed using
591 MrBayes. The GTR+GAMMA model was applied and 20 million steps were run, with
592 the first 10% of which were removed as burn in. Viruses from different farms are
593 labeled with different colors. Scale bar indicates nucleotide substitutions per site. **b**,
594 median-joining haplotype network constructed using ProART. In this analysis $\varepsilon = 0$
595 was applied. Size of the circles represents the number of samples. The larger the circle,
596 the more samples it includes.

597 **Extended Data Figure 4 | Recombination analysis for SADS-CoV and related**
598 **CoVs.** The potential genetic recombination events were detected using RDP. For each
599 virus strain, different colors represent different sources of the genomes.

600 **Extended Data Figure 5 | Isolation and antigenic characterization of SADS-CoV**.
601 Vero cells are shown at 20 hours post infection with mock (**a**) or SADS-CoV (**b**). **c**
602 and **d** are mock or SADS-CoV infected samples stained with rabbit serum raised

against the recombinant SADSr-CoV N protein (red) and DAPI (blue). The experiment was conducted three times independently with similar results.

Extended Data Table 1 | List of all known swine viruses tested by PCR at the beginning of the of SADS outbreak investigation on the four farms[*†]. Feces, intestine or fecal swabs collected from January to April 2017 were subjected for testing. Dash indicates a negative PCR result. ND, not done.

[*]Virus abbreviations: PEDV- Porcine Epidemic Diarrhea Virus; PDCoV- Porcine Delta Coronavirus; TGEV-Porcine Transmissible Gastroenteritis Virus; RV- Porcine Rotavirus; PBV- Porcine Picobirnavirus; PSV- Porcine Sapelovirus; SVA- Porcine Senecavirus A; SIV- Swine Influenza Virus; NADC30- Porcine Reproductive and Respiratory Syndrome Virus, strain NADC30; PRV- Porcine Pseudorabies Virus; FMDV- Foot and Mouth Disease Virus; CSFV- Classical Swine Fever Virus; PCV2- Porcine Circovirus 2; PCV3- Porcine Circovirus 3; APPV- Atypical Porcine Pestivirus; PPV- Porcine Parvovirus. [†]Sampling type and size for each farm: Farm A: 1 feces, 20 intestines and 6 fecal swabs; Farm B: 1 feces and 15 intestines; Farm C: 2 intestines and 1 fecal swab; Farm D: 5 feces and 1 fecal swab.

Extended Data Table 2 | List of SADSr-CoVs detected in bats in Guangdong, China. See Extended Data Figure 1 for sampling sites in relation to SARS and SADS outbreak locations.

Extended Data Table 3 | Test of SADS-CoV entry and infection in Hela cells expressing known coronavirus receptors.

*Gene accession numbers for the genes used in this study: human APN, M22324.1; human ACE2, NM_021804; human DPP4, NM_001935.3; SwAPN (swine APN), NM_214277.1; SwACE2 (swine ACE2), NM_001116542.1; SwDPP4 (swine DPP4), NM_214257.1. †For MERS-CoV infection, HIV-pseudovirus was used. ‡Expression of APN, ACE2 and DPP4 was confirmed by antibodies against fused tags.

Extended Data Table 4 | Experimental infection of SPF piglets using intestine tissue homogenate. Experimental details can be found in Methods. **a**, Animals were recorded every day for sign of diseases including weight loss, diarrhea and death. PCR on fecal swabs was conducted to monitor the presence of SADS-CoV or other pig viruses. **b**, Daily body weight record of all piglets. Unit = kg.

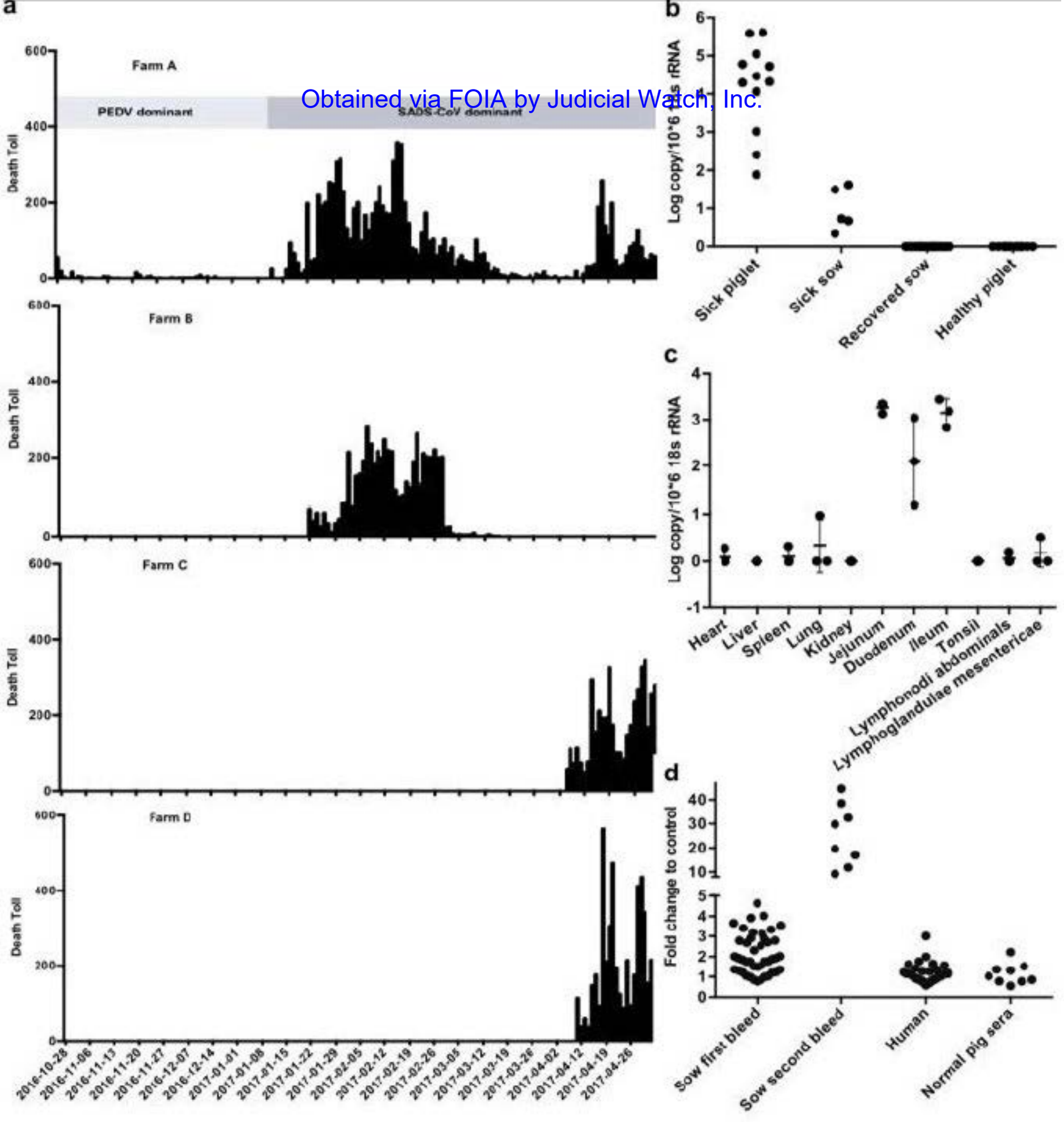
*Euthanized on the day indicated for further analysis. †Animals died during the experiment. ‡The only animal which didn't receive colostrum in this experiment due to supply shortage.

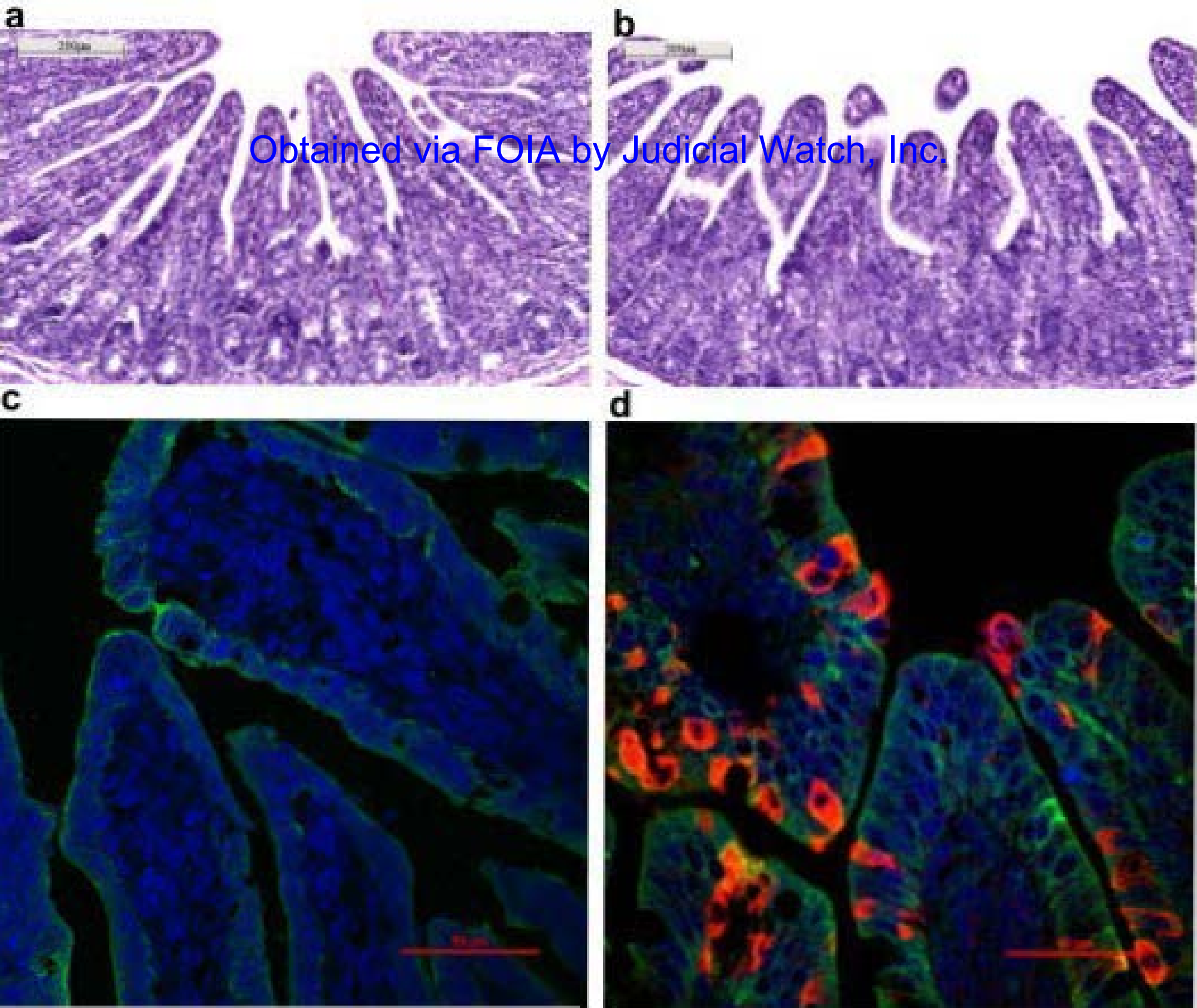
Extended Data Table 5 | Experimental animal infection of farm piglets using cultured SADS-CoV. Experimental details can be found in Methods. **a**, Animals were recorded every day for sign of diseases including weight loss, diarrhea and death. PCR on fecal swabs was conducted to monitor the presence of SADS-CoV or other pig viruses. **b**, Daily body weight record of all piglets. Unit = kg.

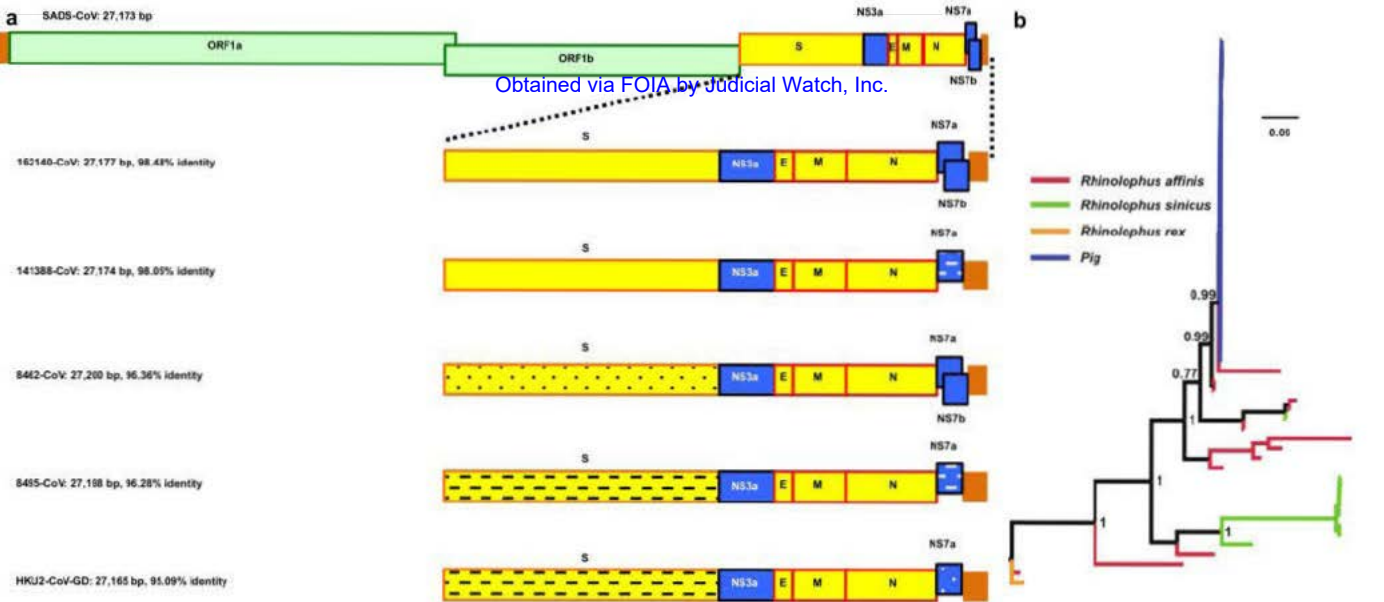
642 *Euthanized on the day indicated for further analysis. †Animals died during the

643 experiment.

644







From: Krafft, Amy (NIH/NIAID) [E]
To: Hauguel, Teresa (NIH/NIAID) [E]; Tibbals, Melinda (NIH/NIAID) [C]; Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: Flu, MERS, SARS portfolios - CTs, # participants
Date: Friday, October 27, 2017 9:02:33 AM
Attachments: image001.png

This sounds like mine. I would say it is not a clinical trial but "clinical research study" collecting nasal swabs from patients in a clinic to test the diagnostic

R01AI111303-04 POINT-OF-CARE DIAGNOSIS AND SURVEILLANCE OF KNOWN AND EMERGING INFLUENZA VIRUSES

Amy E. Krafft, Ph.D.
Program Officer, Flu Therapeutics & Diagnostics Development
Influenza, SARS & Related Viral Respiratory Diseases Section
Respiratory Diseases Branch
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Voice: (b) (6)

Get Help Turning Your Discoveries into New Diagnostics, Vaccines, and Therapeutics. Visit https://www.niaid.nih.gov/research/microbiology-and-infectious-disease-resources to see the full range of available services that provide access to research tools and technologies and preclinical and clinical services to facilitate product development.

Telework: Monday and Wednesday (reachable at (b) (6)

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Thursday, October 26, 2017 5:07 PM
To: Tibbals, Melinda (NIH/NIAID) [C] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Krafft, Amy (NIH/NIAID) [E] (b) (6)
Subject: RE: Flu, MERS, SARS portfolios - CTs, # participants

Melinda,

Of the grants below in my portfolios, only 1 is a clinical trial:

U01AI125056-02 HALLMARKS OF PROTECTIVE IMMUNITY IN SEQUENTIAL RHINOVIRUS INFECTIONS IN HUMANS

Best,
Teresa

Teresa M. Hauguel, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Rockville, MD 20852
Phone (b) (6)
Email (b) (6)

Getting ready to publish? Share the good news with your Program Officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

Please consider the environment before printing this e-mail.

From: Tibbals, Melinda (NIH/NIAID) [C]
Sent: Thursday, October 26, 2017 3:27 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6) Krafft, Amy (NIH/NIAID) [E] (b) (6) Hauguel, Teresa (NIH/NIAID) [E] (b) (6)
Subject: Flu, MERS, SARS portfolios - CTs, # participants

Hi, Erik, Amy, Teresa,

Irene is asking how many clinical trials and participants are in the bacterial portfolios. She's using the information in the hiring request exemptions for KDB.

Are any of the grants below clinical trials?
For the planned enrollment numbers -- are any of the grants below not enrolling participants (meaning are the numbers referring to retrospective chart reviews, using specimens collected from previous studies, etc)? There are 3 grants marked in yellow that have high numbers in particular.

Please let me know by COB Friday.

Thanks so much,
Melinda

Project	Project Title	RaceTot	PCC	Program Official	PI Name
K23AI114844-03	VIRAL AND HOST BIOMARKERS OF HUMAN RHINOVIRUS DISEASE SEVERITY IN TRANSPLANTATION	735	M51B	HAUGUEL, TERESA M.	WADHWANI, ALPANA AMALKANT
R01AI111303-04	POINT-OF-CARE DIAGNOSIS AND SURVEILLANCE OF KNOWN AND EMERGING INFLUENZA VIRUSES	-	M51G 9	KRAFFT, AMY	ROSE, TIMOTHY M
R01AI113047-05	THE EFFECT OF HUMAN PRE-EXPOSURE HISTORY ON ANTIGENIC DRIFT OF INFLUENZA VIRUSES	264	M51B B	HAUGUEL, TERESA M.	HENSLEY, SCOTT ERIC
R01AI114730-03	INFLUENZA VIRUS RECEPTORS ON HUMAN AIRWAY EPITHELIAL CELLS	150	M51B B	HAUGUEL, TERESA M.	PAULSON, JAMES C
R01AI121285-02	STUDIES OF IGHV GERMLINE GENE POLYMORPHISM, UTILIZATION & SHIFTING FOR SEASONAL INFLUENZA VACCINE INDUCED BROADLY NEUTRALIZING ANTIBODY RESPONSES	100	M51A B	HAUGUEL, TERESA M.	MARASCO, WAYNE A
R01AI132206-01	STRUCTURE-GUIDED DESIGN OF CD4 T CELL MEMORY-ENHANCED RHA H7N9 INFLUENZA VACCINE	75	M51A B	HAUGUEL, TERESA M.	DEGROOT, ANNE SEARLS
R21AI130502-01A1	EXOSOMAL MIR-155 REGULATES AIRWAY EPITHELIAL IMMUNE RESPONSES IN INFANTS WITH RHINOVIRUS INFECTION	31	M51B B	HAUGUEL, TERESA M.	NINO, GUSTAVO
R01AI108686-05	IMPACT OF PRIOR INFLUENZA EXPOSURES ON ANTIBODY REPERTORES TO NEW VIRAL STRAINS	24	M51B B	HAUGUEL, TERESA M.	HENSLEY, SCOTT ERIC
U01AI115715-03	MUCOSAL AND SYSTEMIC IMMUNE RESPONSES TO INFLUENZA VIRUS	30	M51B B	HAUGUEL, TERESA M.	GREENBERG, HARRY BERNARD
U01AI125056-02	HALLMARKS OF PROTECTIVE IMMUNITY IN SEQUENTIAL RHINOVIRUS INFECTIONS IN HUMANS	750	M51B B	HAUGUEL, TERESA M.	WOODFOLK, JUDITH A
R01AI110964-04	UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE	2,466	M91O	STEMMY, ERIK J.	DASZAK, PETER
R01AI125197-02	GIANT MAGNETORESISTIVE (GMR) SENSORS FOR MEASURING INFLUENZA VACCINE	6	M51A B	HAUGUEL, TERESA M.	UTZ, PAUL JOSEPH
	Total	4,625			

Melinda Tibbals, RAC, CCRA
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Cell: (b) (6)

From: Tibbals, Melinda (NIH/NIAID) [C]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: number of participants in R01AI110964
Date: Thursday, October 26, 2017 2:32:48 PM

Hi, Erik,
Irene is asking for the number of participants RDB plans to enroll for flu, MERS, SARS grants. The QVR report is indicating 2,460 will be enrolled in R01AI110964, UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE, Peter Daszak.
Will 2460 be enrolled or is this a chart review, specimens from the repository, etc that will use information from participants enrolled in previous studies?
Irene is asking for the info by 3:00ish.
Thanks, Melinda

Melinda Tibbals, RAC, CCRA
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Tel: (b) (6)
Cell: (b) (6)
(b) (6)

From: Booth, Mason (NIH/NIAID) [C]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: DMID Word Nerds
Subject: RE: Confidential - A new bat-origin coronavirus emerging in pigs in China discovered under our NIAID R01
Date: Monday, October 2, 2017 7:50:28 AM
Attachments: FW Potential visit to NIH by our Chinese Co-investigator in June.msg

---

Thank so much, Erik. Is this a revised version of the article sent by EcoHealthAlliance after their Forum (attached)?

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Sunday, October 01, 2017 2:55 PM
To: Erbelding, Emily (NIH/NIAID) [E] (b) (6); NIAID BUGS <BUGS@niaid.nih.gov>
Cc: Lambert, Linda (NIH/NIAID) [E] (b) (6)
Subject: Fwd: Confidential - A new bat-origin coronavirus emerging in pigs in China discovered under our NIAID R01

Dear Emily and BUGS,

Peter Daszak sent the message and manuscript below to Dr Fauci, so I thought I'd share it with you as well. It's about an emerging CoV in China he and his group described that is fairly lethal in pigs. It's in the same CoV family as SARS, and Peter came to a forum in June to present the work. The emergent virus shows some ecological and etiological similarities to what happened when SARS emerged, but does not seem to be pathogenic in humans. Rather, the work highlights the diversity of viruses in bat reservoirs and the importance of zoonotic viruses in future outbreaks.

I'd sent this up to BUGS to consider for NIAID OC, but we were still waiting on the final publication in Nature. Happy to discuss further if you like, and will let you know once the paper is accepted.

Erik

Sent from my iPhone

Begin forwarded message:

From: Peter Daszak (b) (6)
Date: October 1, 2017 at 1:21:51 PM EDT
To: (b) (6)
Cc: "David Morens (b) (6), "David Morens (b) (6), (b) (6), (b) (6), (b) (6), "Stemmy, Erik (NIH/NIAID) [E]" (b) (6), Alison Andre (b) (6), Aleksei Chmura (b) (6)
Subject: Confidential - A new bat-origin coronavirus emerging in pigs in China discovered under our NIAID R01

Dear Dr Fauci and NIAID colleagues,

It was a pleasure to meet you again today. I've attached an unpublished paper, currently in the second round of review with *Nature* that describes a novel bat-origin Coronavirus (SADS-CoV: Swine Acute Diarrheal Syndrome coronavirus) that recently spilled over into pig farms in Southern China, leading to the death of over 25,000 piglets in 5+ farms in Guandong Province.

The virus originates in the same group of bats as SARS-CoV, and emerged in the same place. It's not known to be zoonotic (we've tested 35+ pig farm workers with an antibody assay and none are positive. The pig farm owners tell us the virus is now under control, thanks to culling and separation of infected herds. It's not yet known if this virus has appeared elsewhere, but we are looking. We're also doing assays to find out if it can infect human cells in the lab – so far no evidence of this.

I hope this paper is of interest. You should know that this work was supported by a NIAID R01 that Erik Stemmy is the Program Officer for, and that I'm PI on, with Zhengli Shi as co-PI.

If you want any other information at all, please don't hesitate to email or call and I'd be happy to come over to NIAID to brief you further. I'll also let you know if/when it will be published so that we can try to foster some publicity as appropriate.

Cheers,

Peter

Peter Daszak
President
EcoHealth Alliance
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New York, NY 10001
Tel. (b) (6)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thu, 29 Jun 2017 14:56:25 -0400
To: NIAID BUGS
Cc: Park, Eun-Chung (NIH/NIAID) [E]
Subject: FW: Potential visit to NIH by our Chinese Co-investigator in June?
Attachments: 2017-05-06890 full manuscript.pdf

Hi BUGS,
The Forum speakers today described a novel bat-origin CoV that is currently causing an ongoing epidemic in pigs in China. They have a paper describing the virus under review in Nature, and it might be something NIAID OC may consider publicizing when it is ultimately published. The emergent virus shows some ecological and etiological similarities to what happened when SARS emerged, but does not seem to be pathogenic in humans. Rather, the work highlights the diversity of viruses in bat reservoirs and the importance of zoonotic viruses in future outbreaks.

Erik

From: Peter Daszak (b) (6)
Sent: Thursday, June 29, 2017 2:39 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Hongying Li (b) (6)
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

Hi Erik,

I just wanted to say thanks for hosting us at NIAD today – it was great to have an interested audience with good questions and nice to have a chance to introduce our collaborators to you personally.

I mentioned the upcoming SADS-CoV paper might get into *Nature*. Obviously, this is touch-and-go right now, but I've attached the draft here so you can forward it to your communications team in case they want to get a release out earlier this time.

By the way – we've had some great publicity from the other paper last week. If you go to the following link we've put some of the stories up on our EHA website here:
http://www.ecohealthalliance.org/updates

Hope you enjoy skimming through them, and thanks again for setting up the talk this morning.

Cheers,

Peter

Peter Daszak
President

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New York, NY 10001

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www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

Title: Fatal Swine Disease Outbreak Caused by a Novel Coronavirus of Bat Origin

Authors: Peng Zhou[1]*, Hang Fan[2]*, Tian Lan[3]*, Xing-Lou Yang[1], Wei Zhang[1], Yan Zhu[1], Ya-Wei Zhang[2], Qing-Mei Xie[3], Shailendra Mani[4], Xiao-Shuang Zheng[1], Bei Li[1], Jin-Man Li[2], Hua Guo[1], Guang-Qian Pei[2], Xiao-Ping An[2], Jun-Wei Chen[3], Ling Zhou[3], Kaijie Mai[3], Zi-Xian Wu[3], Danielle E. Anderson[4], Li-Biao Zhang[5], Shi-Yue Li[6], Zhi-Qiang Mi[2], Tong-Tong He[2], Yun Luo[1], Xiang-Ling Liu[1], Jing Chen[1], Yong Huang[2], Qiang Sun[2], Xiang-Li-Lan Zhang[2], Yan-Shan Cheng[3], Yuan Sun[3], Peter Daszak[7], Lin-Fa Wang[4]†, Zheng-Li Shi[1]†, Yi-Gang Tong[2]†, Jing-Yun Ma[3]†

Affiliations:

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[5]Guangdong Key Laboratory of Animal Conservation and Resource Utilization, Guangdong Public Laboratory of Wild Animal Conservation and Utilization, Guangdong Institute of Applied Biological Resources, Guangzhou 510260, China

[6]School of Public Health, Wuhan University, 430072, China

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Spillover of bat-origin coronaviruses is implicated in the emergence of two emerging, high-impact zoonoses, SARS and MERS. Here, we report virological, epidemiological and experimental infection evidence that a novel bat-origin coronavirus, Swine Acute Diarrhea Syndrome coronavirus (SADS-CoV), caused an ongoing outbreak of lethal diarrheal disease in pigs in China. The outbreak began in January 2017 Guangdong Province in the vicinity of the origin of the SARS pandemic in 2002, and has caused the death of 24,693 piglets in four farms to date. We identified SADS related-CoVs with 96-98% sequence identity to SADS-CoV in 11.9% (71/596) of anal swabs collected from bats in Guangdong Province during 2013-16, predominantly in five *Rhinolophus* spp. horseshoe bats that are known reservoirs of SARS-like CoVs. The geographic, temporal, ecological and etiological similarities in the emergence of SADS and SARS highlight the urgent need to identify coronavirus diversity in bats to mitigate future outbreaks that threaten veterinary production, public health and economic growth.

The emergence of severe acute respiratory syndrome in southern China in 2002, which was caused by a previously unknown coronavirus (SARS-CoV)[1-5] and led to more than 8,000 human infections and 774 deaths [http://www.who.int/csr/sars/en/], heralded two new frontiers in emerging infectious diseases. Firstly, it demonstrated that coronaviruses are capable of causing fatal diseases in humans. Secondly, the identification of bats as the reservoir for SARS-related coronaviruses, and likely

53 origin of SARS-CoV[6-8] firmly established bats as an important source of highly lethal
54 zoonotic viruses, which include Hendra, Nipah, Ebola and Marburg viruses[9].
55 The public health threat posed by novel coronaviruses was reinforced by the
56 emergence of the Middle East respiratory syndrome coronavirus (MERS-CoV) in
57 2012[10], which has so far infected 1,952 people with 693 deaths
58 [http://www.who.int/emergencies/mers-cov/en/]. Cases of MERS have been reported
59 in 27 countries, mostly due to imported cases with the exception of a major outbreak
60 in Seoul in 2015 that involved extensive local human-to-human transmissions[11].
61 While dromedary camels have been identified as the main source of MERS-CoV
62 spillover to humans[12], there is evidence suggesting that bats are the original wildlife
63 reservoir. This includes short sequence from a single *Taphozous perforatus* bat in
64 Saudi Arabia, and evidence that bat MERS-related coronaviruses use the same human
65 entry receptor, dipeptidyl peptidase 4 (DPP4; also known as CD26), as
66 MERS-CoV[13-16].
67 Here we report a series of fatal swine disease outbreaks in Guangdong
68 Province, China, approximately 100 km from the location of the purported index case
69 of SARS. Most strikingly, we found that the causative agent for this swine acute
70 diarrhea syndrome (SADS) is a novel coronavirus which is almost 99% identical in
71 genome sequence to a bat coronavirus we detected in 2016 from a bat cave in the
72 vicinity of the index pig farm. This new virus (SADS-CoV) thus appears to have
73 originated from the same genus of horseshoe bats (*Rhinolophus*) as SARS-CoV.

From 28 October 2016, fatal swine disease outbreaks were observed in a pig farm in Qingyuan, Guangdong Province, China, very close to the location of the first known index case of SARS in Foshan (**Extended Data Figure 1**). Porcine epidemic diarrhea virus (PEDV) had caused prior outbreaks at this farm, and was detected in the intestine of deceased piglets at the start of the outbreak. However, PEDV could no longer be detected in deceased piglets after 12th January 2017, despite accelerating mortality (**Fig. 1**A) and extensive testing for other common swine viruses yielded negative results (**Extended Data Table 1**). These findings suggested an outbreak of a novel disease, which we designated swine acute diarrhea syndrome (SADS). Clinical signs are similar to those caused by other known swine enteric coronaviruses [17,18] and include severe and acute diarrhea, and rapid weight loss, leading to death due to nutritional exhaustion in newborn piglets less than four days of age. Infected piglets died 2-6 days following disease onset, while infected sows suffered only mild diarrhea and most recovered in two days. The disease caused no signs of febrile illness in piglets or sows. The disease has spread to three additional pig farms within 20-150 km of the index farm (**Extended Data Figure 1**) and, as of 2nd May 2017, has resulted in the death of 24,693 piglets from four farms (**Fig. 1A**). In Farm A alone, 64% (4659/7268) of all piglets born in February died.

Small intestinal samples from diseased piglets were taken from all four affected farms and subjected to next generation sequencing (NGS) using the Illumina MiSeq platform. Of the 338,036 total reads obtained, 369 mapped to viruses within the NCBI virus database, and 355 (96.2%) of these matched sequences of bat CoV

HKU2, a virus first detected in Chinese horseshoe bats in Hong Kong and Guangdong Province, China[19]. By *de novo* assembly and targeted PCR we sequenced a 27,173-bp coronavirus genome that shared 95% sequence identity to HKU2 (Genbank accession number NC009988.1). Four genomes of SADS-CoV were obtained, designated A, B, C and D corresponding to the four farms from which they were derived. These viruses are 99.9% identical to each other (**Extended Data Table 2**) (GenBank accession number: MF094681−MF094684), suggesting that inter-farm transmission was likely responsible for outbreaks on farms B, C and D.

Using quantitative PCR based on the nucleocapsid protein gene (see **Extended Data Table 3** for primer sequences), we detected SADS-CoV in acutely sick piglets and sows, but not in recovered or healthy pigs on the four farms, nor in nearby farms without evidence of SADS. The virus replicated to higher titers in piglets than in sows (**Fig. 1B**). SADS-CoV displayed tissue tropism for small intestine (**Fig. 1C**), as observed for other swine enteric coronaviruses[20] and HKU2 in bats[19]. Retrospective PCR analysis revealed that SADS-CoV was present on Farm A during the PEDV epidemic, where the first strongly positive SADS-CoV sample was detected on 6 December 2016. From mid-January onwards, SADS-CoV was the dominant viral agent detected in diseased animals (**Extended Data Figure 2**). Although PEDV was also detected occasionally during the outbreaks in Farms B, C and D, SADS-CoV was the dominant virus (**Extended Data Figure 2 & Table 1**).

We rapidly developed an antibody assay based on the S1 domain of the spike protein using the Luciferase Immunoprecipitation System (LIPS)[21]. As SADS is acute

with rapid onset in piglets, serological investigation was conducted only in sows. Among 46 recovered sows tested, 12 were seropositive for SADS-CoV within three weeks of infection (**Fig. 1D**). To investigate possible zoonotic transmission, serum samples from 35 farm workers who had close contact with sick pigs were subjected to the same LIPS test and none of them was positive for SADS-CoV. Continuous monitoring is required to assess whether the virus has the capacity to mutate and lead to human infection in future.

While the overall genome identity of SADS-CoV and bat CoV HKU2 is 95%, the spike gene (S) sequence identity is only 86%, suggesting that HKU2 is not the direct progenitor of SADS-CoV. To test the hypothesis of a bat origin for SADS-CoV, we developed a qPCR assay based on the SADS-CoV RNA dependent RNA polymerase (RdRp) gene (**Extended Data Table 3**) and screened 596 bat anal swabs collected from 2013-2016 from seven different locations in Guangdong Province (**Extended Data Figure 1**). A total of 71 samples (11.9%) tested positive (**Extended Data Table 4**), almost all of which (94.3%) were from *Rhinolophus* spp. bats (*R. pusillus, R. macrotis, R. sinicus, R. rex and R. affinis*), which are also the natural reservoir hosts of SARS-like coronaviruses[6-8, 22-24]. Complete genome sequences were determined by NGS from four samples that shared highest sequence identity to SADS-CoV, based on the amplicon region (GenBank accession number MF094685−MF094688). These four bat-derived genomes are very similar in size (27.2 kb) to SADS-CoV (**Fig. 2A**) and we tentatively nominate them SADS related coronaviruses (SADSr-CoV). Overall sequence identity to SADS-CoV ranges from

96-98%, higher than the 95% for HKU2-CoV. Importantly, the SADSr-CoV 162140 genome showing highest overall genome identity (98.48%) and S protein sequence identity (98.14%) was sampled in August 2016 less than 100 km from the index farm (**Extended Data Figure 1**). The geographic and temporal alignment of the two events strongly suggests that SADSr-CoV 162140 may be the direct ancestor of SADS-CoV. This is further corroborated by phylogenetic analysis (**Fig. 2B**), that shows bat SADSr-CoVs form a distinct cluster with SADS-CoV in the alpha CoV clade. The major differences among SADSr-CoVs lie in the predicted coding regions of the S and 3'-terminal ORF7a and ORF7b genes (**Fig. 2A**). The S1 domain of the S protein determines CoV host tropism[25]. An additional five S1 genes were sequenced (GenBank accession number MF094697−MF094701), and the S1 of sample 162140 and 141388 were found closest to that of SADS-CoV (**Extended Data Figure 3**). The close relationship among these two viruses and SADS-CoV is further supported by phylogentic analysis of the RdRp gene (**Extended Data Figure 4**).

Known coronavirus host cell receptors include angiotensin-converting enzyme 2 (ACE2) for SARS-related CoV, aminopeptidase N (APN) for PEDV, and dipeptidyl peptidase 4 (DPP4) for MERS-CoV[15,16,25]. To investigate the receptor usage of SADS-CoV, we used SADS-CoV positive samples or HIV pseudoviruses carrying the SADS-CoV S protein to infected HeLa cells which over-expressed all three receptor molecule. While the positive control infected by SL-CoV, MERS-CoV pseudovirus or PEDV showed successful infection or entry, we found no evidence of SADS-CoV

entry, suggesting that none of these three molecules are the functional receptor of SADS-CoV (**Extended Data Table 5**).

Swine enteric coronaviruses including PEDV, transmission gastroenteritis virus (TGEV) and porcine diarrhea coronavirus (PDCoV) are known to cause severe watery diarrhea and dehydration accompanied by histopathological lesions in the infected pigs. Clinically PEDV, TGEV, and PDCoV are indistinguishable[26]. In contrast, piglets infected with SADS-CoV mainly die of nutritional exhaustion rather than severe dehydration. Efforts to isolate virus isolation from intestinal tissues of infected piglets and from bat samples with low PCR Ct values have been unsuccessful to date, so that Koch's postulates cannot be fulfilled using traditional approaches. However, we successfully conducted animal challenge experiments using NGS to identify and confirm causality relationship. Fecal samples positive for SADS-CoV and negative for PEDV or any other known swine diarrhea virus by both NGS and PCR were fed to 3-day or 6-day old piglets. All piglets inoculated with SADS-CoV positive fecal matter exhibited severe diarrhea one day after challenge, while control animals remained healthy. On day 4 post infection, the 3-day but not the 6-day group suffered heavy weight loss and showed signs of nutritional exhaustion and became moribund (**Extended Data Table 6 & Figure 5**). Animals were euthanized for further analysis. Histopathological examinations showed similar lesions in the challenged piglets to those in naturally infected piglets (**Fig. 3A and 3B**). Using rabbit anti-recombinant SADSr-CoV NP serum, specific staining was detected mainly in the small intestines (**Fig. 3C and 3D**). Finally, qPCR and NGS were used to verify that

all diseased piglets were SADS-CoV positive and negative for other known swine diarrhea viruses; and that all control piglets were negative for SADS-CoV. It should be noted that piglets were fed with artificial formula during experimental challenge and the stable nutrient supply mitigated death in most of these animals. Conversely, naturally infected piglets often relied upon poor quantity and quality of milk from infected sows for their nutrition.

The rapid emergence and spread of SADS-CoV, and its high mortality rate in piglets constitute a major economic threat to the pork industry. Viral coinfection is rather common in swine, likely due to intensive farming practices. This was also true on the index farm where co-infection with PEDV and SADS-CoV was detected at the beginning of the outbreak, with SADS-CoV dominant towards later stages of the outbreak. As the barrier for the initial spillover of bat viruses into non-bat hosts is thought to be very difficult to overcome[27], the potential facilitating role of PEDV infection in the emergence of SADS-CoV should be further investigated, especially in the context of known antibody-dependent enhancement of CoV infections[28].

Although bats have been associated with many deadly disease outbreaks impacting both human and livestock, tracing the virus origin usually takes years (for Hendra, Nipah and SARS) if not decades (for Ebola and Marburg). To our knowledge this is the first example where a novel etiological agent discovered during a disease outbreak has been linked with a closely related progenitor virus in bats during the disease investigation itself. Two possible routes of transmission from bats to pigs are plausible: direct transmission via bat fecal contamination of a pig feedlot, and indirect

transmission via an amplifying host, as was originally proposed for SARS-CoV via civets[29]. Further investigation is needed to test these alternative hypotheses once virus isolation is successful.

The current study highlights the value of targeted surveillance in response to an emerging infectious disease event. It also demonstrates that by using modern technological platforms such as NGS and LIPS serology, key experiments that traditionally rely on isolation of live virus could be performed rapidly and prior to virus isolation. Finally, the bat origins of this lethal livestock disease, SARS and most likely MERS demonstrate the disproportionate importance of bats as reservoirs of viruses that threaten veterinary and public health[30].

METHODS

Sample collection

Bats were trapped in their natural habitat in Guangdong Province (**Extended Data Figure 1**). Fecal swab samples were collected in viral transport medium (VTM) composed of Hank's balanced salt solution at pH7.4 containing BSA (1%), amphotericin (15 μg/ml), penicillin G (100 units/ml), and streptomycin (50 μg/ml). Stool samples from sick pigs were collected in VTM. When appropriate and feasible, intestine samples were also taken from deceased animals. Samples were aliquoted and stored at -80 ^{0}C until use. Blood samples were collected from recovered sows and farm workers who had close contact with sick pigs. Serum was separated by centrifugation at 3,000 *g* for 15 min within 24 h of collection and preserved at 4 ^{0}C.

Human serum collection was approved by the Medical Ethics Committee of the Wuhan School of Public Health, Wuhan University and Hummingbird IRB.

Virus isolation

The following cells were used for virus isolation in this study: VeroE6 (cultured in DMEM +10% FBS); *Rhinolophus sinicus* primary or immortalized cells generated by our laboratory (all cultured in DMEM/F12 +15% FBS): kidney primary RsKi9409, lung primary RsLu4323, lung immortalized RsLuT, brain immortalized RsBrT and heart immortalized RsHeT; and swine cell lines: two intestinal IPEC (RPMI1640+10%FBS) and SIEC (DMEM+10%FBS), three kidney PK15, LLC-PK1 (DMEM+10% FBS for the two) and IBRS (MEM+10%FBS), and one testes ST (DMEM+10%FBS).

Cultured cell monolayers were maintained in their respective medium. PCR-positive pig fecal or homogenized pig intestinal supernatant (in 200 µl VTM) were filtered and diluted 1:10 with serum-free medium before being added to cells. After incubation at 37 ^{0}C for 1 h, the inoculum was removed and replaced with fresh culture medium containing 2% FCS. The cells were incubated at 37 ^{0}C and observed daily for cytopathic effect (CPE). Four blind passages (three-day interval between every passage) were performed for each sample. After each passage, both the culture supernatant and cell pellet were examined for presence of virus by RT-PCR using the SADS-CoV primers listed in Table S3. Penicillin (100 units/ml) and streptomycin (15 µg/ml) were included in all tissue culture media.

RNA extraction, S1 gene amplification and qPCR

Whenever commercial kits were used, manufacturer's instructions were followed without modification. RNA was extracted from 200 µl of swab samples (bat), feces or homogenized intestine (pig) with the High Pure Viral RNA Kit (Roche). RNA was eluted in 50 µl of elution buffer and was used as the template for RT-PCR. Reverse transcription was performed using the SuperScript III kit (Invitrogen).

To amplify S1 genes from bat samples, nested PCR was performed with primers designed based on HKU2-CoV (Genbank accession number NC009988.1)[19] (**Extended Data Table 3**). The 25-µl first-round PCR mixture contained 2.5 µl 10X PCR reaction buffer, 5 pmol of each primer, 50 mM MgCl2, 0.5 mM dNTP, 0.1 µl Platinum Taq Enzyme (Invitrogen) and 1 µl cDNA. The 50-µl second-round PCR mixture was identical to the first-round PCR mixture except the primers. Amplification of both rounds was performed as follows: 94 °C for 5 min followed by 60 cycles consisting of 94 °C for 30 s, 50 °C for 40 s, 72 °C for 2.5 min, and a final extension of 72 °C for 10 min. PCR products were gel purified and sequenced.

For qPCR analysis, primers based on SADS-CoV RdRp and NP genes were used (**Extended Data Table 3**). RNA extracted from above was reverse-transcribed using PrimeScript RT Master Mix (Takara). The 10-µl qPCR reaction mix contained 5 µl 2× SYBR premix Ex Taq II (Takara), 0.4 µM of each primer and 1 µl cDNA.

Amplification was performed as follows: 95 °C for 30 s followed by 40 cycles consisting of 95 °C for 5 s, 60 °C for 30 s, and a melting curve step.

Luciferase Immunoprecipitation System (LIPS) assay

LIPS was used in this study due to its simplicity and capacity to be rapidly deployed. The SADS-CoV S1 gene was codon optimized for eukaryotic expression and synthesized (GenScript) in frame with the Renilla luciferase gene (Rluc) and a FLAG tag in the pREN2 vector[21]. pREN2-S1 plasmids were transfected into Cos-1 cells using Lipofectamine (Invitrogen). At 48 h post-transfection, cells were harvested, lysed and a luciferease assay was performed to determine Rluc expression for both the empty vector (pREN2) and the pREN2-S1 construct. For testing of unknown pig or human serum samples, 1 µl of serum was incubated with 10 million units of Rluc alone (vector) and Rluc-S1, respectively, together with 3.5 µl of a 30% protein A/G ultralink beads suspension (Thermo Scientific). After extensive washing to remove unbounded luciferase-tagged antigen, captured luciferease amount was determined using the commercial luciferase substrate kit (Promega). The ratio of Rluc-S1/Rluc(Vector) was used to determine the specific S1 reactivity of pig and human sera. Commercial FLAG antibody (Life Technologies) was used as the positive control, and various pig sera (from uninfected animals in China or Singapore; or pigs infected with PEDV, TGEV or Nipah virus) were used as a negative control.

Protein expression and antibody production

The NP gene from SADSr-CoV 3755 (GenBank accession number MF094702), which shared a 98% aa sequence identity to the SADS-CoV NP gene, was inserted into pET-28a+ (Novagen) for prokaryotic expression. Transformed *E. coli* were grown at 37 °C for 12-18 h in media containing 1 mM IPTG. Bacteria were collected by centrifugation and resuspended in 30 ml of 5 mM imidazole and lysed by sonication. The lysate, from which NP protein expression was confirmed with an anti-HIS-tag antibody, was applied to the Ni2+ resin (Thermo Scientific). The purified NP protein, at a concentration of 400 μg/ml, was used to immunize rabbits for antibody production following published methods[31]. After immunization and two boosts with N protein, rabbits were euthanized and sera were collected. Rabbit anti-N sera were diluted 1:10,000 for subsequent Western blots.

Amplification, cloning and expression of the human and swine genes

Construction of expression clones for human ACE2 in pcDNA3.1 has been described previously[8]. Human DPP4 was amplified from human cell lines. Human APN gene was synthesized. Swine APN and ACE2 genes were amplified from piglet intestine. Full-length gene fragments were amplified using specific primers (provided upon request). The human APN, DPP4 and ACE2 genes were cloned into pCDNA3.1 fused with HIS tag. The pig APN and ACE2 genes were cloned into pCAGGS fused with S tag. Purified plasmids were transfected to HeLa cells. After 24 h, HeLa cells expressing human or swine genes were confirmed by immunofluorescence assay (IFA). Human APN, ACE2 and DPP4 expression was detected using mouse anti-HIS

tag monoclonal antibody or rabbit anti-human APN polyclonal antibody (made by ourselves) followed by cyanin 3-labeled goat anti-mouse/rabbit IgG from proteintech (Proteintech Group). Swine APN and ACE2 expression was detected using mouse anti-S tag monoclonal antibody followed by cyanin 3-labeled goat anti-mouse IgG from proteintech (Proteintech Group).

Pseudovirus preparation

The codon-humanized S protein genes of SADS-CoV and MERS-CoV cloned into pcDNA3.1(+) and pHIV-Luc (pNL4.3.Luc.R$^-$E$^-$Luc) were used for pseudovirus construction as described previously[8,32]. Briefly, 15 μg of each pHIV-Luc (pNL4.3.Luc.R$^-$E$^-$Luc) and the S protein expressing plasmids (or empty vector control) were co-transfected into 4 x 10^6 293T cells using Lipo3000 (Invitrogen) transfection system. After 4 h, the medium was replaced with fresh medium. Supernatants were harvested at 48 h post transfection and separated from cell debris by centrifugation at 3,000g, then by passing through a 0.45μm filter (Millipore). The filtered supernatants were stored at -80°C in aliquots until use. To evaluate the incorporation of S proteins into the core of HIV virions, pseudoviruses in the supernatant (20 ml) were concentrated by ultracentrifugation through a 20% sucrose cushion (5ml) at 80,000g for 90 min using a SW41 rotor (Beckman). Pelleted pseudoviruses were dissolved in 50μl phosphate-buffered saline (PBS) and examined by electron microscopy (EM).

Pseudovirus infection

HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared by a lipo2000 system (Invitrogen). Pseudoviruses prepared above were added to each 96-well plate seeded with Hela cells at 24 h post transfection of APN, ACE2 or DPP4 expression plasmids. The unabsorbed viruses were replaced with fresh medium at 3 h post infection. The infection was monitored by measuring the luciferase activity conferred by the reporter gene carried by the pseudovirus, using the Luciferase Assay System (Promega) as follows: cells were lysed at 48 h post infection, and 20 μl of the lysates was taken for determining luciferase activity by the addition of 50 μl of luciferase substrate.

SADS-CoV positive samples infection and IFA.

HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared by a lipo2000 system (Invitrogen) in 96-well plate, with mock-transfected cells as controls. SADS-CoV RNA positive samples were used to infect Hela cells at 24h post transfection. The inoculum was removed after 1h absorption and washed twice with PBS and supplemented with medium. PEDV, SARS-like-CoV WIV16 and MERS-CoV HIV-pseudovirus were used as positive control for swine APN, human/swine ACE2 and human DPP4, respectively. At 24 h post infection, cells were washed with PBS and fixed with 4% formaldehyde in PBS (pH 7.4) for 20 min at room temperature. SL-CoV WIV16 replication was detected using rabbit antibody against the SL-CoV Rp3 nucleocapsid protein followed by cyanin 3-conjugated goat

358 anti-rabbit IgG. PEDV and SADS-CoV replication was detected using rabbit antibody
359 against the HKU2 CoV nucleocapsid protein followed by cyanin 3-conjugated goat
360 anti-rabbit IgG. Nucleus was stained with 4',6'-diamidino-2-phenylindole (DAPI).
361 Staining patterns were examined using the FV1200 confocal microscopy (Olympus).
362 The successful infection of MERS CoV HIV-pseudovirus was indicated by luciferase
363 on 48h post infection.
364
365 **High throughput sequencing and genome assembly**
366 RNA was extracted from the small intestine of deceased pigs and
367 reverse-transcribed into cDNA as described above. Sequencing libraries were
368 constructed using NEBNext Ultra II DNA Library Prep Kit for Illumina (New
369 England Biolabs) according to the manufacturer's instructions. High throughput
370 sequencing was performed with Illumina MiSeq sequencer. Low quality reads and
371 short reads were filtered. Clean reads were searched against a viral database with the
372 BLASTN program. PCR amplifications were applied to fill the gaps. Amplicons from
373 the same sample were pooled for library preparation and sequenced with the same
374 methodology as described above. All filtered reads were assembled using CLC
375 Genomic Workbench (ver 9.0). 5'-RACE was performed to determine the 5'-end of
376 the genomes. Genomes were annotated using Clone Manager Professional Suite 8
377 (Sci-Ed Software).
378
379 **Phylogenetic analysis**

SADS-CoV genome sequences and other representative coronavirus sequences (obtained from GenBank) were aligned using MAFFT (ver 7.221). Phylogenetic analyses with full-length genome, S gene and RNA-dependent RNA polymerase gene (RdRp) were performed using MrBayes v3.2 (Stop Valve=0.01) with GTR+G+I model (General Time Reversible model of nucleotide substitution with a proportion of invariant sites and γ-distributed rates among sites).

Animal infection study

Experiments were carried out strictly in accordance with the recommendations of the Guide for the Care and Use of Laboratory Animals of the National Institutes of Health. The use of animals in this study was approved by the South China Agricultural University Committee of Animal Experiments (approval ID: 201004152).

Two animal challenge experiments were performed (see detailed planning in **Extended Data Table 6**). Healthy, swine diarrhea virus free, piglets (3- or 6-day old) were orally fed with homogenized intestinal samples from SADS-CoV infected piglets. Inocula were confirmed as SADS-CoV positive, but negative for all other known swine diarrhea viruses. Two control groups of piglets were fed with homogenized intestine from healthy piglets or milk only. Animals were observed daily for signs of disease, such as diarrhea, weight loss and nutritional exhaustion. Fecal swabs were collected daily from all animals and screened for all known swine diarrhea viruses. At experimental endpoints, piglets were humanely euthanized and

402 necropsies performed. Ileal, jejunal and duodenal tissues were taken from selected
403 animals and store in at -80 ^{0}C for further analysis.
404
405 **Hematoxylin and eosin (H&E) and immunohistochemistry (IHC) analysis**
406 Frozen (-80 ^{0}C) small intestinal tissues including duodenum, jejunum, and
407 ileum taken from the above experimentally infected pigs were pre-frozen at -20 ^{0}C for
408 10 min. Tissues were then embedded in optimal cutting temperature compound and
409 cut into 8-μm sections using the Cryotome FSE machine (Thermo Scientific).
410 Mounted microscope slides were fixed with paraformaldehyde and stained with H&E
411 for histopathological examination.
412 For IHC analysis, the rabbit antibody raised above was used for specific
413 staining of SADS-CoV antigen. Slides were blocked by incubating with 10% goat
414 serum (Beyotime) at 37 ^{0}C for 30 min, followed by overnight incubation at 4 ^{0}C with
415 the rabbit anti-3755 N protein serum diluted at 1:1000 in PBST buffer containing 1%
416 goat serum. After washing, slides were then incubated for 50 min at room temperature
417 with HRP conjugated protein A+G (Thermo Scientific) diluted at 1:1000 in PBST
418 buffer containing 1% goat serum. Slides were developed using 3,3' diaminobenzidine
419 substrate (Servicebio) before images were taken using the Pannoramic MIDI system
420 (3D HISTECH).
421
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523

524 **AUTHOR CONTRIBUTIONS:** L.F.W, Z.L.S, P.Z, T.Y.G, M.J.Y conceived the
525 study. P.Z, W.Z, Y.Z, M.S, X.S.Z, B.L, X.L.Y, H.G, D.S, Y.L, X.L.L, J.C performed
526 qPCR, serology, histology and virus culturing. H.F, Y.W.Z, J.M.L, G.Q.P, X.P.A,
527 Z.Q.M, T.T.H, Y.H, Q.S, X.L.L.Z performed genome sequencing and annotations.
528 T.L, Q.M.X, J.W.C, L.Z, K.J.M, Z.X.W, L.B.Z, S.Y.L, Y.S,C, Y.S prepared the
529 samples and animal challenges. Z.L.S., P.D., L.B.Z, S.Y.L coordinated collection of
530 bat samples. P.Z, L.F.W, Z.L.S, P.D prepared the draft.

531

AUTHOR INFORMATION

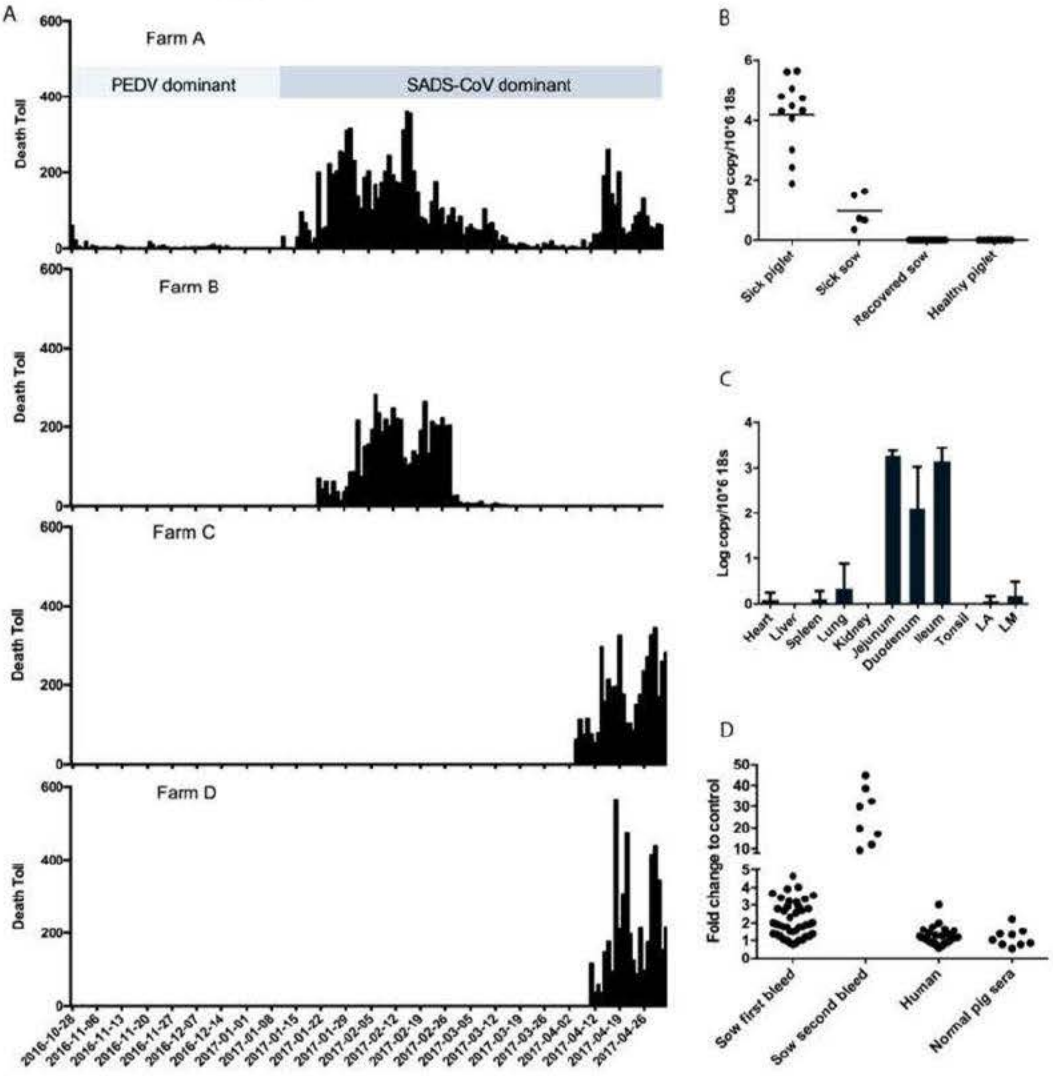
Full-length genomic sequences or S sequences of SADS-CoV and SARSr-CoV have been deposited in GenBank under accession numbers MF094681-MF094688 and MF094697-MF094701, respectively.

The authors declare no competing financial interests. Correspondence and requests for materials should be addressed to ZLS. (zlshi@wh.iov.cn).

FIGURE LEGENDS

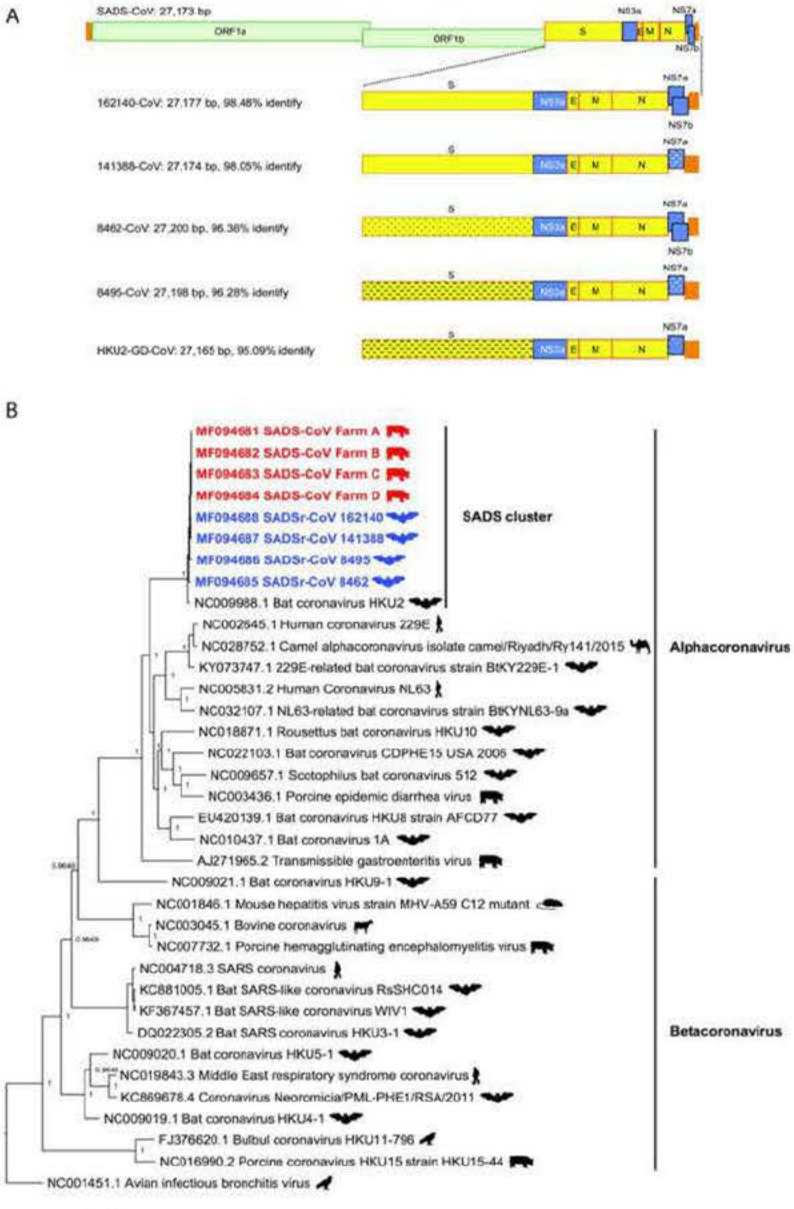
Figure 1. Detection of SADS-CoV infection in pigs in Guangdong, China.

(A) Chronology of outbreaks and the mortality rate on the four different farms. Daily number of pig deaths was recorded from 26 October 2016 to 2 May 2017. The outbreak is ongoing as of the current date. (B) Detection of SADS-CoV by qPCR in different groups of pigs. (C) Tissue distribution of SADS-CoV in diseased pigs. LA- Lymphonodi abdominals; LM- Lymphoglandulae mesentericae. (D) Detection of SADS-CoV antibodies using S1-specific LIPS assay. Infected sows were bled during the initial three weeks of the outbreak, then >1 month after the beginning of the outbreak. Healthy pig sera were set as control.



553 **Figure 2. Genome and phylogeny analysis of SADS-CoV and SADSr-CoV.**

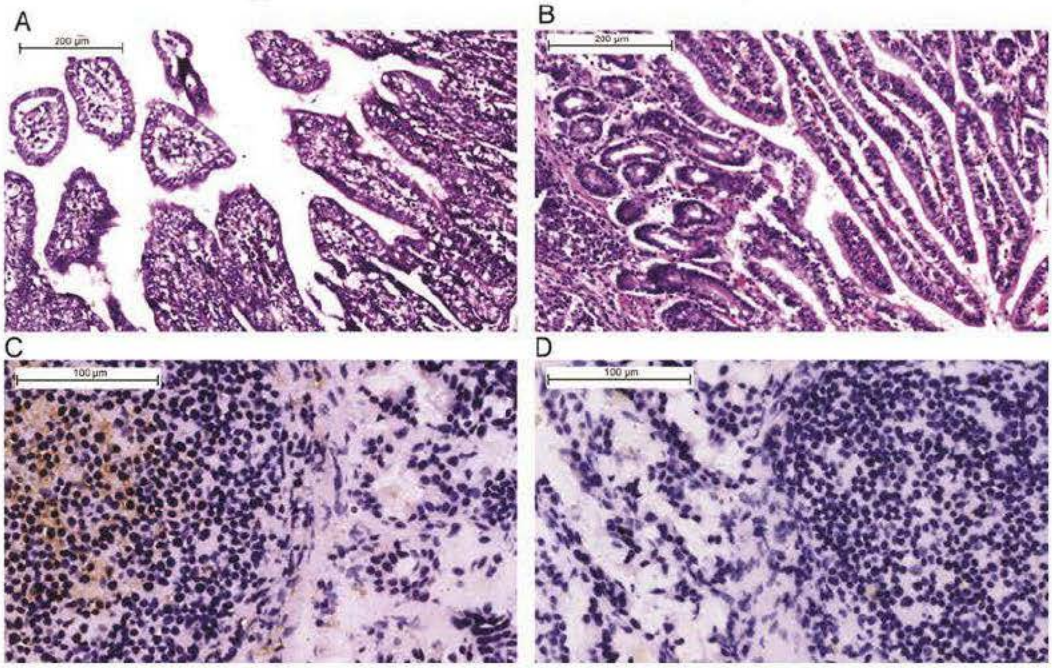
554 (A) Genome organization and comparison. Colored boxes represent genes or UTRs:
555 Green- nonstructural polyproteins ORF1a and 1b; Yellow- structural proteins S, E, M
556 and N; Blue- nonstructural accessory proteins NS3a, NS7a and Ns7b; Orange- UTRs.
557 The level of sequence identity of SADSr-CoV to SADS-CoV was illustrated by
558 patterns; Open box- highly similar; Dots- moderately similar; Dashed line- least
559 similar. (B) Phylogenetic tree based on full-length genome sequences. The Bayesian
560 tree was constructed using MrBayes v3.2 with the average standard deviation of split
561 frequencies under 0.01. The host of each sequence was marked by the animal symbols
562 on the right and newly sequenced SADS-CoVs are highlighted in red while bat
563 SADSr-CoVs in blue.



564

Figure 3 Immunohistopathology of SARS-CoV infected tissues.

(A) and (B), Hematoxylin and eosin staining of jejunum with and without infection. (C) and (D), Immunohistochemistry staining of jejunum with and without infection using rabbit serum raised against the recombinant SADSr-CoV NP protein.



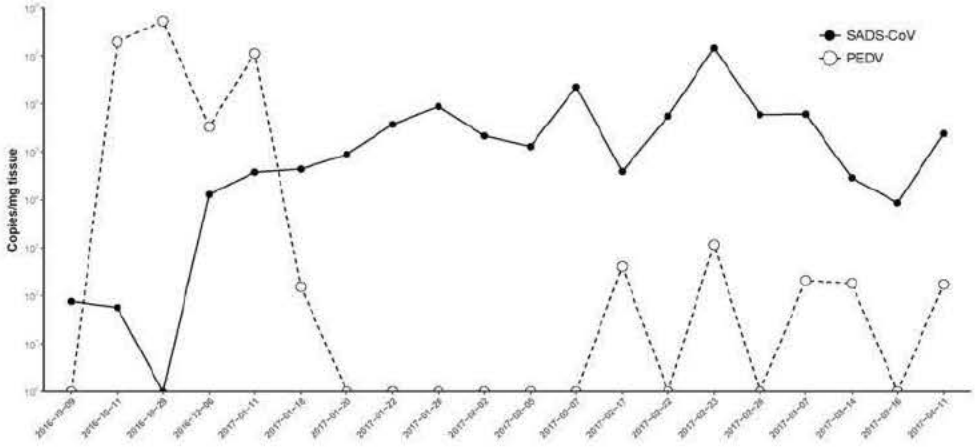
EXTENDED DATA LEGENDS

Extended Data Figure 1. Map of Guangdong Province, China.

SADS-affected farms are labeled A to D with blue swine symbols following the temporal sequence of the outbreaks. Bat sampling sites are identified by black bat symbols. The bat SADSr-CoV most closely related to SADS-CoV (sample 162140) originated Conghua. The red flag marks Foshan city, site of the index case of SARS..

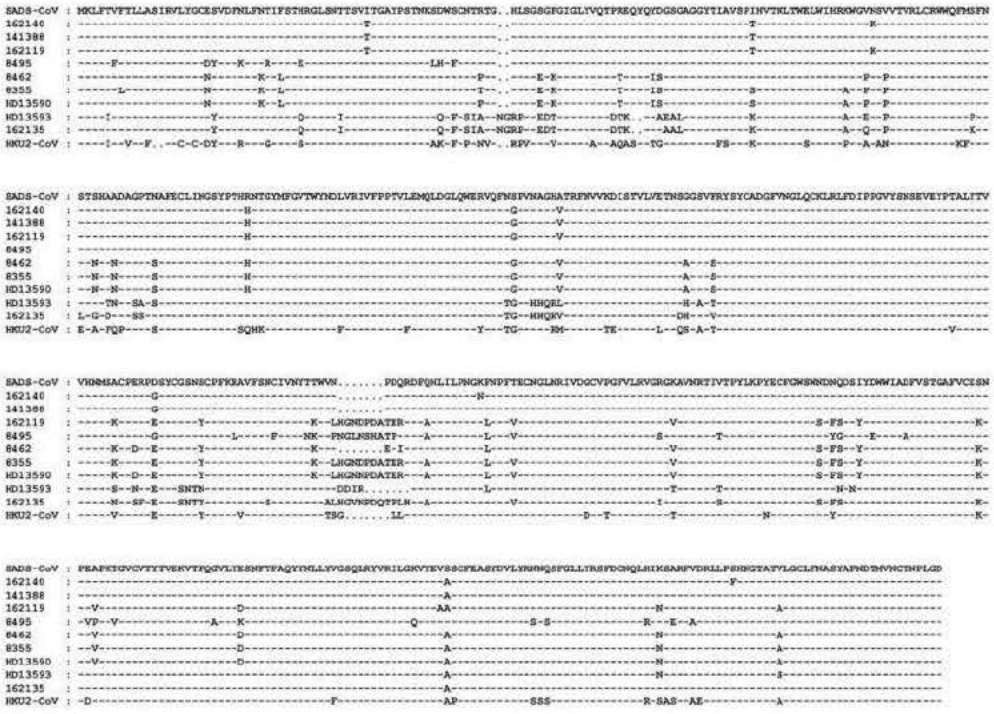
Extended Data Figure 2. Co-circulation of PEDV and SADS-CoV during the initial outbreak on Farm A.

Pooled intestinal samples were collected at dates given on the x-axis from deceased piglets and analyzed by qPCR. The intensity infection for each piglet is shown as a copy number per milligram of intestine (y-axis).



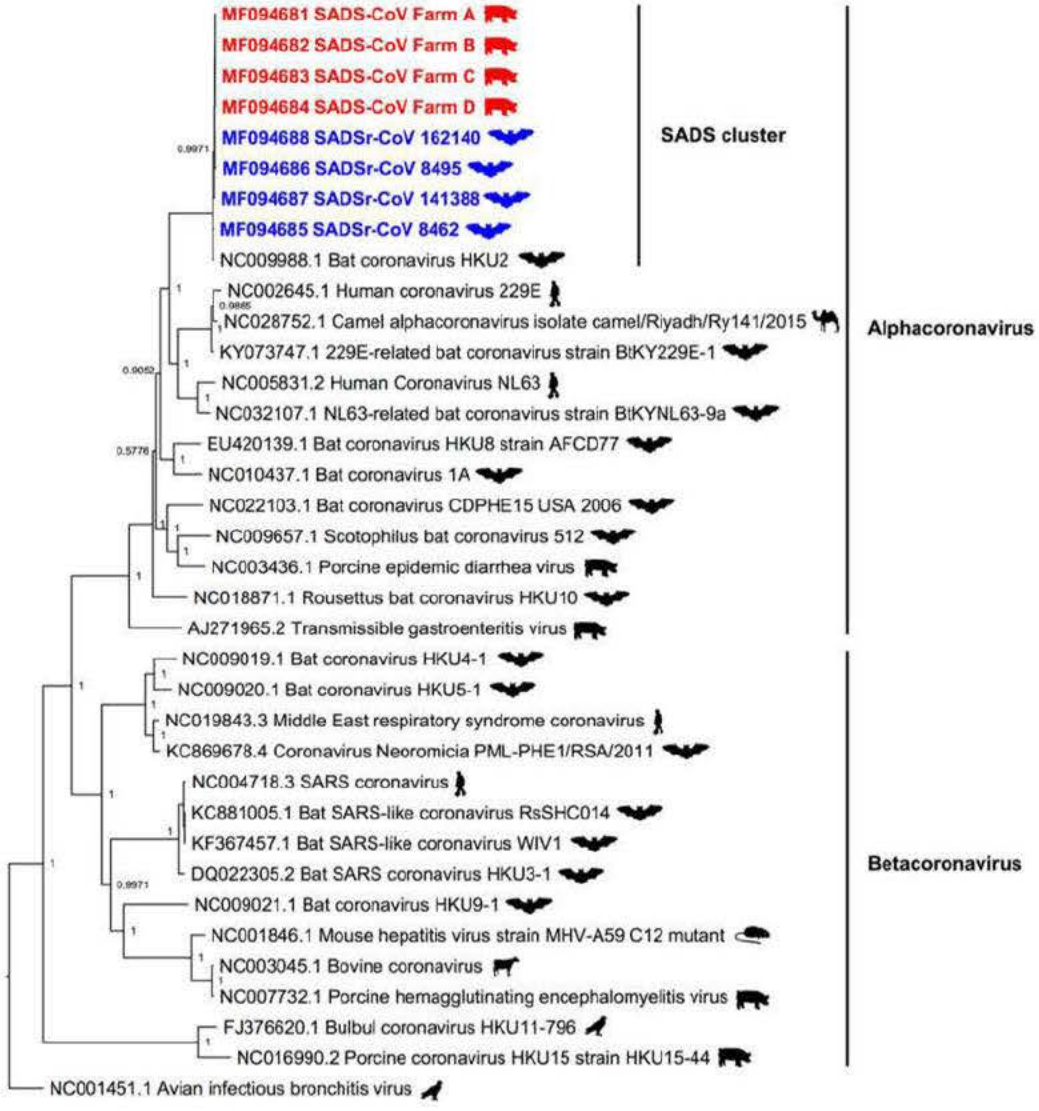
Extended Data Figure 3. Alignment of amino acid sequences of S1 proteins of the SADS cluster of coronaviruses.

The top sequence is from SADS-CoV Farm A. The four SADSr-CoV S1 sequences (162140, 141388, 162119 and 162135) were derived from NGS whole genome sequencing. HKU2-CoV is from a published report[19]. Five additional S1 sequences (8495, 8462, 8355, HD13590 and HD13593) from bats were determined by PCR and Sanger sequencing as described in the text. Dashed lines indicate identical residues while dots represent gaps.



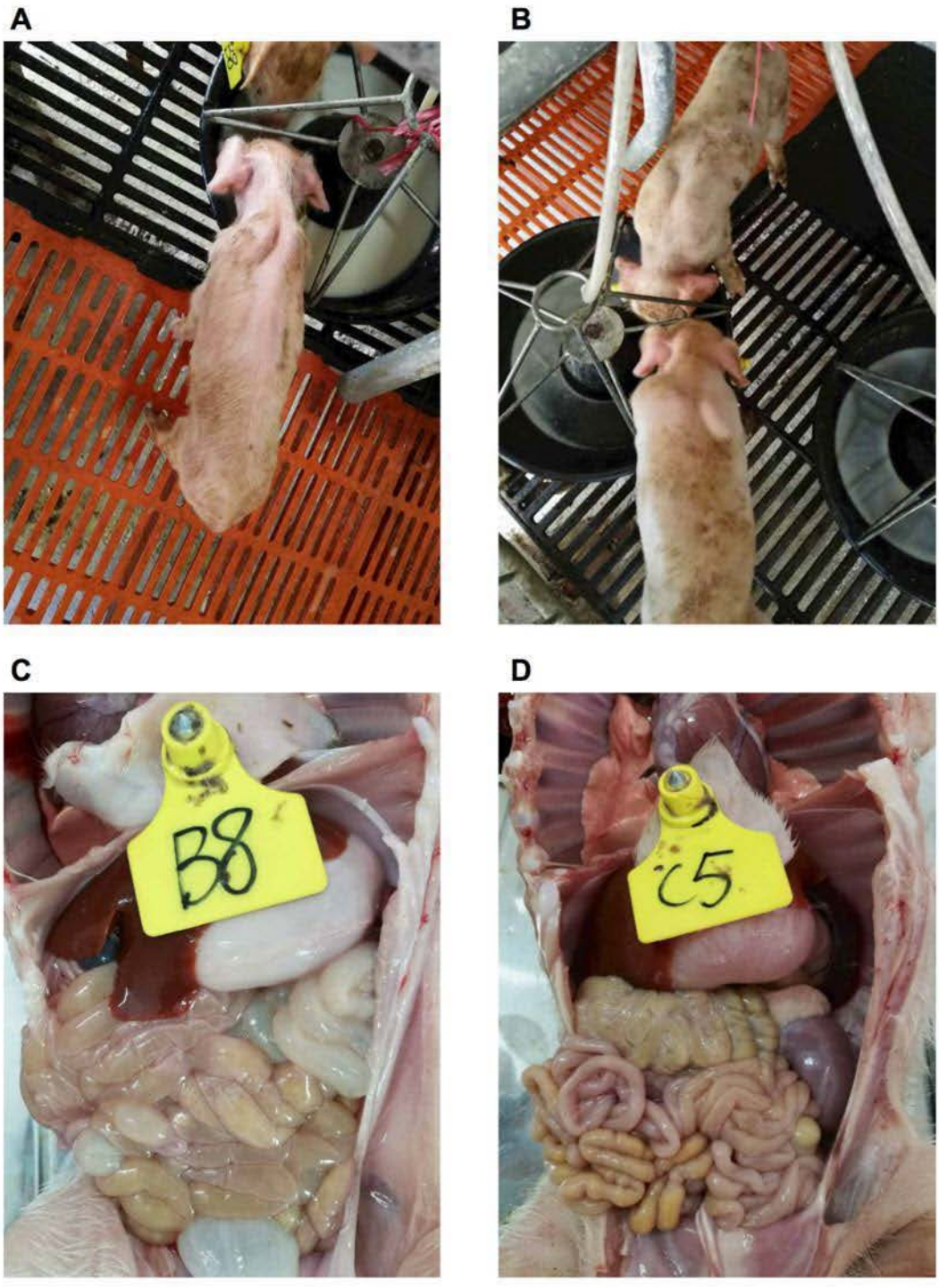
Extended Data Figure 4. Bayesian phylogenetic tree of the sequences encoding RdRp of SADS-CoV and related coronaviruses.

Tree was constructed using MrBayes v3.2 with the average standard deviation of split frequencies under 0.01. The host of each sequence is represented pictorially. Newly sequenced SADS-CoVs are highlighted in red while bat SADSr-CoVs are highlighted in blue.



Extended Data Figure 5. SADS-CoV experimentally infected and healthy piglets.

(A) Piglet on day 2 post SADS-CoV infection. (B) Mock infected piglet on day 2. (C) Intestine from infected piglet at necropsy. (D) Intestine from mock-infected piglet at necropsy.



Extended Data Table 1. List of all known swine viruses tested by PCR at the beginning of the of SADS outbreak investigation on the four farms *.

	PED V	PDC oV	TGE V	R V	PB V	PS V	SV A	SI V	NADC 30	PR V	FMD V	CSF V	PC V2	PC V3	APP V	PP V	Norovir us
Farm A	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND	-
Farm B	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND	-
Farm C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND
Farm D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND

* Dash indicates negative PCR result. ND, not done. Virus abbreviations: PEDV- Porcine Epidemic Diarrhea Virus; PDCoV- Porcine Delta Coronavirus; TGEV-Porcine Transmissible Gastroenteritis Virus; RV- Porcine Rotavirus; PBV- Porcine Picobirnavirus; PSV- Porcine Sapelo Virus; SVA- Porcine Senecavirus A; SIV- Swine Influenza Virus; PPRV- Porcine Reproductive and Respiratory Syndrome Virus, strain NADC30; PRV- Porcine Pseudorabies Virus; FMDV- Foot and Mouth Disease Virus; CSFV- Classical Swine Fever Virus; PCV2- Porcine Circovirus 2; PCV3- Porcine Circovirus 3; APPV- Atypical Porcine Pestivirus; PPV- Porcine Parvovirus.

622 **Extended Data Table 2. List of nucleotide and amino acid (aa) residue variants**
623 **among the SADS-CoV genomes obtained from the four different farms.**
624

Nucleotide residue position*	Gene name	Amino acid (aa) residue position*	Farm A nucleotide (aa)	Farm B nucleotide (aa)	Farm C nucleotide (aa)	Farm D nucleotide (aa)
2236	ORF1a	645	G(A)	G(A)	G(A)	T(S)
2955	ORF1a	884	T(G)	C(G)	T(G)	T(G)
3285	ORF1a	994	G(E)	G(E)	G(E)	T(D)
15395	ORF1b	915	C(T)	C(T)	C(T)	T(T)
18410	ORF1b	1920	C(G)	T(G)	T(G)	T(G)
20219	ORF1b	2523	C(L)	T(L)	T(L)	T(L)
21622	S	379	C(N)	C(N)	C(N)	A(K)

625 Non-synonymous aa substitutions are marked in red. * SADS-CoV from Farm A was used as the
626 reference sequence, from which the residue numbering was derived.

627 **Extended Data Table 3. List of PCR primers used in this study.**

628

Gene	Primer name and location*	Primer sequence	Application
RdRp gene	SADS-RdRp-F (19512-19531) SADS-RdRp-R (19590-19608)	GTTGATTGTAAGGCTTGGCG AACCACACTTCCACTCAGC	qPCR
N gene	SADS-N-F (25810-25830) SADS-N-R (25938-25957)	CTAAAACTAGCCCCACAGGTC TGATTGCGAGAACGAGACTG	qPCR
S gene	HKU2-S1-1F (20066-20085) HKU2-S1-1R (22317-22336)	GGCGCTATGGCTGTTAAGAT CACGAATGTCAGCCTCAACT	Cloning
S gene	HKU2-S1-2F (20157-20176) HKU2-S1-2R (22218-22238)	CCAGTGTCAACACGTCATCT ACGCTGAACTTAGGCATTGTA	Cloning

629 * The numbering system of SADS-CoV from Farm A was used as for Extended Data Table 2.

630

631 **Extended Data Table 4. List of SADSr-CoVs detected in bats in Guangdong,**
632 **China.**

Sampling			PCR analysis	
Time (Month-Year)	Location	Bat Species	Fecal swabs sampled	PCR Positive
Jun 13	Yingde	*Rhinolophus sinicus*	1	1
		Pipistrellus abramus	8	0
		Myotis ricketti	2	0
Jul 13	Yangshan	*Pipistrellus abramus*	1	0
		Hipposideros pratti	36	1
Jul 13; May 14; Jun 15; Aug 16	Ruyuan	*Rhinolophus sinicus*	27	6
		Rhinolophus affinis	11	2
		Rhinolophus macrotis	3	0
		Rhinolophus pusillus	41	6
		Rhinolophus rex	9	7
		Hipposideros pratti	7	0
Sep 14; Jun 15; Aug 16	Conghua	*Rhinolophus sinicus*	70	2
		Rhinolophus affinis	34	7
		Rhinolophus pusillus	11	2
		Hipposideros pomona	10	0
		Myotis ricketti	1	0
Jun 13; Nov 13; Aug 14; Jun 15	Huidong	*Rhinolophus sinicus*	37	2
		Rhinolophus affinis	59	29
		Rhinolophus macrotis	15	2
		Rhinolophus pusillus	1	0
		Hipposideros pomona	2	0
		Myotis ricketti	84	1
Apr 14; Jun 15	Longgang	*Rhinolophus sinicus*	55	1
		Pipistrellus abramus	5	1
Sep 14	Xiangzhou	*Rhinolophus pusillus*	28	0
		Hipposideros pomona	38	1
		Total	596	71 (11.9%)

633
634 See Fig. S1 for sampling sites in relation to SARS and SADS outbreak locations
635

Extended Data Table 5. Multiple human CoV receptors as well as swine APN cannot be utilized as entry receptor for SADS-CoV.

	HuAPN★	HuACE2★	HuDPP4★	SwAPN★	SwACE2★
SADS-CoV*	-	-	-	-	-
SARS-like-CoV	NA	+	NA	NA	+
MERS-CoV#	NA	NA	+	NA	NA
PEDV	NA	NA	NA	NA	NA
Expression$	+ (APN Ab)	+ (HIS-tag Ab)	+ (DPP4 Ab)	+ (S-tag Ab)	+ (S-tag Ab)

★Gene accession numbers for the genes used in this study: human APN, M22324.1; human ACE2, NM_021804; human DPP4, NM_001935.3; swine APN, NM_214277.1; swine ACE2, XM_021079374.1

* For SADS-CoV infection, both positive samples and HIV-pseudovirus were used. Viral positive samples were from SADS infected pig anal swabs: SusAS-7 (4.0×10^5 copy/μl), SusAS-20 (4.3×10^5 copy/μl), SusAS-22 (2.4×10^5 copy/μl).

For MERS-CoV infection, HIV-pseudovirus were used.

$ Expression of APN, DPP4 and ACE2 was confirmed by antibodies against the targeting proteins or fused tags.

649 **Extended Data Table 6. Experimental outline of SADS-CoV infection of piglets.**

650 Experiments were performed with (A) 3-day old or (B) 6-day old piglets. Infection
651 was performed as described in the Material and Methods.

652

A

Groups	Infection material	Number	Age (days)	Infection Dose	Infection route	SADS-CoV titer (copy/μl)	First day				Second day				Fourth day
							Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Nutrition exhaustion and Dying
A	SC1 (SADS-CoV positive)	5	3	3mL	Oral+milk	6.54×10^5	5	5	5	0	5	5	5	0	3
B	DE2 (SADS-CoV positive)	5	3	3mL	Oral+milk	10.62×10^5	5	4	5	0	5	3	5	0	1
C	Mock	4	3	3mL	Oral+milk	0	0	0	0	0	0	0	0	0	0
D	Empty mock	4	3	0ml	Milk only	0	3 mild diarrhea	0	0	0	1	0	0	0	0

B

Groups	Infection material	Number	Age (days)	Infection Dose	Infection route	SADS-CoV titer (copy/mg)	First day				Second day				Fourth day
							Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Nutrition exhaustion and Dying
A	SC1 (SADS-CoV positive)	6	6	2mL	Oral+milk	6.54×10^5	5	3	6	0	1	0	6	0	0
B	DE2 (SADS-CoV positive)	5	6	2mL	Oral+milk	1.20×10^5	3	3	5	0	3 moderate	1	5	0	0
C	Mock	6	6	2mL	Oral+milk	0	0	0	0	0	0	0	0	0	0
D	Empty mock	5	6	0ml	Milk only	0	0	0	0	0	0	0	0	0	0

653

From: Booth, Mason (NIH/NIAID) [C]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: FW: Swine coronavirus paper - EcoHealthAlliance
Date: Wednesday, August 2, 2017 12:46:48 PM
Attachments: 2017-05-06890 full manuscript.pdf

Hi Erik – Did you hear if this paper from EcoHealth Alliance was accepted by Nature, and, if so, what the publication date is?
Thank you!
Mason

From: Peter Daszak (b) (6)
Sent: Thursday, June 29, 2017 2:39 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Hongying Li (b) (6)
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

Hi Erik,

I just wanted to say thanks for hosting us at NIAD today – it was great to have an interested audience with good questions and nice to have a chance to introduce our collaborators to you personally.

I mentioned the upcoming SADS-CoV paper might get into *Nature*. Obviously, this is touch-and-go right now, but I've attached the draft here so you can forward it to your communications team in case they want to get a release out earlier this time.

By the way – we've had some great publicity from the other paper last week. If you go to the following link we've put some of the stories up on our EHA website here:
http://www.ecohealthalliance.org/updates

Hope you enjoy skimming through them, and thanks again for setting up the talk this morning.

Cheers,
Peter

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President
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www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

Title: Fatal Swine Disease Outbreak Caused by a Novel Coronavirus of Bat Origin

Authors: Peng Zhou[1]*, Hang Fan[2]*, Tian Lan[3]*, Xing-Lou Yang[1], Wei Zhang[1], Yan Zhu[1], Ya-Wei Zhang[2], Qing-Mei Xie[3], Shailendra Mani[4], Xiao-Shuang Zheng[1], Bei Li[1], Jin-Man Li[2], Hua Guo[1], Guang-Qian Pei[2], Xiao-Ping An[2], Jun-Wei Chen[3], Ling Zhou[3], Kaijie Mai[3], Zi-Xian Wu[3], Danielle E. Anderson[4], Li-Biao Zhang[5], Shi-Yue Li[6], Zhi-Qiang Mi[2], Tong-Tong He[2], Yun Luo[1], Xiang-Ling Liu[1], Jing Chen[1], Yong Huang[2], Qiang Sun[2], Xiang-Li-Lan Zhang[2], Yan-Shan Cheng[3], Yuan Sun[3], Peter Daszak[7], Lin-Fa Wang[4]†, Zheng-Li Shi[1]†, Yi-Gang Tong[2]†, Jing-Yun Ma[3]†

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Spillover of bat-origin coronaviruses is implicated in the emergence of two emerging, high-impact zoonoses, SARS and MERS. Here, we report virological, epidemiological and experimental infection evidence that a novel bat-origin coronavirus, Swine Acute Diarrhea Syndrome coronavirus (SADS-CoV), caused an ongoing outbreak of lethal diarrheal disease in pigs in China. The outbreak began in January 2017 Guangdong Province in the vicinity of the origin of the SARS pandemic in 2002, and has caused the death of 24,693 piglets in four farms to date. We identified SADS related-CoVs with 96-98% sequence identity to SADS-CoV in 11.9% (71/596) of anal swabs collected from bats in Guangdong Province during 2013-16, predominantly in five *Rhinolophus* spp. horseshoe bats that are known reservoirs of SARS-like CoVs. The geographic, temporal, ecological and etiological similarities in the emergence of SADS and SARS highlight the urgent need to identify coronavirus diversity in bats to mitigate future outbreaks that threaten veterinary production, public health and economic growth.

The emergence of severe acute respiratory syndrome in southern China in 2002, which was caused by a previously unknown coronavirus (SARS-CoV)[1-5] and led to more than 8,000 human infections and 774 deaths [http://www.who.int/csr/sars/en/], heralded two new frontiers in emerging infectious diseases. Firstly, it demonstrated that coronaviruses are capable of causing fatal diseases in humans. Secondly, the identification of bats as the reservoir for SARS-related coronaviruses, and likely

53 origin of SARS-CoV[6-8] firmly established bats as an important source of highly lethal
54 zoonotic viruses, which include Hendra, Nipah, Ebola and Marburg viruses[9].
55 The public health threat posed by novel coronaviruses was reinforced by the
56 emergence of the Middle East respiratory syndrome coronavirus (MERS-CoV) in
57 2012[10], which has so far infected 1,952 people with 693 deaths
58 [http://www.who.int/emergencies/mers-cov/en/]. Cases of MERS have been reported
59 in 27 countries, mostly due to imported cases with the exception of a major outbreak
60 in Seoul in 2015 that involved extensive local human-to-human transmissions[11].
61 While dromedary camels have been identified as the main source of MERS-CoV
62 spillover to humans[12], there is evidence suggesting that bats are the original wildlife
63 reservoir. This includes short sequence from a single *Taphozous perforatus* bat in
64 Saudi Arabia, and evidence that bat MERS-related coronaviruses use the same human
65 entry receptor, dipeptidyl peptidase 4 (DPP4; also known as CD26), as
66 MERS-CoV[13-16].
67 Here we report a series of fatal swine disease outbreaks in Guangdong
68 Province, China, approximately 100 km from the location of the purported index case
69 of SARS. Most strikingly, we found that the causative agent for this swine acute
70 diarrhea syndrome (SADS) is a novel coronavirus which is almost 99% identical in
71 genome sequence to a bat coronavirus we detected in 2016 from a bat cave in the
72 vicinity of the index pig farm. This new virus (SADS-CoV) thus appears to have
73 originated from the same genus of horseshoe bats (*Rhinolophus*) as SARS-CoV.

From 28 October 2016, fatal swine disease outbreaks were observed in a pig farm in Qingyuan, Guangdong Province, China, very close to the location of the first known index case of SARS in Foshan (**Extended Data Figure 1**). Porcine epidemic diarrhea virus (PEDV) had caused prior outbreaks at this farm, and was detected in the intestine of deceased piglets at the start of the outbreak. However, PEDV could no longer be detected in deceased piglets after 12th January 2017, despite accelerating mortality (**Fig. 1**A) and extensive testing for other common swine viruses yielded negative results (**Extended Data Table 1**). These findings suggested an outbreak of a novel disease, which we designated swine acute diarrhea syndrome (SADS). Clinical signs are similar to those caused by other known swine enteric coronaviruses [17,18] and include severe and acute diarrhea, and rapid weight loss, leading to death due to nutritional exhaustion in newborn piglets less than four days of age. Infected piglets died 2-6 days following disease onset, while infected sows suffered only mild diarrhea and most recovered in two days. The disease caused no signs of febrile illness in piglets or sows. The disease has spread to three additional pig farms within 20-150 km of the index farm (**Extended Data Figure 1**) and, as of 2nd May 2017, has resulted in the death of 24,693 piglets from four farms (**Fig. 1A**). In Farm A alone, 64% (4659/7268) of all piglets born in February died.

Small intestinal samples from diseased piglets were taken from all four affected farms and subjected to next generation sequencing (NGS) using the Illumina MiSeq platform. Of the 338,036 total reads obtained, 369 mapped to viruses within the NCBI virus database, and 355 (96.2%) of these matched sequences of bat CoV

HKU2, a virus first detected in Chinese horseshoe bats in Hong Kong and Guangdong Province, China[19]. By *de novo* assembly and targeted PCR we sequenced a 27,173-bp coronavirus genome that shared 95% sequence identity to HKU2 (Genbank accession number NC009988.1). Four genomes of SADS-CoV were obtained, designated A, B, C and D corresponding to the four farms from which they were derived. These viruses are 99.9% identical to each other (**Extended Data Table 2**) (GenBank accession number: MF094681−MF094684), suggesting that inter-farm transmission was likely responsible for outbreaks on farms B, C and D.

Using quantitative PCR based on the nucleocapsid protein gene (see **Extended Data Table 3** for primer sequences), we detected SADS-CoV in acutely sick piglets and sows, but not in recovered or healthy pigs on the four farms, nor in nearby farms without evidence of SADS. The virus replicated to higher titers in piglets than in sows (**Fig. 1B**). SADS-CoV displayed tissue tropism for small intestine (**Fig. 1C**), as observed for other swine enteric coronaviruses[20] and HKU2 in bats[19]. Retrospective PCR analysis revealed that SADS-CoV was present on Farm A during the PEDV epidemic, where the first strongly positive SADS-CoV sample was detected on 6 December 2016. From mid-January onwards, SADS-CoV was the dominant viral agent detected in diseased animals (**Extended Data Figure 2**). Although PEDV was also detected occasionally during the outbreaks in Farms B, C and D, SADS-CoV was the dominant virus (**Extended Data Figure 2 & Table 1**).

We rapidly developed an antibody assay based on the S1 domain of the spike protein using the Luciferase Immunoprecipitation System (LIPS)[21]. As SADS is acute

with rapid onset in piglets, serological investigation was conducted only in sows. Among 46 recovered sows tested, 12 were seropositive for SADS-CoV within three weeks of infection (**Fig. 1D**). To investigate possible zoonotic transmission, serum samples from 35 farm workers who had close contact with sick pigs were subjected to the same LIPS test and none of them was positive for SADS-CoV. Continuous monitoring is required to assess whether the virus has the capacity to mutate and lead to human infection in future.

While the overall genome identity of SADS-CoV and bat CoV HKU2 is 95%, the spike gene (S) sequence identity is only 86%, suggesting that HKU2 is not the direct progenitor of SADS-CoV. To test the hypothesis of a bat origin for SADS-CoV, we developed a qPCR assay based on the SADS-CoV RNA dependent RNA polymerase (RdRp) gene (**Extended Data Table 3**) and screened 596 bat anal swabs collected from 2013-2016 from seven different locations in Guangdong Province (**Extended Data Figure 1**). A total of 71 samples (11.9%) tested positive (**Extended Data Table 4**), almost all of which (94.3%) were from *Rhinolophus* spp. bats (*R. pusillus, R. macrotis, R. sinicus, R. rex and R. affinis*), which are also the natural reservoir hosts of SARS-like coronaviruses[6-8, 22-24]. Complete genome sequences were determined by NGS from four samples that shared highest sequence identity to SADS-CoV, based on the amplicon region (GenBank accession number MF094685−MF094688). These four bat-derived genomes are very similar in size (27.2 kb) to SADS-CoV (**Fig. 2A**) and we tentatively nominate them SADS related coronaviruses (SADSr-CoV). Overall sequence identity to SADS-CoV ranges from

96-98%, higher than the 95% for HKU2-CoV. Importantly, the SADSr-CoV 162140 genome showing highest overall genome identity (98.48%) and S protein sequence identity (98.14%) was sampled in August 2016 less than 100 km from the index farm (**Extended Data Figure 1**). The geographic and temporal alignment of the two events strongly suggests that SADSr-CoV 162140 may be the direct ancestor of SADS-CoV. This is further corroborated by phylogenetic analysis (**Fig. 2B**), that shows bat SADSr-CoVs form a distinct cluster with SADS-CoV in the alpha CoV clade. The major differences among SADSr-CoVs lie in the predicted coding regions of the S and 3'-terminal ORF7a and ORF7b genes (**Fig. 2A**). The S1 domain of the S protein determines CoV host tropism[25]. An additional five S1 genes were sequenced (GenBank accession number MF094697−MF094701), and the S1 of sample 162140 and 141388 were found closest to that of SADS-CoV (**Extended Data Figure 3**). The close relationship among these two viruses and SADS-CoV is further supported by phylogentic analysis of the RdRp gene (**Extended Data Figure 4**).

Known coronavirus host cell receptors include angiotensin-converting enzyme 2 (ACE2) for SARS-related CoV, aminopeptidase N (APN) for PEDV, and dipeptidyl peptidase 4 (DPP4) for MERS-CoV[15,16,25]. To investigate the receptor usage of SADS-CoV, we used SADS-CoV positive samples or HIV pseudoviruses carrying the SADS-CoV S protein to infected HeLa cells which over-expressed all three receptor molecule. While the positive control infected by SL-CoV, MERS-CoV pseudovirus or PEDV showed successful infection or entry, we found no evidence of SADS-CoV

entry, suggesting that none of these three molecules are the functional receptor of SADS-CoV (**Extended Data Table 5**).

Swine enteric coronaviruses including PEDV, transmission gastroenteritis virus (TGEV) and porcine diarrhea coronavirus (PDCoV) are known to cause severe watery diarrhea and dehydration accompanied by histopathological lesions in the infected pigs. Clinically PEDV, TGEV, and PDCoV are indistinguishable[26]. In contrast, piglets infected with SADS-CoV mainly die of nutritional exhaustion rather than severe dehydration. Efforts to isolate virus isolation from intestinal tissues of infected piglets and from bat samples with low PCR Ct values have been unsuccessful to date, so that Koch's postulates cannot be fulfilled using traditional approaches. However, we successfully conducted animal challenge experiments using NGS to identify and confirm causality relationship. Fecal samples positive for SADS-CoV and negative for PEDV or any other known swine diarrhea virus by both NGS and PCR were fed to 3-day or 6-day old piglets. All piglets inoculated with SADS-CoV positive fecal matter exhibited severe diarrhea one day after challenge, while control animals remained healthy. On day 4 post infection, the 3-day but not the 6-day group suffered heavy weight loss and showed signs of nutritional exhaustion and became moribund (**Extended Data Table 6 & Figure 5**). Animals were euthanized for further analysis. Histopathological examinations showed similar lesions in the challenged piglets to those in naturally infected piglets (**Fig. 3A and 3B**). Using rabbit anti-recombinant SADSr-CoV NP serum, specific staining was detected mainly in the small intestines (**Fig. 3C and 3D**). Finally, qPCR and NGS were used to verify that

all diseased piglets were SADS-CoV positive and negative for other known swine diarrhea viruses; and that all control piglets were negative for SADS-CoV. It should be noted that piglets were fed with artificial formula during experimental challenge and the stable nutrient supply mitigated death in most of these animals. Conversely, naturally infected piglets often relied upon poor quantity and quality of milk from infected sows for their nutrition.

The rapid emergence and spread of SADS-CoV, and its high mortality rate in piglets constitute a major economic threat to the pork industry. Viral coinfection is rather common in swine, likely due to intensive farming practices. This was also true on the index farm where co-infection with PEDV and SADS-CoV was detected at the beginning of the outbreak, with SADS-CoV dominant towards later stages of the outbreak. As the barrier for the initial spillover of bat viruses into non-bat hosts is thought to be very difficult to overcome[27], the potential facilitating role of PEDV infection in the emergence of SADS-CoV should be further investigated, especially in the context of known antibody-dependent enhancement of CoV infections[28].

Although bats have been associated with many deadly disease outbreaks impacting both human and livestock, tracing the virus origin usually takes years (for Hendra, Nipah and SARS) if not decades (for Ebola and Marburg). To our knowledge this is the first example where a novel etiological agent discovered during a disease outbreak has been linked with a closely related progenitor virus in bats during the disease investigation itself. Two possible routes of transmission from bats to pigs are plausible: direct transmission via bat fecal contamination of a pig feedlot, and indirect

transmission via an amplifying host, as was originally proposed for SARS-CoV via civets[29]. Further investigation is needed to test these alternative hypotheses once virus isolation is successful.

The current study highlights the value of targeted surveillance in response to an emerging infectious disease event. It also demonstrates that by using modern technological platforms such as NGS and LIPS serology, key experiments that traditionally rely on isolation of live virus could be performed rapidly and prior to virus isolation. Finally, the bat origins of this lethal livestock disease, SARS and most likely MERS demonstrate the disproportionate importance of bats as reservoirs of viruses that threaten veterinary and public health[30].

METHODS

Sample collection

Bats were trapped in their natural habitat in Guangdong Province (**Extended Data Figure 1**). Fecal swab samples were collected in viral transport medium (VTM) composed of Hank's balanced salt solution at pH7.4 containing BSA (1%), amphotericin (15 μg/ml), penicillin G (100 units/ml), and streptomycin (50 μg/ml). Stool samples from sick pigs were collected in VTM. When appropriate and feasible, intestine samples were also taken from deceased animals. Samples were aliquoted and stored at -80 ^{0}C until use. Blood samples were collected from recovered sows and farm workers who had close contact with sick pigs. Serum was separated by centrifugation at 3,000 *g* for 15 min within 24 h of collection and preserved at 4 ^{0}C.

Human serum collection was approved by the Medical Ethics Committee of the Wuhan School of Public Health, Wuhan University and Hummingbird IRB.

Virus isolation

The following cells were used for virus isolation in this study: VeroE6 (cultured in DMEM +10% FBS); *Rhinolophus sinicus* primary or immortalized cells generated by our laboratory (all cultured in DMEM/F12 +15% FBS): kidney primary RsKi9409, lung primary RsLu4323, lung immortalized RsLuT, brain immortalized RsBrT and heart immortalized RsHeT; and swine cell lines: two intestinal IPEC (RPMI1640+10%FBS) and SIEC (DMEM+10%FBS), three kidney PK15, LLC-PK1 (DMEM+10% FBS for the two) and IBRS (MEM+10%FBS), and one testes ST (DMEM+10%FBS).

Cultured cell monolayers were maintained in their respective medium. PCR-positive pig fecal or homogenized pig intestinal supernatant (in 200 µl VTM) were filtered and diluted 1:10 with serum-free medium before being added to cells. After incubation at 37 ^{0}C for 1 h, the inoculum was removed and replaced with fresh culture medium containing 2% FCS. The cells were incubated at 37 ^{0}C and observed daily for cytopathic effect (CPE). Four blind passages (three-day interval between every passage) were performed for each sample. After each passage, both the culture supernatant and cell pellet were examined for presence of virus by RT-PCR using the SADS-CoV primers listed in Table S3. Penicillin (100 units/ml) and streptomycin (15 µg/ml) were included in all tissue culture media.

RNA extraction, S1 gene amplification and qPCR

Whenever commercial kits were used, manufacturer's instructions were followed without modification. RNA was extracted from 200 µl of swab samples (bat), feces or homogenized intestine (pig) with the High Pure Viral RNA Kit (Roche). RNA was eluted in 50 µl of elution buffer and was used as the template for RT-PCR. Reverse transcription was performed using the SuperScript III kit (Invitrogen).

To amplify S1 genes from bat samples, nested PCR was performed with primers designed based on HKU2-CoV (Genbank accession number NC009988.1)[19] (**Extended Data Table 3**). The 25-µl first-round PCR mixture contained 2.5 µl 10X PCR reaction buffer, 5 pmol of each primer, 50 mM MgCl2, 0.5 mM dNTP, 0.1 µl Platinum Taq Enzyme (Invitrogen) and 1 µl cDNA. The 50-µl second-round PCR mixture was identical to the first-round PCR mixture except the primers. Amplification of both rounds was performed as follows: 94 °C for 5 min followed by 60 cycles consisting of 94 °C for 30 s, 50 °C for 40 s, 72 °C for 2.5 min, and a final extension of 72 °C for 10 min. PCR products were gel purified and sequenced.

For qPCR analysis, primers based on SADS-CoV RdRp and NP genes were used (**Extended Data Table 3**). RNA extracted from above was reverse-transcribed using PrimeScript RT Master Mix (Takara). The 10-µl qPCR reaction mix contained 5 µl 2× SYBR premix Ex Taq II (Takara), 0.4 µM of each primer and 1 µl cDNA.

Amplification was performed as follows: 95 °C for 30 s followed by 40 cycles consisting of 95 °C for 5 s, 60 °C for 30 s, and a melting curve step.

Luciferase Immunoprecipitation System (LIPS) assay

LIPS was used in this study due to its simplicity and capacity to be rapidly deployed. The SADS-CoV S1 gene was codon optimized for eukaryotic expression and synthesized (GenScript) in frame with the Renilla luciferase gene (Rluc) and a FLAG tag in the pREN2 vector[21]. pREN2-S1 plasmids were transfected into Cos-1 cells using Lipofectamine (Invitrogen). At 48 h post-transfection, cells were harvested, lysed and a luciferease assay was performed to determine Rluc expression for both the empty vector (pREN2) and the pREN2-S1 construct. For testing of unknown pig or human serum samples, 1 µl of serum was incubated with 10 million units of Rluc alone (vector) and Rluc-S1, respectively, together with 3.5 µl of a 30% protein A/G ultralink beads suspension (Thermo Scientific). After extensive washing to remove unbounded luciferase-tagged antigen, captured luciferease amount was determined using the commercial luciferase substrate kit (Promega). The ratio of Rluc-S1/Rluc(Vector) was used to determine the specific S1 reactivity of pig and human sera. Commercial FLAG antibody (Life Technologies) was used as the positive control, and various pig sera (from uninfected animals in China or Singapore; or pigs infected with PEDV, TGEV or Nipah virus) were used as a negative control.

Protein expression and antibody production

The NP gene from SADSr-CoV 3755 (GenBank accession number MF094702), which shared a 98% aa sequence identity to the SADS-CoV NP gene, was inserted into pET-28a+ (Novagen) for prokaryotic expression. Transformed *E. coli* were grown at 37 °C for 12-18 h in media containing 1 mM IPTG. Bacteria were collected by centrifugation and resuspended in 30 ml of 5 mM imidazole and lysed by sonication. The lysate, from which NP protein expression was confirmed with an anti-HIS-tag antibody, was applied to the Ni2+ resin (Thermo Scientific). The purified NP protein, at a concentration of 400 μg/ml, was used to immunize rabbits for antibody production following published methods[31]. After immunization and two boosts with N protein, rabbits were euthanized and sera were collected. Rabbit anti-N sera were diluted 1:10,000 for subsequent Western blots.

Amplification, cloning and expression of the human and swine genes

Construction of expression clones for human ACE2 in pcDNA3.1 has been described previously[8]. Human DPP4 was amplified from human cell lines. Human APN gene was synthesized. Swine APN and ACE2 genes were amplified from piglet intestine. Full-length gene fragments were amplified using specific primers (provided upon request). The human APN, DPP4 and ACE2 genes were cloned into pCDNA3.1 fused with HIS tag. The pig APN and ACE2 genes were cloned into pCAGGS fused with S tag. Purified plasmids were transfected to HeLa cells. After 24 h, HeLa cells expressing human or swine genes were confirmed by immunofluorescence assay (IFA). Human APN, ACE2 and DPP4 expression was detected using mouse anti-HIS

tag monoclonal antibody or rabbit anti-human APN polyclonal antibody (made by ourselves) followed by cyanin 3-labeled goat anti-mouse/rabbit IgG from proteintech (Proteintech Group). Swine APN and ACE2 expression was detected using mouse anti-S tag monoclonal antibody followed by cyanin 3-labeled goat anti-mouse IgG from proteintech (Proteintech Group).

Pseudovirus preparation

The codon-humanized S protein genes of SADS-CoV and MERS-CoV cloned into pcDNA3.1(+) and pHIV-Luc (pNL4.3.Luc.R$^-$E$^-$Luc) were used for pseudovirus construction as described previously[8,32]. Briefly, 15 μg of each pHIV-Luc (pNL4.3.Luc.R$^-$E$^-$Luc) and the S protein expressing plasmids (or empty vector control) were co-transfected into 4 x 10^6 293T cells using Lipo3000 (Invitrogen) transfection system. After 4 h, the medium was replaced with fresh medium. Supernatants were harvested at 48 h post transfection and separated from cell debris by centrifugation at 3,000g, then by passing through a 0.45μm filter (Millipore). The filtered supernatants were stored at -80°C in aliquots until use. To evaluate the incorporation of S proteins into the core of HIV virions, pseudoviruses in the supernatant (20 ml) were concentrated by ultracentrifugation through a 20% sucrose cushion (5ml) at 80,000g for 90 min using a SW41 rotor (Beckman). Pelleted pseudoviruses were dissolved in 50μl phosphate-buffered saline (PBS) and examined by electron microscopy (EM).

Pseudovirus infection

HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared by a lipo2000 system (Invitrogen). Pseudoviruses prepared above were added to each 96-well plate seeded with Hela cells at 24 h post transfection of APN, ACE2 or DPP4 expression plasmids. The unabsorbed viruses were replaced with fresh medium at 3 h post infection. The infection was monitored by measuring the luciferase activity conferred by the reporter gene carried by the pseudovirus, using the Luciferase Assay System (Promega) as follows: cells were lysed at 48 h post infection, and 20 μl of the lysates was taken for determining luciferase activity by the addition of 50 μl of luciferase substrate.

SADS-CoV positive samples infection and IFA.

HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared by a lipo2000 system (Invitrogen) in 96-well plate, with mock-transfected cells as controls. SADS-CoV RNA positive samples were used to infect Hela cells at 24h post transfection. The inoculum was removed after 1h absorption and washed twice with PBS and supplemented with medium. PEDV, SARS-like-CoV WIV16 and MERS-CoV HIV-pseudovirus were used as positive control for swine APN, human/swine ACE2 and human DPP4, respectively. At 24 h post infection, cells were washed with PBS and fixed with 4% formaldehyde in PBS (pH 7.4) for 20 min at room temperature. SL-CoV WIV16 replication was detected using rabbit antibody against the SL-CoV Rp3 nucleocapsid protein followed by cyanin 3-conjugated goat

358 anti-rabbit IgG. PEDV and SADS-CoV replication was detected using rabbit antibody
359 against the HKU2 CoV nucleocapsid protein followed by cyanin 3-conjugated goat
360 anti-rabbit IgG. Nucleus was stained with 4',6'-diamidino-2-phenylindole (DAPI).
361 Staining patterns were examined using the FV1200 confocal microscopy (Olympus).
362 The successful infection of MERS CoV HIV-pseudovirus was indicated by luciferase
363 on 48h post infection.
364
365 **High throughput sequencing and genome assembly**
366 RNA was extracted from the small intestine of deceased pigs and
367 reverse-transcribed into cDNA as described above. Sequencing libraries were
368 constructed using NEBNext Ultra II DNA Library Prep Kit for Illumina (New
369 England Biolabs) according to the manufacturer's instructions. High throughput
370 sequencing was performed with Illumina MiSeq sequencer. Low quality reads and
371 short reads were filtered. Clean reads were searched against a viral database with the
372 BLASTN program. PCR amplifications were applied to fill the gaps. Amplicons from
373 the same sample were pooled for library preparation and sequenced with the same
374 methodology as described above. All filtered reads were assembled using CLC
375 Genomic Workbench (ver 9.0). 5'-RACE was performed to determine the 5'-end of
376 the genomes. Genomes were annotated using Clone Manager Professional Suite 8
377 (Sci-Ed Software).
378
379 **Phylogenetic analysis**

SADS-CoV genome sequences and other representative coronavirus sequences (obtained from GenBank) were aligned using MAFFT (ver 7.221). Phylogenetic analyses with full-length genome, S gene and RNA-dependent RNA polymerase gene (RdRp) were performed using MrBayes v3.2 (Stop Valve=0.01) with GTR+G+I model (General Time Reversible model of nucleotide substitution with a proportion of invariant sites and γ-distributed rates among sites).

Animal infection study

Experiments were carried out strictly in accordance with the recommendations of the Guide for the Care and Use of Laboratory Animals of the National Institutes of Health. The use of animals in this study was approved by the South China Agricultural University Committee of Animal Experiments (approval ID: 201004152).

Two animal challenge experiments were performed (see detailed planning in **Extended Data Table 6**). Healthy, swine diarrhea virus free, piglets (3- or 6-day old) were orally fed with homogenized intestinal samples from SADS-CoV infected piglets. Inocula were confirmed as SADS-CoV positive, but negative for all other known swine diarrhea viruses. Two control groups of piglets were fed with homogenized intestine from healthy piglets or milk only. Animals were observed daily for signs of disease, such as diarrhea, weight loss and nutritional exhaustion. Fecal swabs were collected daily from all animals and screened for all known swine diarrhea viruses. At experimental endpoints, piglets were humanely euthanized and

402 necropsies performed. Ileal, jejunal and duodenal tissues were taken from selected
403 animals and store in at -80 ^{0}C for further analysis.
404
405 **Hematoxylin and eosin (H&E) and immunohistochemistry (IHC) analysis**
406 Frozen (-80 ^{0}C) small intestinal tissues including duodenum, jejunum, and
407 ileum taken from the above experimentally infected pigs were pre-frozen at -20 ^{0}C for
408 10 min. Tissues were then embedded in optimal cutting temperature compound and
409 cut into 8-μm sections using the Cryotome FSE machine (Thermo Scientific).
410 Mounted microscope slides were fixed with paraformaldehyde and stained with H&E
411 for histopathological examination.
412 For IHC analysis, the rabbit antibody raised above was used for specific
413 staining of SADS-CoV antigen. Slides were blocked by incubating with 10% goat
414 serum (Beyotime) at 37 ^{0}C for 30 min, followed by overnight incubation at 4 ^{0}C with
415 the rabbit anti-3755 N protein serum diluted at 1:1000 in PBST buffer containing 1%
416 goat serum. After washing, slides were then incubated for 50 min at room temperature
417 with HRP conjugated protein A+G (Thermo Scientific) diluted at 1:1000 in PBST
418 buffer containing 1% goat serum. Slides were developed using 3,3' diaminobenzidine
419 substrate (Servicebio) before images were taken using the Pannoramic MIDI system
420 (3D HISTECH).
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526 qPCR, serology, histology and virus culturing. H.F, Y.W.Z, J.M.L, G.Q.P, X.P.A,
527 Z.Q.M, T.T.H, Y.H, Q.S, X.L.L.Z performed genome sequencing and annotations.
528 T.L, Q.M.X, J.W.C, L.Z, K.J.M, Z.X.W, L.B.Z, S.Y.L, Y.S,C, Y.S prepared the
529 samples and animal challenges. Z.L.S., P.D., L.B.Z, S.Y.L coordinated collection of
530 bat samples. P.Z, L.F.W, Z.L.S, P.D prepared the draft.

531

AUTHOR INFORMATION

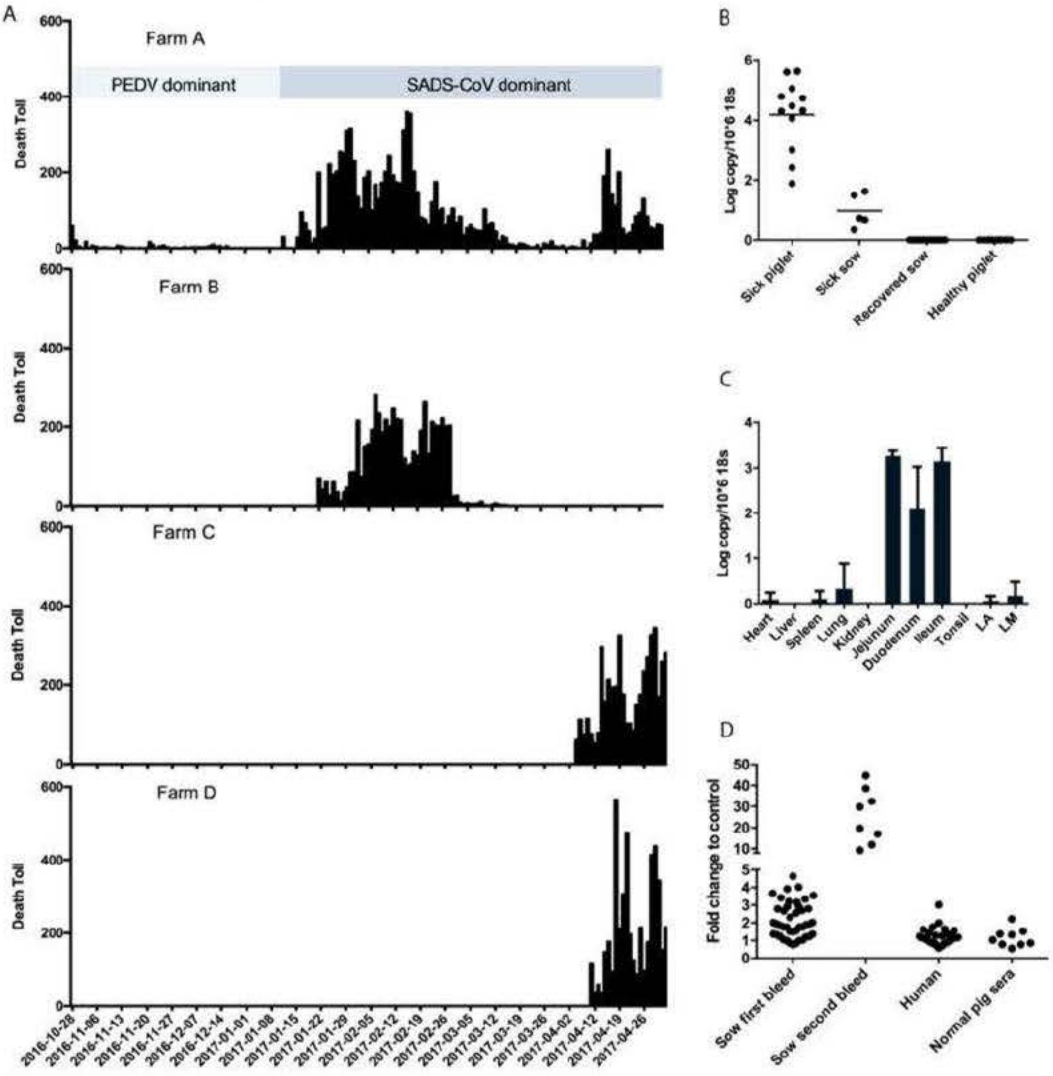
Full-length genomic sequences or S sequences of SADS-CoV and SARSr-CoV have been deposited in GenBank under accession numbers MF094681-MF094688 and MF094697-MF094701, respectively.

The authors declare no competing financial interests. Correspondence and requests for materials should be addressed to ZLS. (zlshi@wh.iov.cn).

FIGURE LEGENDS

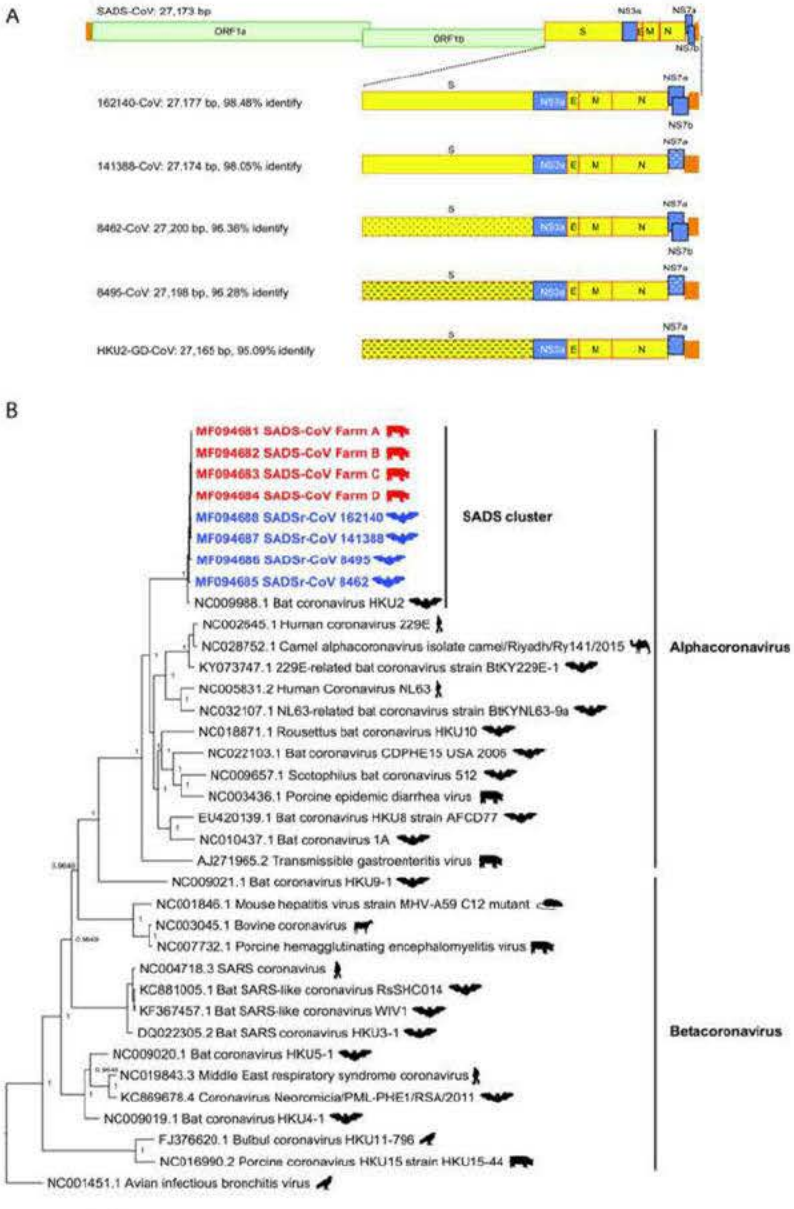
Figure 1. Detection of SADS-CoV infection in pigs in Guangdong, China.

(A) Chronology of outbreaks and the mortality rate on the four different farms. Daily number of pig deaths was recorded from 26 October 2016 to 2 May 2017. The outbreak is ongoing as of the current date. (B) Detection of SADS-CoV by qPCR in different groups of pigs. (C) Tissue distribution of SADS-CoV in diseased pigs. LA- Lymphonodi abdominals; LM- Lymphoglandulae mesentericae. (D) Detection of SADS-CoV antibodies using S1-specific LIPS assay. Infected sows were bled during the initial three weeks of the outbreak, then >1 month after the beginning of the outbreak. Healthy pig sera were set as control.



553 **Figure 2. Genome and phylogeny analysis of SADS-CoV and SADSr-CoV.**

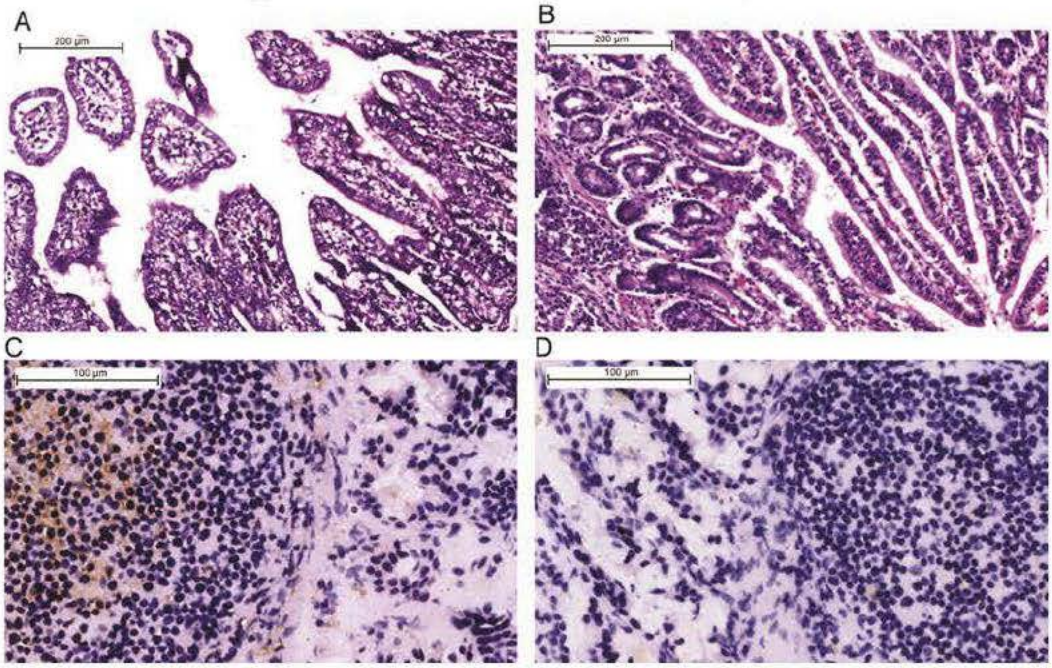
554 (A) Genome organization and comparison. Colored boxes represent genes or UTRs:
555 Green- nonstructural polyproteins ORF1a and 1b; Yellow- structural proteins S, E, M
556 and N; Blue- nonstructural accessory proteins NS3a, NS7a and Ns7b; Orange- UTRs.
557 The level of sequence identity of SADSr-CoV to SADS-CoV was illustrated by
558 patterns; Open box- highly similar; Dots- moderately similar; Dashed line- least
559 similar. (B) Phylogenetic tree based on full-length genome sequences. The Bayesian
560 tree was constructed using MrBayes v3.2 with the average standard deviation of split
561 frequencies under 0.01. The host of each sequence was marked by the animal symbols
562 on the right and newly sequenced SADS-CoVs are highlighted in red while bat
563 SADSr-CoVs in blue.



564

Figure 3 Immunohistopathology of SARS-CoV infected tissues.

(A) and (B), Hematoxylin and eosin staining of jejunum with and without infection. (C) and (D), Immunohistochemistry staining of jejunum with and without infection using rabbit serum raised against the recombinant SADSr-CoV NP protein.



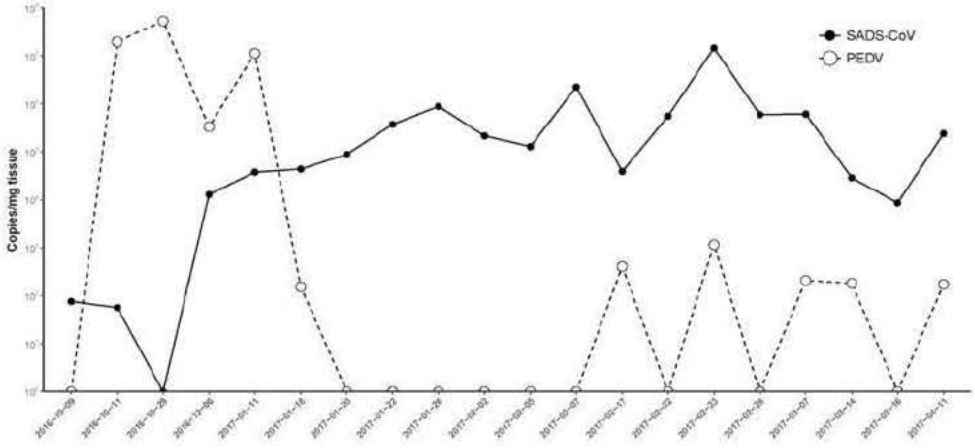
EXTENDED DATA LEGENDS

Extended Data Figure 1. Map of Guangdong Province, China.

SADS-affected farms are labeled A to D with blue swine symbols following the temporal sequence of the outbreaks. Bat sampling sites are identified by black bat symbols. The bat SADSr-CoV most closely related to SADS-CoV (sample 162140) originated Conghua. The red flag marks Foshan city, site of the index case of SARS..

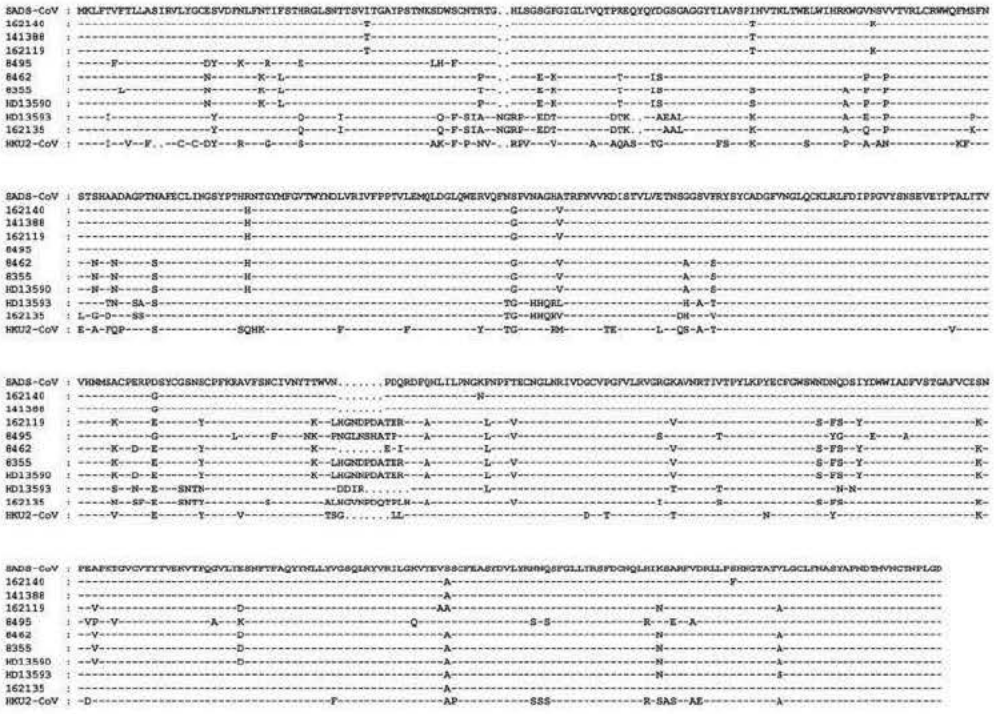
Extended Data Figure 2. Co-circulation of PEDV and SADS-CoV during the initial outbreak on Farm A.

Pooled intestinal samples were collected at dates given on the x-axis from deceased piglets and analyzed by qPCR. The intensity infection for each piglet is shown as a copy number per milligram of intestine (y-axis).



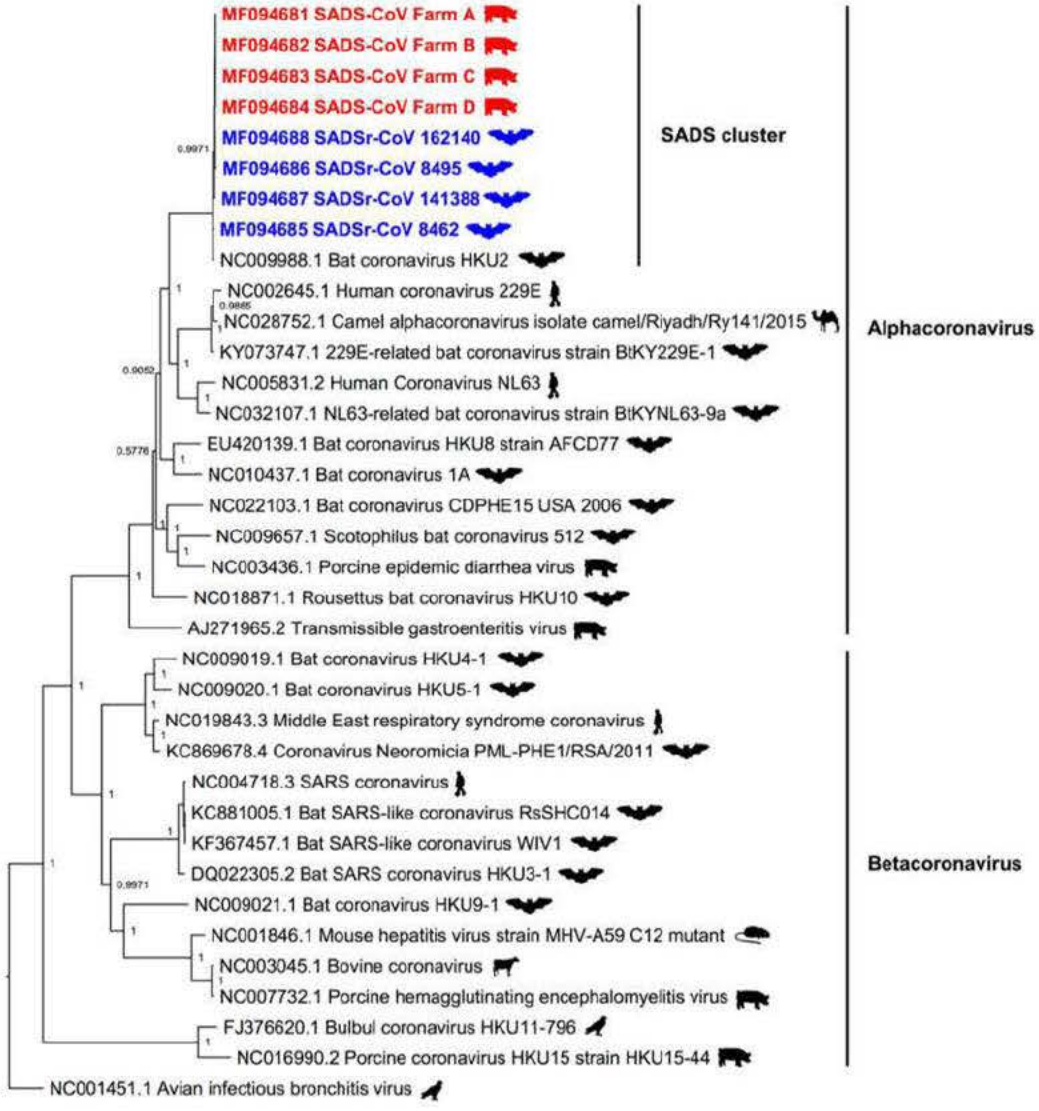
Extended Data Figure 3. Alignment of amino acid sequences of S1 proteins of the SADS cluster of coronaviruses.

The top sequence is from SADS-CoV Farm A. The four SADSr-CoV S1 sequences (162140, 141388, 162119 and 162135) were derived from NGS whole genome sequencing. HKU2-CoV is from a published report[19]. Five additional S1 sequences (8495, 8462, 8355, HD13590 and HD13593) from bats were determined by PCR and Sanger sequencing as described in the text. Dashed lines indicate identical residues while dots represent gaps.



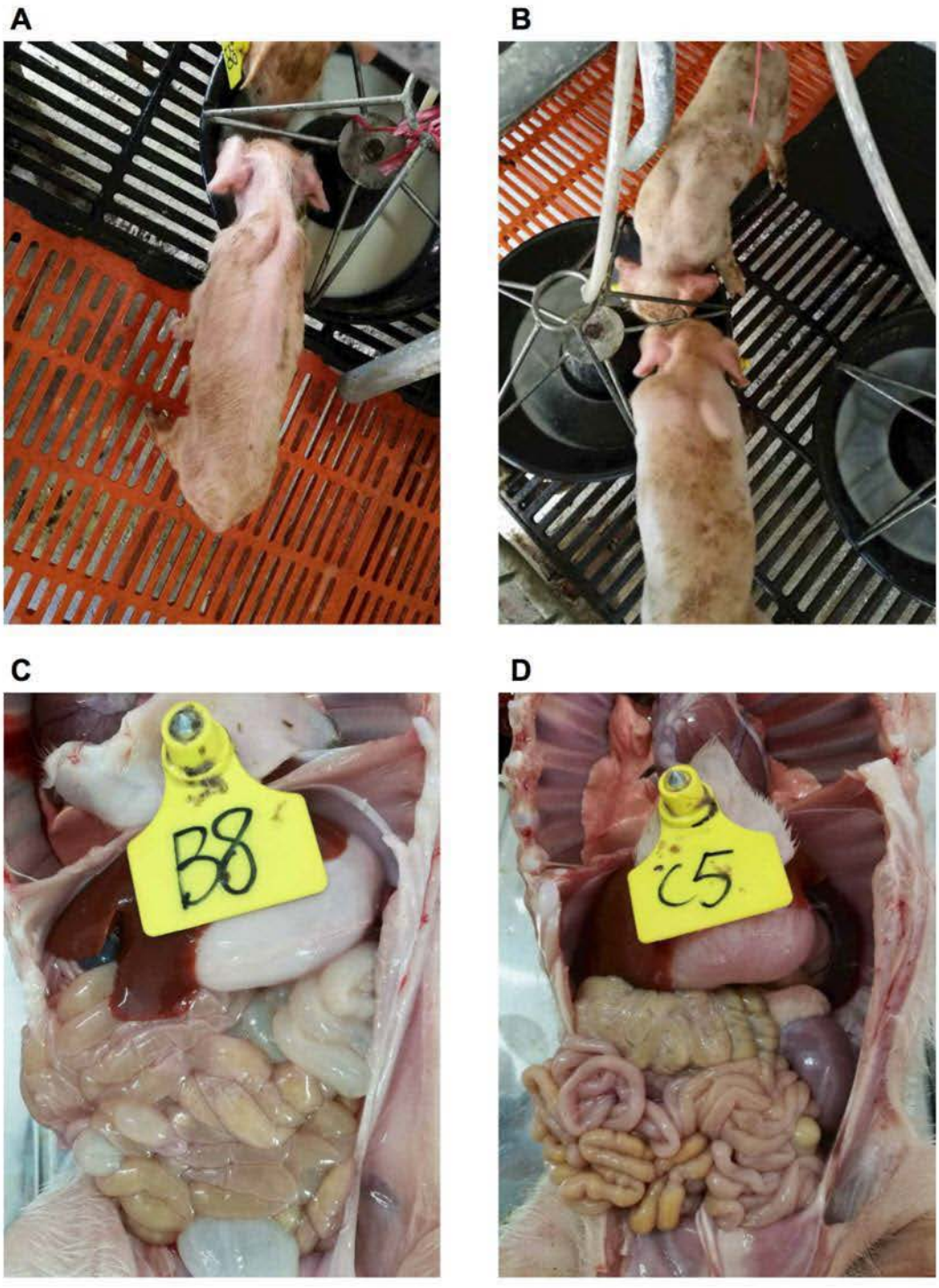
Extended Data Figure 4. Bayesian phylogenetic tree of the sequences encoding RdRp of SADS-CoV and related coronaviruses.

Tree was constructed using MrBayes v3.2 with the average standard deviation of split frequencies under 0.01. The host of each sequence is represented pictorially. Newly sequenced SADS-CoVs are highlighted in red while bat SADSr-CoVs are highlighted in blue.



Extended Data Figure 5. SADS-CoV experimentally infected and healthy piglets.

(A) Piglet on day 2 post SADS-CoV infection. (B) Mock infected piglet on day 2. (C) Intestine from infected piglet at necropsy. (D) Intestine from mock-infected piglet at necropsy.



Extended Data Table 1. List of all known swine viruses tested by PCR at the beginning of the of SADS outbreak investigation on the four farms *.

	PED V	PDC oV	TGE V	R V	PB V	PS V	SV A	SI V	NADC 30	PR V	FMD V	CSF V	PC V2	PC V3	APP V	PP V	Norovir us
Farm A	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND	-
Farm B	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND	-
Farm C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND
Farm D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND

* Dash indicates negative PCR result. ND, not done. Virus abbreviations: PEDV- Porcine Epidemic Diarrhea Virus; PDCoV- Porcine Delta Coronavirus; TGEV-Porcine Transmissible Gastroenteritis Virus; RV- Porcine Rotavirus; PBV- Porcine Picobirnavirus; PSV- Porcine Sapelo Virus; SVA- Porcine Senecavirus A; SIV- Swine Influenza Virus; PPRV- Porcine Reproductive and Respiratory Syndrome Virus, strain NADC30; PRV- Porcine Pseudorabies Virus; FMDV- Foot and Mouth Disease Virus; CSFV- Classical Swine Fever Virus; PCV2- Porcine Circovirus 2; PCV3- Porcine Circovirus 3; APPV- Atypical Porcine Pestivirus; PPV- Porcine Parvovirus.

622 **Extended Data Table 2. List of nucleotide and amino acid (aa) residue variants**
623 **among the SADS-CoV genomes obtained from the four different farms.**
624

Nucleotide residue position*	Gene name	Amino acid (aa) residue position*	Farm A nucleotide (aa)	Farm B nucleotide (aa)	Farm C nucleotide (aa)	Farm D nucleotide (aa)
2236	ORF1a	645	G(A)	G(A)	G(A)	T(S)
2955	ORF1a	884	T(G)	C(G)	T(G)	T(G)
3285	ORF1a	994	G(E)	G(E)	G(E)	T(D)
15395	ORF1b	915	C(T)	C(T)	C(T)	T(T)
18410	ORF1b	1920	C(G)	T(G)	T(G)	T(G)
20219	ORF1b	2523	C(L)	T(L)	T(L)	T(L)
21622	S	379	C(N)	C(N)	C(N)	A(K)

625 Non-synonymous aa substitutions are marked in red. * SADS-CoV from Farm A was used as the
626 reference sequence, from which the residue numbering was derived.

627 **Extended Data Table 3. List of PCR primers used in this study.**

628

Gene	Primer name and location*	Primer sequence	Application
RdRp gene	SADS-RdRp-F (19512-19531) SADS-RdRp-R (19590-19608)	GTTGATTGTAAGGCTTGGCG AACCACACTTCCACTCAGC	qPCR
N gene	SADS-N-F (25810-25830) SADS-N-R (25938-25957)	CTAAAACTAGCCCCACAGGTC TGATTGCGAGAACGAGACTG	qPCR
S gene	HKU2-S1-1F (20066-20085) HKU2-S1-1R (22317-22336)	GGCGCTATGGCTGTTAAGAT CACGAATGTCAGCCTCAACT	Cloning
S gene	HKU2-S1-2F (20157-20176) HKU2-S1-2R (22218-22238)	CCAGTGTCAACACGTCATCT ACGCTGAACTTAGGCATTGTA	Cloning

629 * The numbering system of SADS-CoV from Farm A was used as for Extended Data Table 2.

630

631 **Extended Data Table 4. List of SADSr-CoVs detected in bats in Guangdong,**
632 **China.**

Sampling			PCR analysis	
Time (Month-Year)	Location	Bat Species	Fecal swabs sampled	PCR Positive
Jun 13	Yingde	*Rhinolophus sinicus*	1	1
		Pipistrellus abramus	8	0
		Myotis ricketti	2	0
Jul 13	Yangshan	*Pipistrellus abramus*	1	0
		Hipposideros pratti	36	1
Jul 13; May 14; Jun 15; Aug 16	Ruyuan	*Rhinolophus sinicus*	27	6
		Rhinolophus affinis	11	2
		Rhinolophus macrotis	3	0
		Rhinolophus pusillus	41	6
		Rhinolophus rex	9	7
		Hipposideros pratti	7	0
Sep 14; Jun 15; Aug 16	Conghua	*Rhinolophus sinicus*	70	2
		Rhinolophus affinis	34	7
		Rhinolophus pusillus	11	2
		Hipposideros pomona	10	0
		Myotis ricketti	1	0
Jun 13; Nov 13; Aug 14; Jun 15	Huidong	*Rhinolophus sinicus*	37	2
		Rhinolophus affinis	59	29
		Rhinolophus macrotis	15	2
		Rhinolophus pusillus	1	0
		Hipposideros pomona	2	0
		Myotis ricketti	84	1
Apr 14; Jun 15	Longgang	*Rhinolophus sinicus*	55	1
		Pipistrellus abramus	5	1
Sep 14	Xiangzhou	*Rhinolophus pusillus*	28	0
		Hipposideros pomona	38	1
		Total	596	71 (11.9%)

633
634 See Fig. S1 for sampling sites in relation to SARS and SADS outbreak locations
635

Extended Data Table 5. Multiple human CoV receptors as well as swine APN cannot be utilized as entry receptor for SADS-CoV.

	HuAPN★	HuACE2★	HuDPP4★	SwAPN★	SwACE2★
SADS-CoV*	-	-	-	-	-
SARS-like-CoV	NA	+	NA	NA	+
MERS-CoV#	NA	NA	+	NA	NA
PEDV	NA	NA	NA	NA	NA
Expression$	+ (APN Ab)	+ (HIS-tag Ab)	+ (DPP4 Ab)	+ (S-tag Ab)	+ (S-tag Ab)

★Gene accession numbers for the genes used in this study: human APN, M22324.1; human ACE2, NM_021804; human DPP4, NM_001935.3; swine APN, NM_214277.1; swine ACE2, XM_021079374.1

* For SADS-CoV infection, both positive samples and HIV-pseudovirus were used. Viral positive samples were from SADS infected pig anal swabs: SusAS-7 (4.0×10^5 copy/μl), SusAS-20 (4.3×10^5 copy/μl), SusAS-22 (2.4×10^5 copy/μl).

For MERS-CoV infection, HIV-pseudovirus were used.

$ Expression of APN, DPP4 and ACE2 was confirmed by antibodies against the targeting proteins or fused tags.

649 **Extended Data Table 6. Experimental outline of SADS-CoV infection of piglets.**

650 Experiments were performed with (A) 3-day old or (B) 6-day old piglets. Infection
651 was performed as described in the Material and Methods.

652

A

Groups	Infection material	Number	Age (days)	Infection Dose	Infection route	SADS-CoV titer (copy/μl)	First day				Second day				Fourth day
							Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Nutrition exhaustion and Dying
A	SC1 (SADS-CoV positive)	5	3	3mL	Oral+milk	6.54×10^5	5	5	5	0	5	5	5	0	3
B	DE2 (SADS-CoV positive)	5	3	3mL	Oral+milk	10.62×10^5	5	4	5	0	5	3	5	0	1
C	Mock	4	3	3mL	Oral+milk	0	0	0	0	0	0	0	0	0	0
D	Empty mock	4	3	0ml	Milk only	0	3 mild diarrhea	0	0	0	1	0	0	0	0

B

Groups	Infection material	Number	Age (days)	Infection Dose	Infection route	SADS-CoV titer (copy/mg)	First day				Second day				Fourth day
							Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Nutrition exhaustion and Dying
A	SC1 (SADS-CoV positive)	6	6	2mL	Oral+milk	6.54×10^5	5	3	6	0	1	0	6	0	0
B	DE2 (SADS-CoV positive)	5	6	2mL	Oral+milk	1.20×10^5	3	3	5	0	3 moderate	1	5	0	0
C	Mock	6	6	2mL	Oral+milk	0	0	0	0	0	0	0	0	0	0
D	Empty mock	5	6	0ml	Milk only	0	0	0	0	0	0	0	0	0	0

653

From: Peter Daszak
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Hongying Li
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?
Date: Thursday, June 29, 2017 2:39:46 PM
Attachments: 2017-05-06890 full manuscript.pdf

Hi Erik,

I just wanted to say thanks for hosting us at NIAD today – it was great to have an interested audience with good questions and nice to have a chance to introduce our collaborators to you personally.

I mentioned the upcoming SADS-CoV paper might get into *Nature*. Obviously, this is touch-and-go right now, but I've attached the draft here so you can forward it to your communications team in case they want to get a release out earlier this time.

By the way – we've had some great publicity from the other paper last week. If you go to the following link we've put some of the stories up on our EHA website here:

http://www.ecohealthalliance.org/updates

Hope you enjoy skimming through them, and thanks again for setting up the talk this morning.

Cheers,

Peter

Peter Daszak
President
EcoHealth Alliance
460 West 34th Street – 17th Floor
New York, NY 10001
Tel. (b) (6)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, June 29, 2017 7:22 AM
To: Peter Daszak
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

Also, please let me know when you arrive at security and I'll meet you there. My mobile is (b) (6)

Erik

From: Peter Daszak (b) (6)
Sent: Thursday, June 29, 2017 12:43 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Hongying Li (b) (6)
Cc: Aleksei Chmura (b) (6); Alison Andre (b) (6)
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

Erik,

In case NIAID has issues with USB drives etc., here is a pdf version of our talk for tomorrow morning. I hope you can have that as a backup from your email in case we can't download our talk from our laptops.

Look forward to seeing you.

Cheers,

Title: Fatal Swine Disease Outbreak Caused by a Novel Coronavirus of Bat Origin

Authors: Peng Zhou[1]*, Hang Fan[2]*, Tian Lan[3]*, Xing-Lou Yang[1], Wei Zhang[1], Yan Zhu[1], Ya-Wei Zhang[2], Qing-Mei Xie[3], Shailendra Mani[4], Xiao-Shuang Zheng[1], Bei Li[1], Jin-Man Li[2], Hua Guo[1], Guang-Qian Pei[2], Xiao-Ping An[2], Jun-Wei Chen[3], Ling Zhou[3], Kaijie Mai[3], Zi-Xian Wu[3], Danielle E. Anderson[4], Li-Biao Zhang[5], Shi-Yue Li[6], Zhi-Qiang Mi[2], Tong-Tong He[2], Yun Luo[1], Xiang-Ling Liu[1], Jing Chen[1], Yong Huang[2], Qiang Sun[2], Xiang-Li-Lan Zhang[2], Yan-Shan Cheng[3], Yuan Sun[3], Peter Daszak[7], Lin-Fa Wang[4]†, Zheng-Li Shi[1]†, Yi-Gang Tong[2]†, Jing-Yun Ma[3]†

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[7]EcoHealth Alliance, New York, USA

*These authors contributed equally to this work

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Spillover of bat-origin coronaviruses is implicated in the emergence of two emerging, high-impact zoonoses, SARS and MERS. Here, we report virological, epidemiological and experimental infection evidence that a novel bat-origin coronavirus, Swine Acute Diarrhea Syndrome coronavirus (SADS-CoV), caused an ongoing outbreak of lethal diarrheal disease in pigs in China. The outbreak began in January 2017 Guangdong Province in the vicinity of the origin of the SARS pandemic in 2002, and has caused the death of 24,693 piglets in four farms to date. We identified SADS related-CoVs with 96-98% sequence identity to SADS-CoV in 11.9% (71/596) of anal swabs collected from bats in Guangdong Province during 2013-16, predominantly in five *Rhinolophus* spp. horseshoe bats that are known reservoirs of SARS-like CoVs. The geographic, temporal, ecological and etiological similarities in the emergence of SADS and SARS highlight the urgent need to identify coronavirus diversity in bats to mitigate future outbreaks that threaten veterinary production, public health and economic growth.

The emergence of severe acute respiratory syndrome in southern China in 2002, which was caused by a previously unknown coronavirus (SARS-CoV)[1-5] and led to more than 8,000 human infections and 774 deaths [http://www.who.int/csr/sars/en/], heralded two new frontiers in emerging infectious diseases. Firstly, it demonstrated that coronaviruses are capable of causing fatal diseases in humans. Secondly, the identification of bats as the reservoir for SARS-related coronaviruses, and likely

53 origin of SARS-CoV[6-8] firmly established bats as an important source of highly lethal
54 zoonotic viruses, which include Hendra, Nipah, Ebola and Marburg viruses[9].
55 The public health threat posed by novel coronaviruses was reinforced by the
56 emergence of the Middle East respiratory syndrome coronavirus (MERS-CoV) in
57 2012[10], which has so far infected 1,952 people with 693 deaths
58 [http://www.who.int/emergencies/mers-cov/en/]. Cases of MERS have been reported
59 in 27 countries, mostly due to imported cases with the exception of a major outbreak
60 in Seoul in 2015 that involved extensive local human-to-human transmissions[11].
61 While dromedary camels have been identified as the main source of MERS-CoV
62 spillover to humans[12], there is evidence suggesting that bats are the original wildlife
63 reservoir. This includes short sequence from a single *Taphozous perforatus* bat in
64 Saudi Arabia, and evidence that bat MERS-related coronaviruses use the same human
65 entry receptor, dipeptidyl peptidase 4 (DPP4; also known as CD26), as
66 MERS-CoV[13-16].
67 Here we report a series of fatal swine disease outbreaks in Guangdong
68 Province, China, approximately 100 km from the location of the purported index case
69 of SARS. Most strikingly, we found that the causative agent for this swine acute
70 diarrhea syndrome (SADS) is a novel coronavirus which is almost 99% identical in
71 genome sequence to a bat coronavirus we detected in 2016 from a bat cave in the
72 vicinity of the index pig farm. This new virus (SADS-CoV) thus appears to have
73 originated from the same genus of horseshoe bats (*Rhinolophus*) as SARS-CoV.

From 28 October 2016, fatal swine disease outbreaks were observed in a pig farm in Qingyuan, Guangdong Province, China, very close to the location of the first known index case of SARS in Foshan (**Extended Data Figure 1**). Porcine epidemic diarrhea virus (PEDV) had caused prior outbreaks at this farm, and was detected in the intestine of deceased piglets at the start of the outbreak. However, PEDV could no longer be detected in deceased piglets after 12th January 2017, despite accelerating mortality (**Fig. 1**A) and extensive testing for other common swine viruses yielded negative results (**Extended Data Table 1**). These findings suggested an outbreak of a novel disease, which we designated swine acute diarrhea syndrome (SADS). Clinical signs are similar to those caused by other known swine enteric coronaviruses [17,18] and include severe and acute diarrhea, and rapid weight loss, leading to death due to nutritional exhaustion in newborn piglets less than four days of age. Infected piglets died 2-6 days following disease onset, while infected sows suffered only mild diarrhea and most recovered in two days. The disease caused no signs of febrile illness in piglets or sows. The disease has spread to three additional pig farms within 20-150 km of the index farm (**Extended Data Figure 1**) and, as of 2nd May 2017, has resulted in the death of 24,693 piglets from four farms (**Fig. 1A**). In Farm A alone, 64% (4659/7268) of all piglets born in February died.

Small intestinal samples from diseased piglets were taken from all four affected farms and subjected to next generation sequencing (NGS) using the Illumina MiSeq platform. Of the 338,036 total reads obtained, 369 mapped to viruses within the NCBI virus database, and 355 (96.2%) of these matched sequences of bat CoV

HKU2, a virus first detected in Chinese horseshoe bats in Hong Kong and Guangdong Province, China[19]. By *de novo* assembly and targeted PCR we sequenced a 27,173-bp coronavirus genome that shared 95% sequence identity to HKU2 (Genbank accession number NC009988.1). Four genomes of SADS-CoV were obtained, designated A, B, C and D corresponding to the four farms from which they were derived. These viruses are 99.9% identical to each other (**Extended Data Table 2**) (GenBank accession number: MF094681−MF094684), suggesting that inter-farm transmission was likely responsible for outbreaks on farms B, C and D.

Using quantitative PCR based on the nucleocapsid protein gene (see **Extended Data Table 3** for primer sequences), we detected SADS-CoV in acutely sick piglets and sows, but not in recovered or healthy pigs on the four farms, nor in nearby farms without evidence of SADS. The virus replicated to higher titers in piglets than in sows (**Fig. 1B**). SADS-CoV displayed tissue tropism for small intestine (**Fig. 1C**), as observed for other swine enteric coronaviruses[20] and HKU2 in bats[19]. Retrospective PCR analysis revealed that SADS-CoV was present on Farm A during the PEDV epidemic, where the first strongly positive SADS-CoV sample was detected on 6 December 2016. From mid-January onwards, SADS-CoV was the dominant viral agent detected in diseased animals (**Extended Data Figure 2**). Although PEDV was also detected occasionally during the outbreaks in Farms B, C and D, SADS-CoV was the dominant virus (**Extended Data Figure 2 & Table 1**).

We rapidly developed an antibody assay based on the S1 domain of the spike protein using the Luciferase Immunoprecipitation System (LIPS)[21]. As SADS is acute

with rapid onset in piglets, serological investigation was conducted only in sows. Among 46 recovered sows tested, 12 were seropositive for SADS-CoV within three weeks of infection (**Fig. 1D**). To investigate possible zoonotic transmission, serum samples from 35 farm workers who had close contact with sick pigs were subjected to the same LIPS test and none of them was positive for SADS-CoV. Continuous monitoring is required to assess whether the virus has the capacity to mutate and lead to human infection in future.

While the overall genome identity of SADS-CoV and bat CoV HKU2 is 95%, the spike gene (S) sequence identity is only 86%, suggesting that HKU2 is not the direct progenitor of SADS-CoV. To test the hypothesis of a bat origin for SADS-CoV, we developed a qPCR assay based on the SADS-CoV RNA dependent RNA polymerase (RdRp) gene (**Extended Data Table 3**) and screened 596 bat anal swabs collected from 2013-2016 from seven different locations in Guangdong Province (**Extended Data Figure 1**). A total of 71 samples (11.9%) tested positive (**Extended Data Table 4**), almost all of which (94.3%) were from *Rhinolophus* spp. bats (*R. pusillus, R. macrotis, R. sinicus, R. rex and R. affinis*), which are also the natural reservoir hosts of SARS-like coronaviruses[6-8, 22-24]. Complete genome sequences were determined by NGS from four samples that shared highest sequence identity to SADS-CoV, based on the amplicon region (GenBank accession number MF094685−MF094688). These four bat-derived genomes are very similar in size (27.2 kb) to SADS-CoV (**Fig. 2A**) and we tentatively nominate them SADS related coronaviruses (SADSr-CoV). Overall sequence identity to SADS-CoV ranges from

96-98%, higher than the 95% for HKU2-CoV. Importantly, the SADSr-CoV 162140 genome showing highest overall genome identity (98.48%) and S protein sequence identity (98.14%) was sampled in August 2016 less than 100 km from the index farm (**Extended Data Figure 1**). The geographic and temporal alignment of the two events strongly suggests that SADSr-CoV 162140 may be the direct ancestor of SADS-CoV. This is further corroborated by phylogenetic analysis (**Fig. 2B**), that shows bat SADSr-CoVs form a distinct cluster with SADS-CoV in the alpha CoV clade. The major differences among SADSr-CoVs lie in the predicted coding regions of the S and 3'-terminal ORF7a and ORF7b genes (**Fig. 2A**). The S1 domain of the S protein determines CoV host tropism[25]. An additional five S1 genes were sequenced (GenBank accession number MF094697−MF094701), and the S1 of sample 162140 and 141388 were found closest to that of SADS-CoV (**Extended Data Figure 3**). The close relationship among these two viruses and SADS-CoV is further supported by phylogentic analysis of the RdRp gene (**Extended Data Figure 4**).

Known coronavirus host cell receptors include angiotensin-converting enzyme 2 (ACE2) for SARS-related CoV, aminopeptidase N (APN) for PEDV, and dipeptidyl peptidase 4 (DPP4) for MERS-CoV[15,16,25]. To investigate the receptor usage of SADS-CoV, we used SADS-CoV positive samples or HIV pseudoviruses carrying the SADS-CoV S protein to infected HeLa cells which over-expressed all three receptor molecule. While the positive control infected by SL-CoV, MERS-CoV pseudovirus or PEDV showed successful infection or entry, we found no evidence of SADS-CoV

entry, suggesting that none of these three molecules are the functional receptor of SADS-CoV (**Extended Data Table 5**).

Swine enteric coronaviruses including PEDV, transmission gastroenteritis virus (TGEV) and porcine diarrhea coronavirus (PDCoV) are known to cause severe watery diarrhea and dehydration accompanied by histopathological lesions in the infected pigs. Clinically PEDV, TGEV, and PDCoV are indistinguishable[26]. In contrast, piglets infected with SADS-CoV mainly die of nutritional exhaustion rather than severe dehydration. Efforts to isolate virus isolation from intestinal tissues of infected piglets and from bat samples with low PCR Ct values have been unsuccessful to date, so that Koch's postulates cannot be fulfilled using traditional approaches. However, we successfully conducted animal challenge experiments using NGS to identify and confirm causality relationship. Fecal samples positive for SADS-CoV and negative for PEDV or any other known swine diarrhea virus by both NGS and PCR were fed to 3-day or 6-day old piglets. All piglets inoculated with SADS-CoV positive fecal matter exhibited severe diarrhea one day after challenge, while control animals remained healthy. On day 4 post infection, the 3-day but not the 6-day group suffered heavy weight loss and showed signs of nutritional exhaustion and became moribund (**Extended Data Table 6 & Figure 5**). Animals were euthanized for further analysis. Histopathological examinations showed similar lesions in the challenged piglets to those in naturally infected piglets (**Fig. 3A and 3B**). Using rabbit anti-recombinant SADSr-CoV NP serum, specific staining was detected mainly in the small intestines (**Fig. 3C and 3D**). Finally, qPCR and NGS were used to verify that

all diseased piglets were SADS-CoV positive and negative for other known swine diarrhea viruses; and that all control piglets were negative for SADS-CoV. It should be noted that piglets were fed with artificial formula during experimental challenge and the stable nutrient supply mitigated death in most of these animals. Conversely, naturally infected piglets often relied upon poor quantity and quality of milk from infected sows for their nutrition.

The rapid emergence and spread of SADS-CoV, and its high mortality rate in piglets constitute a major economic threat to the pork industry. Viral coinfection is rather common in swine, likely due to intensive farming practices. This was also true on the index farm where co-infection with PEDV and SADS-CoV was detected at the beginning of the outbreak, with SADS-CoV dominant towards later stages of the outbreak. As the barrier for the initial spillover of bat viruses into non-bat hosts is thought to be very difficult to overcome[27], the potential facilitating role of PEDV infection in the emergence of SADS-CoV should be further investigated, especially in the context of known antibody-dependent enhancement of CoV infections[28].

Although bats have been associated with many deadly disease outbreaks impacting both human and livestock, tracing the virus origin usually takes years (for Hendra, Nipah and SARS) if not decades (for Ebola and Marburg). To our knowledge this is the first example where a novel etiological agent discovered during a disease outbreak has been linked with a closely related progenitor virus in bats during the disease investigation itself. Two possible routes of transmission from bats to pigs are plausible: direct transmission via bat fecal contamination of a pig feedlot, and indirect

transmission via an amplifying host, as was originally proposed for SARS-CoV via civets[29]. Further investigation is needed to test these alternative hypotheses once virus isolation is successful.

The current study highlights the value of targeted surveillance in response to an emerging infectious disease event. It also demonstrates that by using modern technological platforms such as NGS and LIPS serology, key experiments that traditionally rely on isolation of live virus could be performed rapidly and prior to virus isolation. Finally, the bat origins of this lethal livestock disease, SARS and most likely MERS demonstrate the disproportionate importance of bats as reservoirs of viruses that threaten veterinary and public health[30].

METHODS

Sample collection

Bats were trapped in their natural habitat in Guangdong Province (**Extended Data Figure 1**). Fecal swab samples were collected in viral transport medium (VTM) composed of Hank's balanced salt solution at pH7.4 containing BSA (1%), amphotericin (15 μg/ml), penicillin G (100 units/ml), and streptomycin (50 μg/ml). Stool samples from sick pigs were collected in VTM. When appropriate and feasible, intestine samples were also taken from deceased animals. Samples were aliquoted and stored at -80 ^{0}C until use. Blood samples were collected from recovered sows and farm workers who had close contact with sick pigs. Serum was separated by centrifugation at 3,000 *g* for 15 min within 24 h of collection and preserved at 4 ^{0}C.

Human serum collection was approved by the Medical Ethics Committee of the Wuhan School of Public Health, Wuhan University and Hummingbird IRB.

Virus isolation

The following cells were used for virus isolation in this study: VeroE6 (cultured in DMEM +10% FBS); *Rhinolophus sinicus* primary or immortalized cells generated by our laboratory (all cultured in DMEM/F12 +15% FBS): kidney primary RsKi9409, lung primary RsLu4323, lung immortalized RsLuT, brain immortalized RsBrT and heart immortalized RsHeT; and swine cell lines: two intestinal IPEC (RPMI1640+10%FBS) and SIEC (DMEM+10%FBS), three kidney PK15, LLC-PK1 (DMEM+10% FBS for the two) and IBRS (MEM+10%FBS), and one testes ST (DMEM+10%FBS).

Cultured cell monolayers were maintained in their respective medium. PCR-positive pig fecal or homogenized pig intestinal supernatant (in 200 µl VTM) were filtered and diluted 1:10 with serum-free medium before being added to cells. After incubation at 37 ^{0}C for 1 h, the inoculum was removed and replaced with fresh culture medium containing 2% FCS. The cells were incubated at 37 ^{0}C and observed daily for cytopathic effect (CPE). Four blind passages (three-day interval between every passage) were performed for each sample. After each passage, both the culture supernatant and cell pellet were examined for presence of virus by RT-PCR using the SADS-CoV primers listed in Table S3. Penicillin (100 units/ml) and streptomycin (15 µg/ml) were included in all tissue culture media.

RNA extraction, S1 gene amplification and qPCR

Whenever commercial kits were used, manufacturer's instructions were followed without modification. RNA was extracted from 200 µl of swab samples (bat), feces or homogenized intestine (pig) with the High Pure Viral RNA Kit (Roche). RNA was eluted in 50 µl of elution buffer and was used as the template for RT-PCR. Reverse transcription was performed using the SuperScript III kit (Invitrogen).

To amplify S1 genes from bat samples, nested PCR was performed with primers designed based on HKU2-CoV (Genbank accession number NC009988.1)[19] (**Extended Data Table 3**). The 25-µl first-round PCR mixture contained 2.5 µl 10X PCR reaction buffer, 5 pmol of each primer, 50 mM MgCl2, 0.5 mM dNTP, 0.1 µl Platinum Taq Enzyme (Invitrogen) and 1 µl cDNA. The 50-µl second-round PCR mixture was identical to the first-round PCR mixture except the primers. Amplification of both rounds was performed as follows: 94 °C for 5 min followed by 60 cycles consisting of 94 °C for 30 s, 50 °C for 40 s, 72 °C for 2.5 min, and a final extension of 72 °C for 10 min. PCR products were gel purified and sequenced.

For qPCR analysis, primers based on SADS-CoV RdRp and NP genes were used (**Extended Data Table 3**). RNA extracted from above was reverse-transcribed using PrimeScript RT Master Mix (Takara). The 10-µl qPCR reaction mix contained 5 µl 2× SYBR premix Ex Taq II (Takara), 0.4 µM of each primer and 1 µl cDNA.

Amplification was performed as follows: 95 °C for 30 s followed by 40 cycles consisting of 95 °C for 5 s, 60 °C for 30 s, and a melting curve step.

Luciferase Immunoprecipitation System (LIPS) assay

LIPS was used in this study due to its simplicity and capacity to be rapidly deployed. The SADS-CoV S1 gene was codon optimized for eukaryotic expression and synthesized (GenScript) in frame with the Renilla luciferase gene (Rluc) and a FLAG tag in the pREN2 vector[21]. pREN2-S1 plasmids were transfected into Cos-1 cells using Lipofectamine (Invitrogen). At 48 h post-transfection, cells were harvested, lysed and a luciferease assay was performed to determine Rluc expression for both the empty vector (pREN2) and the pREN2-S1 construct. For testing of unknown pig or human serum samples, 1 µl of serum was incubated with 10 million units of Rluc alone (vector) and Rluc-S1, respectively, together with 3.5 µl of a 30% protein A/G ultralink beads suspension (Thermo Scientific). After extensive washing to remove unbounded luciferase-tagged antigen, captured luciferease amount was determined using the commercial luciferase substrate kit (Promega). The ratio of Rluc-S1/Rluc(Vector) was used to determine the specific S1 reactivity of pig and human sera. Commercial FLAG antibody (Life Technologies) was used as the positive control, and various pig sera (from uninfected animals in China or Singapore; or pigs infected with PEDV, TGEV or Nipah virus) were used as a negative control.

Protein expression and antibody production

The NP gene from SADSr-CoV 3755 (GenBank accession number MF094702), which shared a 98% aa sequence identity to the SADS-CoV NP gene, was inserted into pET-28a+ (Novagen) for prokaryotic expression. Transformed *E. coli* were grown at 37 °C for 12-18 h in media containing 1 mM IPTG. Bacteria were collected by centrifugation and resuspended in 30 ml of 5 mM imidazole and lysed by sonication. The lysate, from which NP protein expression was confirmed with an anti-HIS-tag antibody, was applied to the Ni2+ resin (Thermo Scientific). The purified NP protein, at a concentration of 400 μg/ml, was used to immunize rabbits for antibody production following published methods[31]. After immunization and two boosts with N protein, rabbits were euthanized and sera were collected. Rabbit anti-N sera were diluted 1:10,000 for subsequent Western blots.

Amplification, cloning and expression of the human and swine genes

Construction of expression clones for human ACE2 in pcDNA3.1 has been described previously[8]. Human DPP4 was amplified from human cell lines. Human APN gene was synthesized. Swine APN and ACE2 genes were amplified from piglet intestine. Full-length gene fragments were amplified using specific primers (provided upon request). The human APN, DPP4 and ACE2 genes were cloned into pCDNA3.1 fused with HIS tag. The pig APN and ACE2 genes were cloned into pCAGGS fused with S tag. Purified plasmids were transfected to HeLa cells. After 24 h, HeLa cells expressing human or swine genes were confirmed by immunofluorescence assay (IFA). Human APN, ACE2 and DPP4 expression was detected using mouse anti-HIS

tag monoclonal antibody or rabbit anti-human APN polyclonal antibody (made by ourselves) followed by cyanin 3-labeled goat anti-mouse/rabbit IgG from proteintech (Proteintech Group). Swine APN and ACE2 expression was detected using mouse anti-S tag monoclonal antibody followed by cyanin 3-labeled goat anti-mouse IgG from proteintech (Proteintech Group).

Pseudovirus preparation

The codon-humanized S protein genes of SADS-CoV and MERS-CoV cloned into pcDNA3.1(+) and pHIV-Luc (pNL4.3.Luc.R$^-$E$^-$Luc) were used for pseudovirus construction as described previously[8,32]. Briefly, 15 μg of each pHIV-Luc (pNL4.3.Luc.R$^-$E$^-$Luc) and the S protein expressing plasmids (or empty vector control) were co-transfected into 4 x 10^6 293T cells using Lipo3000 (Invitrogen) transfection system. After 4 h, the medium was replaced with fresh medium. Supernatants were harvested at 48 h post transfection and separated from cell debris by centrifugation at 3,000g, then by passing through a 0.45μm filter (Millipore). The filtered supernatants were stored at -80°C in aliquots until use. To evaluate the incorporation of S proteins into the core of HIV virions, pseudoviruses in the supernatant (20 ml) were concentrated by ultracentrifugation through a 20% sucrose cushion (5ml) at 80,000g for 90 min using a SW41 rotor (Beckman). Pelleted pseudoviruses were dissolved in 50μl phosphate-buffered saline (PBS) and examined by electron microscopy (EM).

Pseudovirus infection

HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared by a lipo2000 system (Invitrogen). Pseudoviruses prepared above were added to each 96-well plate seeded with Hela cells at 24 h post transfection of APN, ACE2 or DPP4 expression plasmids. The unabsorbed viruses were replaced with fresh medium at 3 h post infection. The infection was monitored by measuring the luciferase activity conferred by the reporter gene carried by the pseudovirus, using the Luciferase Assay System (Promega) as follows: cells were lysed at 48 h post infection, and 20 μl of the lysates was taken for determining luciferase activity by the addition of 50 μl of luciferase substrate.

SADS-CoV positive samples infection and IFA.

HeLa cells transiently expressing APN, ACE2 or DPP4 were prepared by a lipo2000 system (Invitrogen) in 96-well plate, with mock-transfected cells as controls. SADS-CoV RNA positive samples were used to infect Hela cells at 24h post transfection. The inoculum was removed after 1h absorption and washed twice with PBS and supplemented with medium. PEDV, SARS-like-CoV WIV16 and MERS-CoV HIV-pseudovirus were used as positive control for swine APN, human/swine ACE2 and human DPP4, respectively. At 24 h post infection, cells were washed with PBS and fixed with 4% formaldehyde in PBS (pH 7.4) for 20 min at room temperature. SL-CoV WIV16 replication was detected using rabbit antibody against the SL-CoV Rp3 nucleocapsid protein followed by cyanin 3-conjugated goat

358 anti-rabbit IgG. PEDV and SADS-CoV replication was detected using rabbit antibody
359 against the HKU2 CoV nucleocapsid protein followed by cyanin 3-conjugated goat
360 anti-rabbit IgG. Nucleus was stained with 4',6'-diamidino-2-phenylindole (DAPI).
361 Staining patterns were examined using the FV1200 confocal microscopy (Olympus).
362 The successful infection of MERS CoV HIV-pseudovirus was indicated by luciferase
363 on 48h post infection.
364
365 **High throughput sequencing and genome assembly**
366 RNA was extracted from the small intestine of deceased pigs and
367 reverse-transcribed into cDNA as described above. Sequencing libraries were
368 constructed using NEBNext Ultra II DNA Library Prep Kit for Illumina (New
369 England Biolabs) according to the manufacturer's instructions. High throughput
370 sequencing was performed with Illumina MiSeq sequencer. Low quality reads and
371 short reads were filtered. Clean reads were searched against a viral database with the
372 BLASTN program. PCR amplifications were applied to fill the gaps. Amplicons from
373 the same sample were pooled for library preparation and sequenced with the same
374 methodology as described above. All filtered reads were assembled using CLC
375 Genomic Workbench (ver 9.0). 5'-RACE was performed to determine the 5'-end of
376 the genomes. Genomes were annotated using Clone Manager Professional Suite 8
377 (Sci-Ed Software).
378
379 **Phylogenetic analysis**

SADS-CoV genome sequences and other representative coronavirus sequences (obtained from GenBank) were aligned using MAFFT (ver 7.221). Phylogenetic analyses with full-length genome, S gene and RNA-dependent RNA polymerase gene (RdRp) were performed using MrBayes v3.2 (Stop Valve=0.01) with GTR+G+I model (General Time Reversible model of nucleotide substitution with a proportion of invariant sites and γ-distributed rates among sites).

Animal infection study

Experiments were carried out strictly in accordance with the recommendations of the Guide for the Care and Use of Laboratory Animals of the National Institutes of Health. The use of animals in this study was approved by the South China Agricultural University Committee of Animal Experiments (approval ID: 201004152).

Two animal challenge experiments were performed (see detailed planning in **Extended Data Table 6**). Healthy, swine diarrhea virus free, piglets (3- or 6-day old) were orally fed with homogenized intestinal samples from SADS-CoV infected piglets. Inocula were confirmed as SADS-CoV positive, but negative for all other known swine diarrhea viruses. Two control groups of piglets were fed with homogenized intestine from healthy piglets or milk only. Animals were observed daily for signs of disease, such as diarrhea, weight loss and nutritional exhaustion. Fecal swabs were collected daily from all animals and screened for all known swine diarrhea viruses. At experimental endpoints, piglets were humanely euthanized and

402 necropsies performed. Ileal, jejunal and duodenal tissues were taken from selected
403 animals and store in at -80 ^{0}C for further analysis.
404
405 **Hematoxylin and eosin (H&E) and immunohistochemistry (IHC) analysis**
406 Frozen (-80 ^{0}C) small intestinal tissues including duodenum, jejunum, and
407 ileum taken from the above experimentally infected pigs were pre-frozen at -20 ^{0}C for
408 10 min. Tissues were then embedded in optimal cutting temperature compound and
409 cut into 8-μm sections using the Cryotome FSE machine (Thermo Scientific).
410 Mounted microscope slides were fixed with paraformaldehyde and stained with H&E
411 for histopathological examination.
412 For IHC analysis, the rabbit antibody raised above was used for specific
413 staining of SADS-CoV antigen. Slides were blocked by incubating with 10% goat
414 serum (Beyotime) at 37 ^{0}C for 30 min, followed by overnight incubation at 4 ^{0}C with
415 the rabbit anti-3755 N protein serum diluted at 1:1000 in PBST buffer containing 1%
416 goat serum. After washing, slides were then incubated for 50 min at room temperature
417 with HRP conjugated protein A+G (Thermo Scientific) diluted at 1:1000 in PBST
418 buffer containing 1% goat serum. Slides were developed using 3,3' diaminobenzidine
419 substrate (Servicebio) before images were taken using the Pannoramic MIDI system
420 (3D HISTECH).
421
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523

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525 study. P.Z, W.Z, Y.Z, M.S, X.S.Z, B.L, X.L.Y, H.G, D.S, Y.L, X.L.L, J.C performed
526 qPCR, serology, histology and virus culturing. H.F, Y.W.Z, J.M.L, G.Q.P, X.P.A,
527 Z.Q.M, T.T.H, Y.H, Q.S, X.L.L.Z performed genome sequencing and annotations.
528 T.L, Q.M.X, J.W.C, L.Z, K.J.M, Z.X.W, L.B.Z, S.Y.L, Y.S,C, Y.S prepared the
529 samples and animal challenges. Z.L.S., P.D., L.B.Z, S.Y.L coordinated collection of
530 bat samples. P.Z, L.F.W, Z.L.S, P.D prepared the draft.

531

AUTHOR INFORMATION

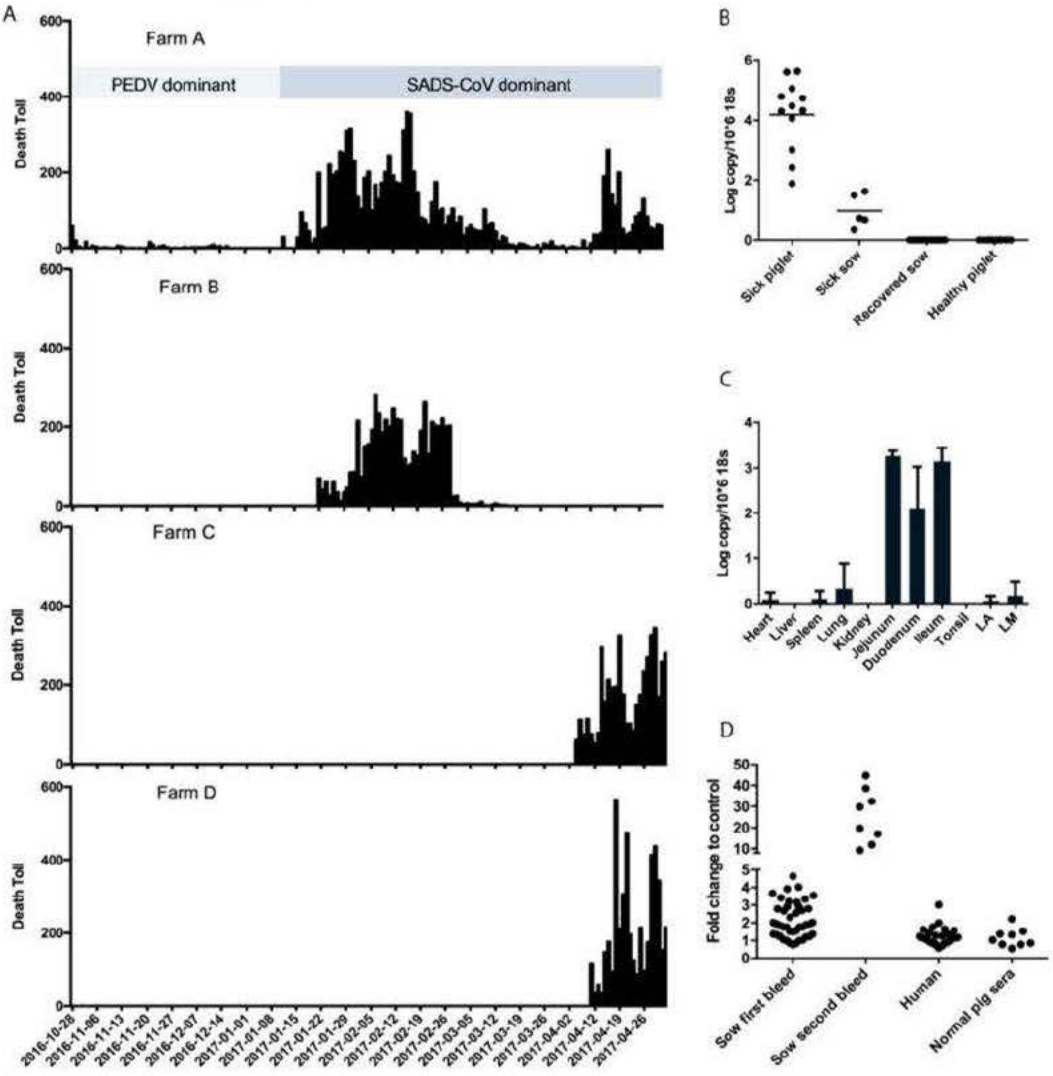
Full-length genomic sequences or S sequences of SADS-CoV and SARSr-CoV have been deposited in GenBank under accession numbers MF094681-MF094688 and MF094697-MF094701, respectively.

The authors declare no competing financial interests. Correspondence and requests for materials should be addressed to ZLS. (zlshi@wh.iov.cn).

FIGURE LEGENDS

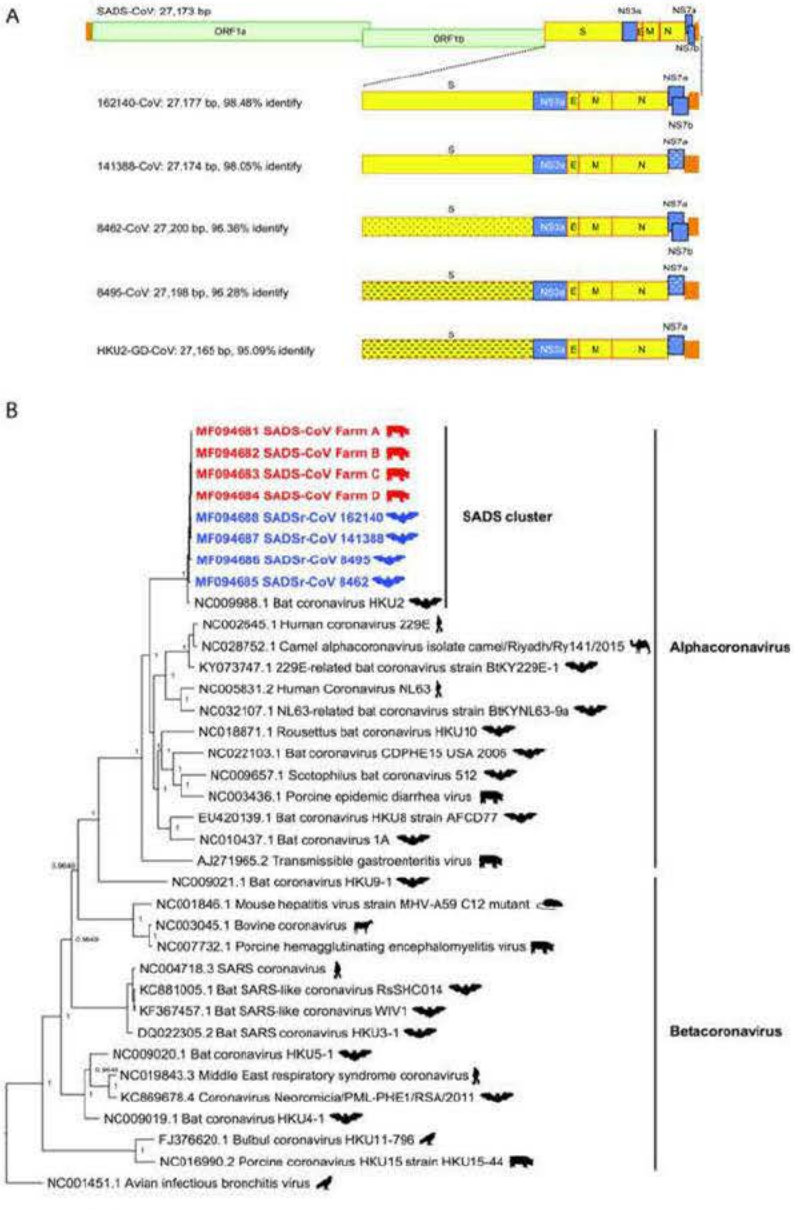
Figure 1. Detection of SADS-CoV infection in pigs in Guangdong, China.

(A) Chronology of outbreaks and the mortality rate on the four different farms. Daily number of pig deaths was recorded from 26 October 2016 to 2 May 2017. The outbreak is ongoing as of the current date. (B) Detection of SADS-CoV by qPCR in different groups of pigs. (C) Tissue distribution of SADS-CoV in diseased pigs. LA- Lymphonodi abdominals; LM- Lymphoglandulae mesentericae. (D) Detection of SADS-CoV antibodies using S1-specific LIPS assay. Infected sows were bled during the initial three weeks of the outbreak, then >1 month after the beginning of the outbreak. Healthy pig sera were set as control.



553 **Figure 2. Genome and phylogeny analysis of SADS-CoV and SADSr-CoV.**

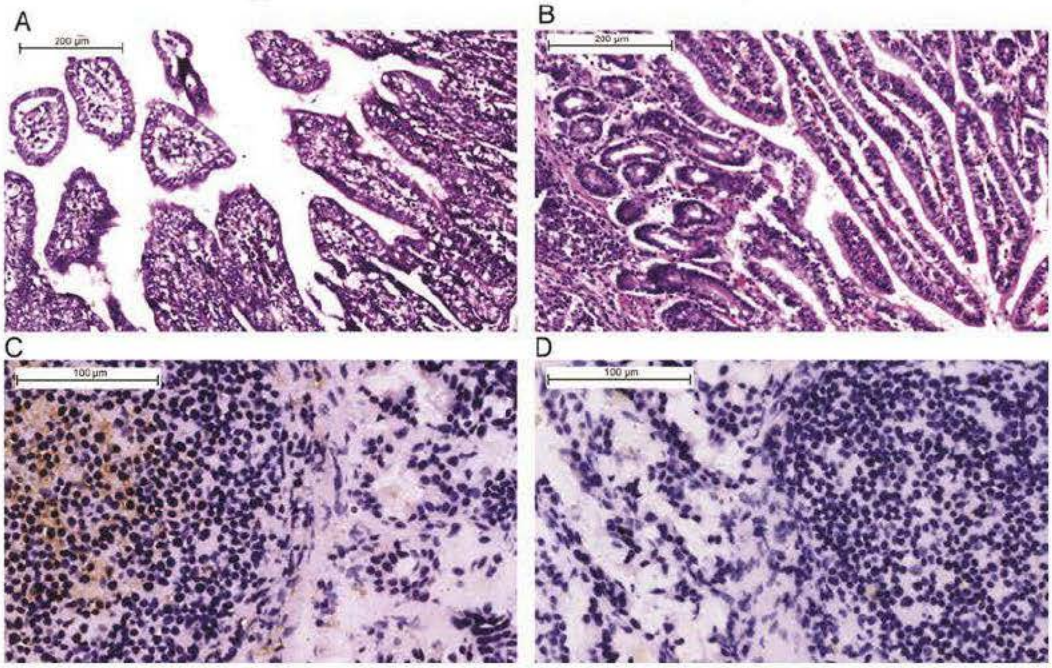
554 (A) Genome organization and comparison. Colored boxes represent genes or UTRs:
555 Green- nonstructural polyproteins ORF1a and 1b; Yellow- structural proteins S, E, M
556 and N; Blue- nonstructural accessory proteins NS3a, NS7a and Ns7b; Orange- UTRs.
557 The level of sequence identity of SADSr-CoV to SADS-CoV was illustrated by
558 patterns; Open box- highly similar; Dots- moderately similar; Dashed line- least
559 similar. (B) Phylogenetic tree based on full-length genome sequences. The Bayesian
560 tree was constructed using MrBayes v3.2 with the average standard deviation of split
561 frequencies under 0.01. The host of each sequence was marked by the animal symbols
562 on the right and newly sequenced SADS-CoVs are highlighted in red while bat
563 SADSr-CoVs in blue.



564

Figure 3 Immunohistopathology of SARS-CoV infected tissues.

(A) and (B), Hematoxylin and eosin staining of jejunum with and without infection. (C) and (D), Immunohistochemistry staining of jejunum with and without infection using rabbit serum raised against the recombinant SADSr-CoV NP protein.



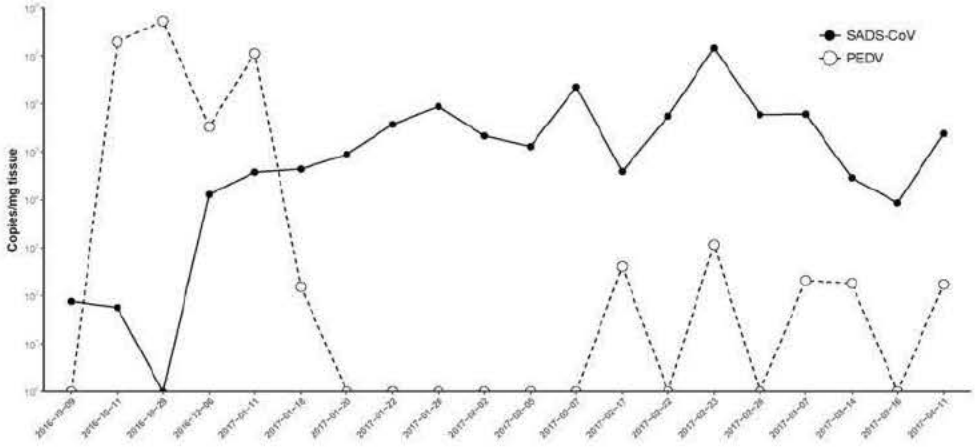
EXTENDED DATA LEGENDS

Extended Data Figure 1. Map of Guangdong Province, China.

SADS-affected farms are labeled A to D with blue swine symbols following the temporal sequence of the outbreaks. Bat sampling sites are identified by black bat symbols. The bat SADSr-CoV most closely related to SADS-CoV (sample 162140) originated Conghua. The red flag marks Foshan city, site of the index case of SARS..

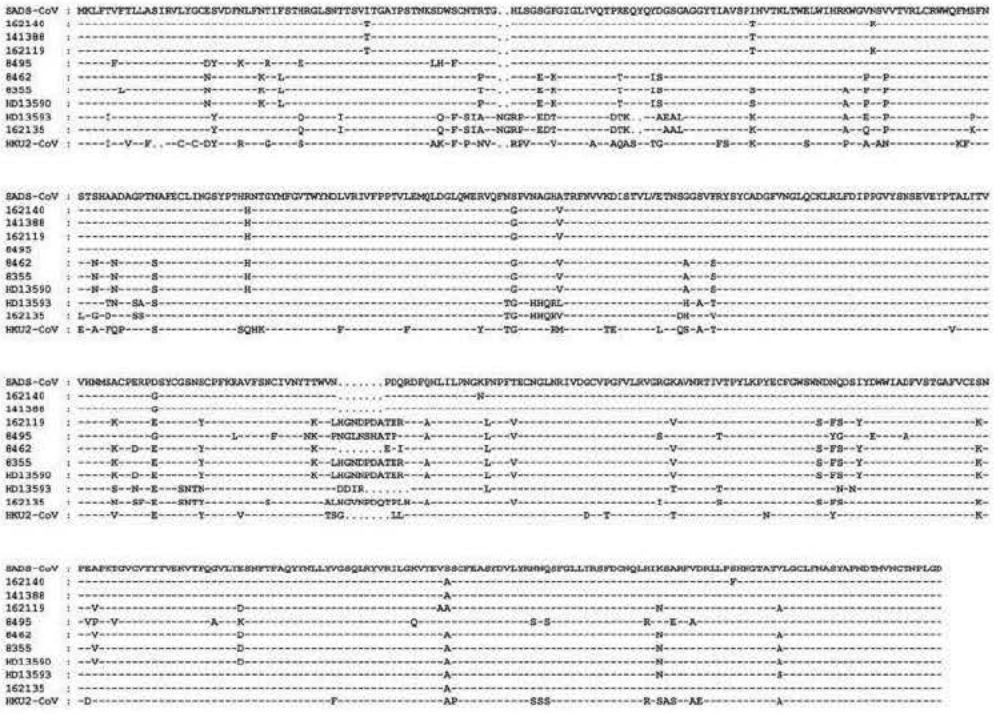
Extended Data Figure 2. Co-circulation of PEDV and SADS-CoV during the initial outbreak on Farm A.

Pooled intestinal samples were collected at dates given on the x-axis from deceased piglets and analyzed by qPCR. The intensity infection for each piglet is shown as a copy number per milligram of intestine (y-axis).



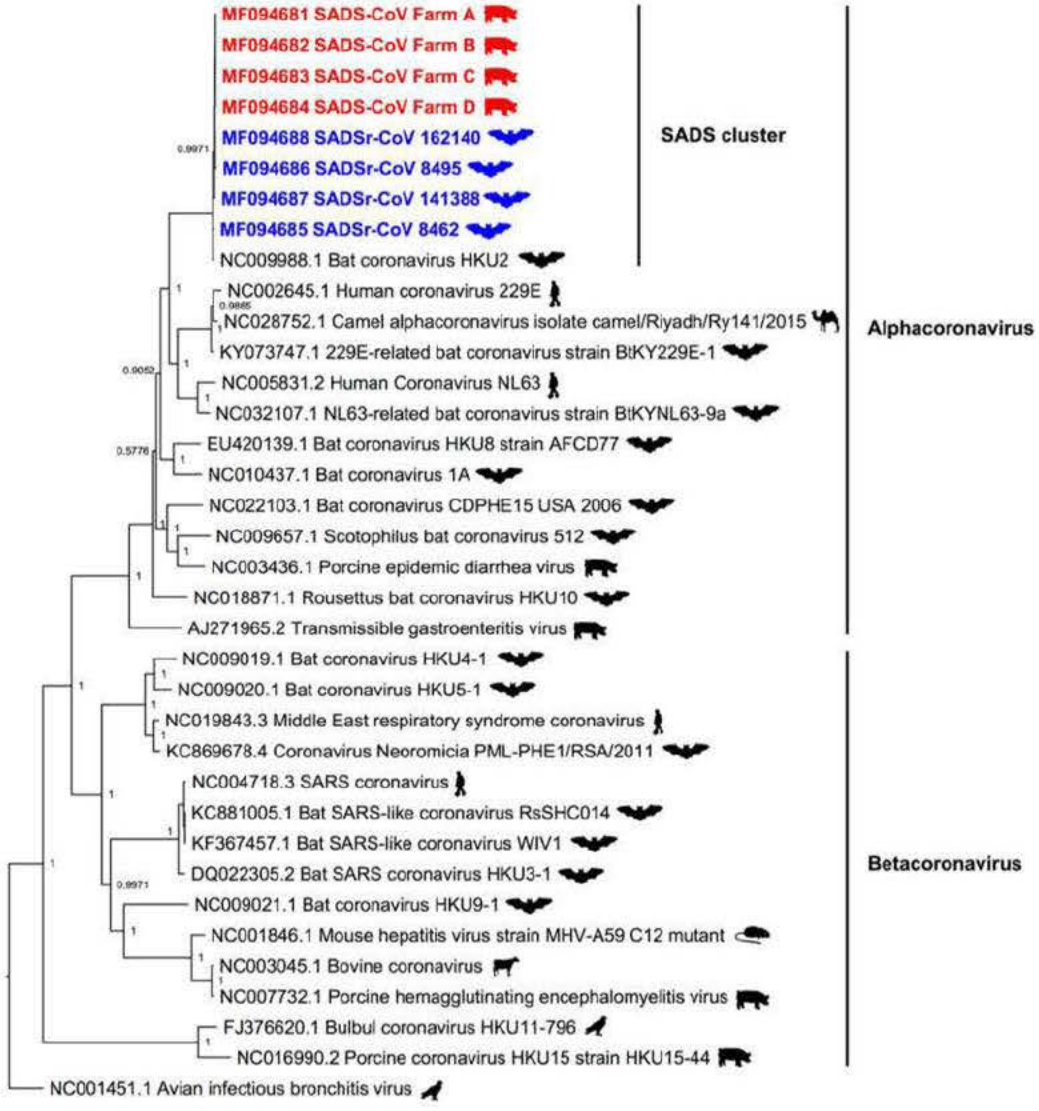
Extended Data Figure 3. Alignment of amino acid sequences of S1 proteins of the SADS cluster of coronaviruses.

The top sequence is from SADS-CoV Farm A. The four SADSr-CoV S1 sequences (162140, 141388, 162119 and 162135) were derived from NGS whole genome sequencing. HKU2-CoV is from a published report[19]. Five additional S1 sequences (8495, 8462, 8355, HD13590 and HD13593) from bats were determined by PCR and Sanger sequencing as described in the text. Dashed lines indicate identical residues while dots represent gaps.



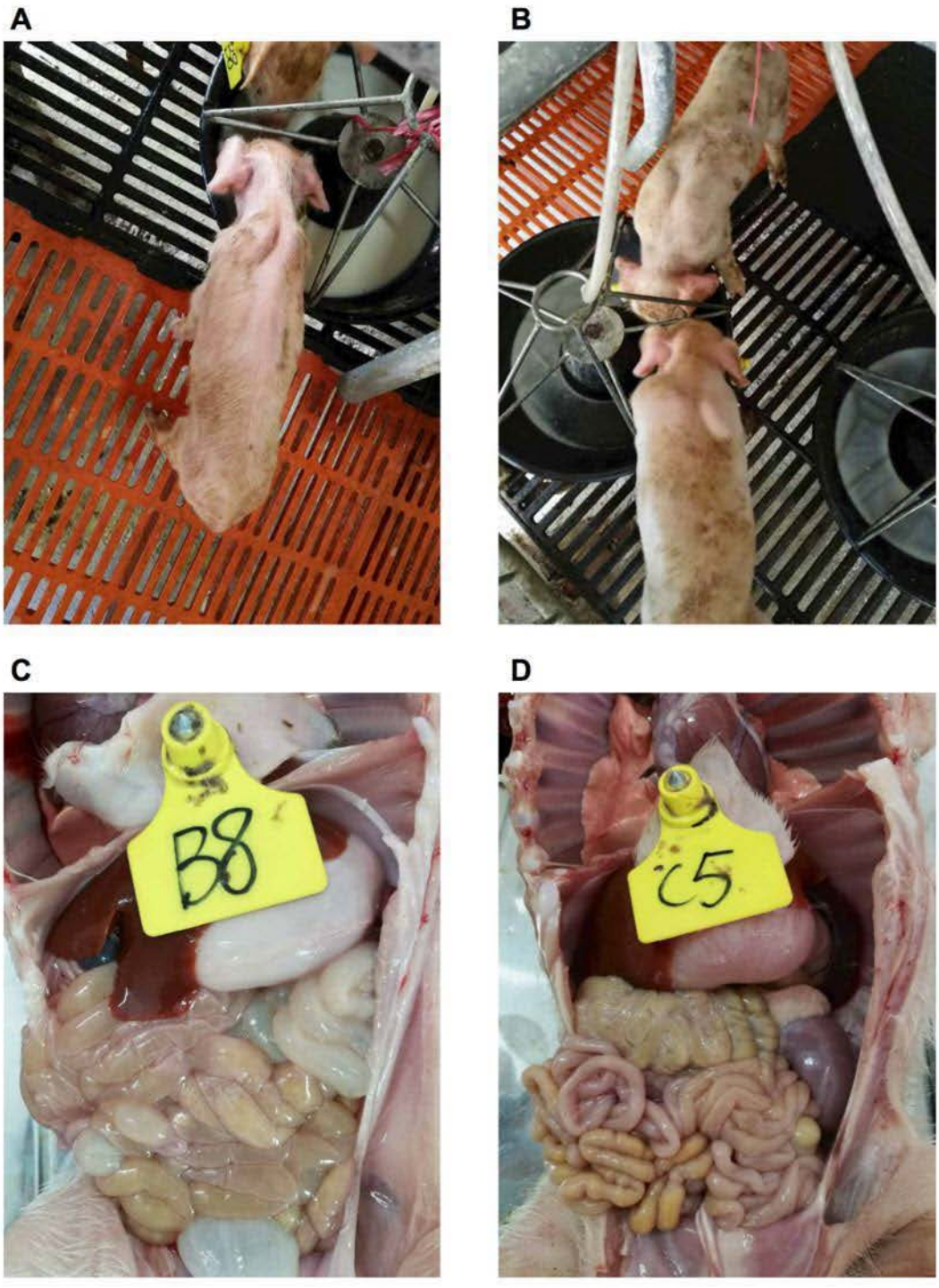
Extended Data Figure 4. Bayesian phylogenetic tree of the sequences encoding RdRp of SADS-CoV and related coronaviruses.

Tree was constructed using MrBayes v3.2 with the average standard deviation of split frequencies under 0.01. The host of each sequence is represented pictorially. Newly sequenced SADS-CoVs are highlighted in red while bat SADSr-CoVs are highlighted in blue.



Extended Data Figure 5. SADS-CoV experimentally infected and healthy piglets.

(A) Piglet on day 2 post SADS-CoV infection. (B) Mock infected piglet on day 2. (C) Intestine from infected piglet at necropsy. (D) Intestine from mock-infected piglet at necropsy.



Extended Data Table 1. List of all known swine viruses tested by PCR at the beginning of the of SADS outbreak investigation on the four farms *.

	PED V	PDC oV	TGE V	R V	PB V	PS V	SV A	SI V	NADC 30	PR V	FMD V	CSF V	PC V2	PC V3	APP V	PP V	Norovir us
Farm A	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND	-
Farm B	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND	-
Farm C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND
Farm D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	ND

* Dash indicates negative PCR result. ND, not done. Virus abbreviations: PEDV- Porcine Epidemic Diarrhea Virus; PDCoV- Porcine Delta Coronavirus; TGEV-Porcine Transmissible Gastroenteritis Virus; RV- Porcine Rotavirus; PBV- Porcine Picobirnavirus; PSV- Porcine Sapelo Virus; SVA- Porcine Senecavirus A; SIV- Swine Influenza Virus; PPRV- Porcine Reproductive and Respiratory Syndrome Virus, strain NADC30; PRV- Porcine Pseudorabies Virus; FMDV- Foot and Mouth Disease Virus; CSFV- Classical Swine Fever Virus; PCV2- Porcine Circovirus 2; PCV3- Porcine Circovirus 3; APPV- Atypical Porcine Pestivirus; PPV- Porcine Parvovirus.

622 **Extended Data Table 2. List of nucleotide and amino acid (aa) residue variants**
623 **among the SADS-CoV genomes obtained from the four different farms.**
624

Nucleotide residue position*	Gene name	Amino acid (aa) residue position*	Farm A nucleotide (aa)	Farm B nucleotide (aa)	Farm C nucleotide (aa)	Farm D nucleotide (aa)
2236	ORF1a	645	G(A)	G(A)	G(A)	T(S)
2955	ORF1a	884	T(G)	C(G)	T(G)	T(G)
3285	ORF1a	994	G(E)	G(E)	G(E)	T(D)
15395	ORF1b	915	C(T)	C(T)	C(T)	T(T)
18410	ORF1b	1920	C(G)	T(G)	T(G)	T(G)
20219	ORF1b	2523	C(L)	T(L)	T(L)	T(L)
21622	S	379	C(N)	C(N)	C(N)	A(K)

625 Non-synonymous aa substitutions are marked in red. * SADS-CoV from Farm A was used as the
626 reference sequence, from which the residue numbering was derived.

627 **Extended Data Table 3. List of PCR primers used in this study.**

628

Gene	Primer name and location*	Primer sequence	Application
RdRp gene	SADS-RdRp-F (19512-19531) SADS-RdRp-R (19590-19608)	GTTGATTGTAAGGCTTGGCG AACCACACTTCCACTCAGC	qPCR
N gene	SADS-N-F (25810-25830) SADS-N-R (25938-25957)	CTAAAACTAGCCCCACAGGTC TGATTGCGAGAACGAGACTG	qPCR
S gene	HKU2-S1-1F (20066-20085) HKU2-S1-1R (22317-22336)	GGCGCTATGGCTGTTAAGAT CACGAATGTCAGCCTCAACT	Cloning
S gene	HKU2-S1-2F (20157-20176) HKU2-S1-2R (22218-22238)	CCAGTGTCAACACGTCATCT ACGCTGAACTTAGGCATTGTA	Cloning

629 * The numbering system of SADS-CoV from Farm A was used as for Extended Data Table 2.

630

631 **Extended Data Table 4. List of SADSr-CoVs detected in bats in Guangdong,**
632 **China.**

Sampling			PCR analysis	
Time (Month-Year)	Location	Bat Species	Fecal swabs sampled	PCR Positive
Jun 13	Yingde	*Rhinolophus sinicus*	1	1
		Pipistrellus abramus	8	0
		Myotis ricketti	2	0
Jul 13	Yangshan	*Pipistrellus abramus*	1	0
		Hipposideros pratti	36	1
Jul 13; May 14; Jun 15; Aug 16	Ruyuan	*Rhinolophus sinicus*	27	6
		Rhinolophus affinis	11	2
		Rhinolophus macrotis	3	0
		Rhinolophus pusillus	41	6
		Rhinolophus rex	9	7
		Hipposideros pratti	7	0
Sep 14; Jun 15; Aug 16	Conghua	*Rhinolophus sinicus*	70	2
		Rhinolophus affinis	34	7
		Rhinolophus pusillus	11	2
		Hipposideros pomona	10	0
		Myotis ricketti	1	0
Jun 13; Nov 13; Aug 14; Jun 15	Huidong	*Rhinolophus sinicus*	37	2
		Rhinolophus affinis	59	29
		Rhinolophus macrotis	15	2
		Rhinolophus pusillus	1	0
		Hipposideros pomona	2	0
		Myotis ricketti	84	1
Apr 14; Jun 15	Longgang	*Rhinolophus sinicus*	55	1
		Pipistrellus abramus	5	1
Sep 14	Xiangzhou	*Rhinolophus pusillus*	28	0
		Hipposideros pomona	38	1
		Total	596	71 (11.9%)

633
634 See Fig. S1 for sampling sites in relation to SARS and SADS outbreak locations
635

Extended Data Table 5. Multiple human CoV receptors as well as swine APN cannot be utilized as entry receptor for SADS-CoV.

	HuAPN★	HuACE2★	HuDPP4★	SwAPN★	SwACE2★
SADS-CoV*	-	-	-	-	-
SARS-like-CoV	NA	+	NA	NA	+
MERS-CoV#	NA	NA	+	NA	NA
PEDV	NA	NA	NA	NA	NA
Expression$	+ (APN Ab)	+ (HIS-tag Ab)	+ (DPP4 Ab)	+ (S-tag Ab)	+ (S-tag Ab)

★Gene accession numbers for the genes used in this study: human APN, M22324.1; human ACE2, NM_021804; human DPP4, NM_001935.3; swine APN, NM_214277.1; swine ACE2, XM_021079374.1

* For SADS-CoV infection, both positive samples and HIV-pseudovirus were used. Viral positive samples were from SADS infected pig anal swabs: SusAS-7 (4.0×10^5 copy/μl), SusAS-20 (4.3×10^5 copy/μl), SusAS-22 (2.4×10^5 copy/μl).

For MERS-CoV infection, HIV-pseudovirus were used.

$ Expression of APN, DPP4 and ACE2 was confirmed by antibodies against the targeting proteins or fused tags.

649 **Extended Data Table 6. Experimental outline of SADS-CoV infection of piglets.**

650 Experiments were performed with (A) 3-day old or (B) 6-day old piglets. Infection
651 was performed as described in the Material and Methods.

652

A

Groups	Infection material	Number	Age (days)	Infection Dose	Infection route	SADS-CoV titer (copy/μl)	First day				Second day				Fourth day
							Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Nutrition exhaustion and Dying
A	SC1 (SADS-CoV positive)	5	3	3mL	Oral+milk	6.54×10^5	5	5	5	0	5	5	5	0	3
B	DE2 (SADS-CoV positive)	5	3	3mL	Oral+milk	10.62×10^5	5	4	5	0	5	3	5	0	1
C	Mock	4	3	3mL	Oral+milk	0	0	0	0	0	0	0	0	0	0
D	Empty mock	4	3	0ml	Milk only	0	3 mild diarrhea	0	0	0	1	0	0	0	0

B

Groups	Infection material	Number	Age (days)	Infection Dose	Infection route	SADS-CoV titer (copy/mg)	First day				Second day				Fourth day
							Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Severe diarrhea	Weight loss	SADS-CoV postive	PEDV/PDCoV/RV positive	Nutrition exhaustion and Dying
A	SC1 (SADS-CoV positive)	6	6	2mL	Oral+milk	6.54×10^5	5	3	6	0	1	0	6	0	0
B	DE2 (SADS-CoV positive)	5	6	2mL	Oral+milk	1.20×10^5	3	3	5	0	3 moderate	1	5	0	0
C	Mock	6	6	2mL	Oral+milk	0	0	0	0	0	0	0	0	0	0
D	Empty mock	5	6	0ml	Milk only	0	0	0	0	0	0	0	0	0	0

653

Peter
Peter Daszak
President
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EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Monday, June 26, 2017 9:30 AM
To: Hongying Li
Cc: Peter Daszak; Aleksei Chmura; Alison Andre
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

Thank you Hongying. I will forward it to security. Looking forward to your visit later this week.
Erik

From: Hongying Li (b) (6)
Sent: Monday, June 26, 2017 9:25 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Peter Daszak (b) (6); Aleksei Chmura (b) (6); Alison Andre (b) (6)
Subject: Re: Potential visit to NIH by our Chinese Co-investigator in June?

Dear Erik,
Not sure if this is too late, but wanted to send you the updated attendee information with Peng Zhou's visa number. Please find it in the attachment. Let me know if there is any question.
Thanks,
Hongying

> On Jun 16, 2017, at 11:22 AM, Hongying Li (b) (6) wrote:
> Dear Erik,
> Please find the security screening information for Zhengli Shi, Peng Zhou, and Hongying Li in the attachment. (b) (6) , but will let you know as soon as we have any further confirmed information.
> Please let me know if there is any question. Thank you!
> Best,
> Hongying
> <5601 Foreign Visitor Form-China.xlsx>
>
> > On May 24, 2017, at 3:16 PM, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:
> > Hi Peter,
> > Thanks for this information. I've attached a form that will help expedite security screening for Dr Zhou and Hongying Li. Can you please have them complete the information on the second sheet of the attachment? I'll need to turn it in to our security office at least a week before your visit, so

if you could get it back to me by June 19th or 20th that would be great. Also, please let them know they should bring their passports with them. Everyone else will need a photo ID as well.
Let me know if you need directions to our building. I would suggest planning to arrive between 8:15 and 8:30, as there can be a line at security if there are other public meetings occurring that day. There is no visitor parking at our facilities, but there is a public parking garage on our block that I can get validation stickers for if you'll be driving. We are also a short walk from the Twinbrook Metro stop, if you plan to travel by train.
Erik

From: Peter Daszak (b) (6)
Sent: Wednesday, May 24, 2017 3:05 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Hongying Li (b) (6); Aleksei Chmura (b) (6); Alison Andre (b) (6)
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?
Importance: High

Hi Erik,
Great to hear from you and looking forward to the talk on June 29th
We're proposing for 4 people to visit NIAID and I've attached bios for all of them to this email. Note that Dr Shi, Dr. Zhou and Hongying Li are all Chinese nationals, and I'm not sure what sort of clearance you'll need for that, so please let me know and we'll work on getting the relevant documents to you

1. Myself, PI on the NIAID CoV grant, President of EcoHealth Alliance, EHA lead on the USAID PREDICT project
2. Dr. Zhengli Shi, Co-Investigator on the NIAID CoV grant, Director of Center for Emerging Diseases at The Wuhan Institute of Virology
3. Dr. Peng Zhou, Associate Professor at Wuhan Institute of Virology
4. Hongying Li, Research Scientist and Country Liaison for China at EcoHealth Alliance

Re a title for the talk, bearing in mind it should be broader than just SARS-CoV, what about the following:
"SARS, MERS and the risk of novel viral emergence from bats"
Zhengli and I will do a double act, and we'll cover the work we're doing on the NIAID project, as well as the broadscale surveillance of bats for novel viruses in PREDICT.
Cheers,
Peter

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From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, May 18, 2017 8:26 AM
To: Peter Daszak
Cc: Hongying Li; Aleksei Chmura; Alison Andre
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

Hi Peter,

We've got you on the calendar for June 29th. Can you send me a title for the talk, short summary, and brief bios for the presenters?

Thank you!

Erik

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Monday, April 24, 2017 4:47 PM
To: Peter Daszak (b) (6)
Cc: Hongying Li (b) (6); Aleksei Chmura (b) (6); Alison Andre (b) (6)
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

Ok! I'll see about scheduling you for the slot on June 29th. Can you send me a title and short synopsis? Since our whole division would be attending it would be great if you could cover some of the collaborative work with PREDICT and not solely focus on the MERS work.

Erik

From: Peter Daszak (b) (6)
Sent: Monday, April 24, 2017 4:44 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Hongying Li (b) (6); Aleksei Chmura (b) (6); Alison Andre (b) (6)
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

That would be perfect. The conference that Zhengli's attending starts on the evening of the 29th in Colorado so she could get a midday plane and still make it.

We'll plan to come to DC the afternoon or evening before and then do the symposium and meet with you.

Cheers,

Peter

Peter Daszak
President

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From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Monday, April 24, 2017 4:35 PM
To: Peter Daszak
Cc: Hongying Li; Aleksei Chmura; Alison Andre
Subject: RE: Potential visit to NIH by our Chinese Co-investigator in June?

Hi Peter,

I would be happy to have you visit us in June. I am available on the 28th. If there is any flexibility in your schedule, Thursday mornings we have a division-wide seminar from 9-10am, and that would be an ideal time to have you present on your work to the larger audience. I understand if that's not possible, thought, but thought I would check to see. Please let me know.

Thanks,

Erik

From: Peter Daszak (b) (6)
Sent: Monday, April 24, 2017 4:11 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Hongying Li (b) (6); Aleksei Chmura (b) (6); Alison Andre (b) (6)
Subject: Potential visit to NIH by our Chinese Co-investigator in June?
Importance: High

Dear Erik,

Our Chinese Co-investigator, Zhengli Shi from the Wuhan Institute of Virology, will be visiting the US in June to give a talk at a conference here. I'd really like to come and visit you and your colleagues at NIH with her while she's here. We could have a meeting to talk about progress on the project and could even do a seminar if there is a format for these.

Zhengli's timeline is fixed, and I wondered if you and your colleagues would be available on Wednesday June 28th? If not, we can look at alternative dates…

Cheers,

Peter

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<5601 Foreign Visitor Form.xlsx>

Hongying Li, MPH 李泓萤
China Programs Coordinator

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(b) (6) (U.S. mobile)
(b) (6) (China mobile)
Hongying Li (Skype)
(b) (6) (WeChat)

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

From: Folkers, Greg (NIH/NIAID) [E]
Subject: EcoHealth Alliance Maps Global Distribution of 'Missing' Viruses Across Wildlife Species
Date: Wednesday, June 21, 2017 3:25:53 PM

EcoHealth Alliance Maps Global Distribution of 'Missing' Viruses Across Wildlife Species

Scientists Identify Highest Risk Mammal Species and Locations for Emerging Viruses

NEW YORK – June 21, 2017 – EcoHealth Alliance, a global nonprofit organization working at the intersection of environmental, animal and public health, announced a paper published online in the journal *Nature*, highlighting the first comprehensive analysis of all viruses known to infect mammals. The study shows that **bats carry a significantly higher proportion of viruses able to infect people** than any other group of mammals; and it **identifies the species and geographic regions on the planet with the highest number of yet-to-be discovered, or 'missing', viruses likely to infect people**. This work provides a new way to predict where and how we should work to identify and pre-empt the next potential viral pandemic before it emerges.

The study team built a comprehensive database of all known viruses infecting over 750 mammal species and around 600 viruses. They used mathematical models to identify the host species characteristics associated with having a larger number of viruses capable of infecting people (zoonotic viruses). They show that zoonotic potential is predicted by a host species evolutionary relatedness to humans, the degree of human-wildlife contact, and other factors including the taxonomic order it belongs to. They used this analysis to demonstrate for the first time that, after correcting for uneven research effort and other variables, bats harbor the highest proportion of zoonotic viruses of any mammal group. "In 2005, our team showed that SARS originates in bats. Ever since that finding, scientists have wondered whether bats are 'special' reservoirs for viruses. We now show definitively that bats carry a higher proportion of yet-to-be-identified viruses of potential risk to people than any other mammal group," says **EcoHealth Alliance's President and senior author on the study, Dr. Peter Daszak**. The paper points out that viral discovery research on wild bats could help prevent pandemics. Bats are important to ecosystem health, through pollinating tropical fruits, removing insect crop pests and disease vectors, and providing other critical ecosystem services. While the data show bats carry potentially important viruses, it's important to remember that the only way these viruses can emerge in people is if we make contact with bats, alter their environment, hunt them or otherwise disturb their ecology. Effective **bat conservation** can help reduce the risk of zoonotic disease through better understanding and effective management of human-bat interactions.

The study uses the analyses to produce detailed maps showing where on the planet we are most likely to find as-yet-undiscovered viruses that could emerge in people, or 'missing zoonoses.' These maps differ among mammal groups. For example, hotspots of 'missing zoonoses' for bats are in South and Central America and parts of Asia, for primates in tropical Central America, Africa, and southeast Asia. "The holy grail in pandemic prevention is to understand where the next zoonotic virus is likely to emerge and from what species. Our study provides the first ever predictive map of where these undiscovered zoonoses can be found across the world. This information is critical to prioritize surveillance to identify and stop the next pandemic," says **Dr. Kevin Olival, lead author on the study**. Finally, the paper provides a new way to estimate how likely a newly-discovered virus from wildlife could be to infect people. It shows that measuring the evolutionary breadth of its host species can predict its potential to infect people. This approach is now being used as part of a multi-country project to identify new viruses in wildlife and help prevent their emergence – **the USAID PREDICT program.** This work was funded by grants R01AI079231 and R01AI110964 from the **National Institute of Allergy and Infectious Diseases** and from the **USAID Emerging Pandemic Threats program.**

About EcoHealth Alliance

Building on over 45 years of groundbreaking science, EcoHealth Alliance is a global, nonprofit organization dedicated to pandemic prevention and ecosystem health. Approximately 60 percent of emerging infectious diseases like Ebola, HIV, Zika, SARS, and MERS originated in animals before spilling over to human populations. Using environmental and health data covering the past 60 years, EcoHealth Alliance scientists created the first-ever, global disease hotspots map that identified at-risk regions to determine where field programs can help predict and prevent the next pandemic crisis. That work is the foundation of EcoHealth Alliance's rigorous, science-based approach working in more than 30 countries worldwide. EcoHealth Alliance has a strong working relationship with Bat Conservation International to promote the conservation of bats and recognition of their critical role on our planet.

For more information, please visit www.ecohealthalliance.org.

batcon.org
BAT CONSERVATION INTERNATIONAL

Bat Conservation International

Bat Conservation International is a nonprofit organization with members in 60 countries and a growing range of international partners. Founded in 1982, BCI uses science, education and conservation action to protect bats and their habitats around the world. Learn more about bats and their critical role in maintaining healthy ecosystems and human economies at BCI's website: www.batcon.org.

For more information, contact Kelly Carnes at kcarnes@batcon.org

From: Peter Daszak
To: Park, Eun-Chung (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]
Cc: Kevin Olival, PhD; Anthony Ramos; Coleman, Amanda (NIH/NIAID) [C]
Subject: RE: Potential media interest from a Nature paper in press based on our work funded by two NIAID R01s
Date: Friday, June 16, 2017 1:18:26 PM
Attachments: Olival et al. Host and viral traits predict zoonotic spillover from mammals Nature 2017 proofs.pdf

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I've attached the final proofs of the paper, so you can see what it's going to look like.

It's scheduled for publication at 1pm EST on Wednesday June 21st online, then the 29th in paper, and of course is embargoed until then.

Also, to let you know that we used your comments in our updated press release which we're circulating to journalists now, and already fielding calls on.

Cheers,

Peter

Peter Daszak
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EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

From: Park, Eun-Chung (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, June 14, 2017 5:19 PM
To: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Cc: Kevin Olival, PhD; Anthony Ramos; Coleman, Amanda (NIH/NIAID) [C]
Subject: RE: Potential media interest from a Nature paper in press based on our work funded by two NIAID R01s

Peter,

I am attaching the document containing comments from our communication office.

Sincerely,

Eunchung

Eun-Chung Park, PhD
Program Officer,
NIAID, NIH
PH: (b) (6)
(b) (6)

From: Peter Daszak (b) (6)
Sent: Wednesday, June 14, 2017 12:30 PM
To: Park, Eun-Chung (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Kevin Olival, PhD (b) (6); Anthony Ramos (b) (6); Coleman, Amanda (NIH/NIAID) [C] (b) (6)
Subject: RE: Potential media interest from a Nature paper in press based on our work funded by two NIAID R01s
Importance: High

No problem.

Hi Amanda. I've attached the pdf of the final version as accepted – not yet in Nature typesetting. We're just waiting on the corrected proofs from Nature and we'll send these on as soon as we get them.

As you know this is embargoed, but unfortunately right now we don't know the official publication date. We think it might be released online next Wednesday June 21st, but will confirm as soon as we hear back from Nature.

By the way – if you want a quote from me or Kevin, or have any questions – no problem – we're around this week and would be happy to help!

Cheers,

Peter

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From: Park, Eun-Chung (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, June 14, 2017 10:36 AM
To: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Cc: Kevin Olival, PhD; Anthony Ramos; Coleman, Amanda (NIH/NIAID) [C]
Subject: RE: Potential media interest from a Nature paper in press based on our work funded by two NIAID R01s

Peter,

Our communication office asks if you can provide the manuscript. I copy Amanda Coleman here, and if you can send to all of us, that will be helpful. Thank you.

Sincerely,

Eunchung

Eun-Chung Park, PhD
Program Officer,
NIAID, NIH
PH: (b) (6)
(b) (6)

From: Peter Daszak (b) (6)
Sent: Tuesday, June 13, 2017 10:08 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Park, Eun-Chung (NIH/NIAID) [E]
(b) (6)
Cc: Kevin Olival, PhD (b) (6); Anthony Ramos
(b) (6)
Subject: Potential media interest from a Nature paper in press based on our work funded by two NIAID R01s
Importance: High

Hi Erik and Eun-Chung

Good News! I want to give you advance notice about a paper Kevin Olival and I have in press with *Nature* that might generate some publicity. It's called "Host and Viral Traits Predict Zoonotic Spillover from Mammals". We acknowledge the current R01 (R01AI110964) on SARS-like CoVs in China that you're Program Officer for, Erik, as well as the R01 on predicting spillover from bat-origin viruses (R01AI079231) that you were Program Officer for a few years ago Eun-Chung – the work for this paper began under that R01, and it's taken a few years of database building and analysis to get to this stage!

I've inserted the abstract below, as accepted by Nature so you can see the content, as well as a draft Press Release we're working on. I don't know what the current standard is for publicity from NIAID-funded work, but I wanted to let you know in advance, in case you'd like to put a story up about this on your website, or talk to the media about it prior to the embargo.

The timing is tight. As always, we don't know exactly when Nature will release it, but we expect it will be online next week, maybe as early as **Wednesday 21st June.** We've already had pre-proofs and have corrected these so we're getting our ducks in a row for that date so that we don't miss any publicity. We'll let you know as soon as we hear the final decision.

Host and viral traits predict zoonotic spillover from mammals

Kevin J. Olival1, Parviez R. Hosseini1, Carlos Zambrana-Torrelio1, Noam Ross1, Tiffany L. Bogich1 & Peter Daszak1

The majority of human emerging infectious diseases are zoonotic, with viruses that originate in wild mammals of particular concern (for example, HIV, Ebola and SARS)1–3. Understanding patterns of viral diversity in wildlife and determinants of successful crossspecies transmission, or spillover, are therefore key goals for pandemic surveillance programs4. However, few analytical tools exist to identify which host species are likely to harbour the next human virus, or which viruses can cross species boundaries5–7. Here we conduct a comprehensive analysis of mammalian host–virus relationships and show that both the total number of viruses that infect a given species and the proportion likely to be zoonotic are predictable. After controlling for research effort, the proportion of zoonotic viruses per species is predicted by phylogenetic relatedness to humans, host taxonomy and human population within a species range—which may reflect human–wildlife contact. We demonstrate that bats harbour a significantly higher proportion of zoonotic viruses than all other mammalian orders. We also identify the taxa and geographic regions with the largest estimated number of 'missing viruses' and 'missing zoonoses' and therefore of highest value for future surveillance. We then show that phylogenetic host breadth and other viral traits are significant predictors of zoonotic potential, providing a novel framework to assess if a newly discovered mammalian virus could infect people.

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LETTER

doi:10.1038/nature22975

Host and viral traits predict zoonotic spillover from mammals

Kevin J. Olival[1], Parviez R. Hosseini[1], Carlos Zambrana-Torrelio[1], Noam Ross[1], Tiffany L. Bogich[1] & Peter Daszak[1]

The majority of human emerging infectious diseases are zoonotic, with viruses that originate in wild mammals of particular concern (for example, HIV, Ebola and SARS)[1–3]. Understanding patterns of viral diversity in wildlife and determinants of successful cross-species transmission, or spillover, are therefore key goals for pandemic surveillance programs[4]. However, few analytical tools exist to identify which host species are likely to harbour the next human virus, or which viruses can cross species boundaries[5–7]. Here we conduct a comprehensive analysis of mammalian host–virus relationships and show that both the total number of viruses that infect a given species and the proportion likely to be zoonotic are predictable. After controlling for research effort, the proportion of zoonotic viruses per species is predicted by phylogenetic relatedness to humans, host taxonomy and human population within a species range—which may reflect human–wildlife contact. We demonstrate that bats harbour a significantly higher proportion of zoonotic viruses than all other mammalian orders. We also identify the taxa and geographic regions with the largest estimated number of 'missing viruses' and 'missing zoonoses' and therefore of highest value for future surveillance. We then show that phylogenetic host breadth and other viral traits are significant predictors of zoonotic potential, providing a novel framework to assess if a newly discovered mammalian virus could infect people.

Viral zoonoses are a serious threat to public health and global security, and have caused the majority of recent pandemics in people[4], yet our understanding of the factors driving viral diversity in mammals, viral host range, and cross-species transmission to humans remains poor. Recent studies have described broad patterns of pathogen host range[1,3] and various host or microbial factors that facilitate cross-species transmission[5,7,8], or have focused on factors promoting pathogen and parasite sharing within specific mammalian taxonomic groups including primates[9–11], bats[12–14], and rodents[12,15]—but to date there has been no comprehensive, species-level analysis of viral sharing between humans and all mammals. Here we create, and then analyse, a database of 2,805 mammal–virus associations, including 754 mammal species (14% of global mammal diversity) from 15 orders and 586 unique viral species (every recognized virus found in mammals[16]) from 28 viral families (Methods). We use these data to test hypotheses on the determinants of viral richness and viral sharing with humans. We fit three inter-related models to elucidate specific components of the process of zoonotic spillover (Extended Data Fig. 1). First, we identify factors that influence total viral richness (that is, the number of unique viral species found in a given host, including those which may have the potential to infect humans). Second, we identify and rank the ecological, phylogenetic and life-history traits that make some species more likely hosts of zoonoses than others. Third, recognizing that not all mammalian viruses will have the biological capacity to infect humans, we identify and rank viral traits that increase the likelihood of a virus being zoonotic.

In examining the raw data, we found that observed viral richness within mammals varies at a host order and viral family level, and is highest for Bunya-, Flavi- and Arenaviruses in rodents; Flavi-, Bunya- and Rhabdoviruses in bats; and Herpesviruses in non-human primates (Extended Data Fig. 2). Of 586 mammalian viruses in our dataset, 263 (44.9%) have been detected in humans, 75 of which are exclusively human and 188 (71.5% of human viruses) zoonotic—defined operationally here as viruses detected at least once in humans and at least once in another mammal species (Methods). The proportion of zoonotic viruses is higher for RNA (159 of 382, 41.6%) than DNA (29 of 205, 14.1%) viruses. The observed number of viruses per wild host species was comparable when averaged across orders, but bats, primates, and rodents had a higher proportion of observed zoonotic viruses compared to other groups of mammals (Fig. 1). Species in other orders (for example, Cingulata, Pilosa, Didelphimorphia, Eulipotyphla) also shared a majority of their observed viruses with humans, but data were limited in these less diverse and poorly studied orders. Several species of domesticated ungulates (orders Cetartiodactyla and Perissodactyla) are outliers for their number of observed viruses, but these species have a relatively low proportion of zoonotic viruses (Fig. 1; Supplementary Discussion).

Previous analyses show that zoonotic disease emergence events and human pathogen species richness are spatially correlated with mammal and bird diversity[2,17]. However, these studies weight all species equally. In reality, the risk of zoonotic viral transmission, or spillover, probably varies among host species owing to differences in underlying viral richness, opportunity for contact with humans, propensity to exhibit clinical signs that exacerbate viral shedding[18], other ecological, behavioural and life-history differences[5,12,15], and phylogenetic proximity to humans[10]. We hypothesize that the number of viruses a given mammal species shares with humans increases with phylogenetic proximity to humans and with opportunity for human contact. We used generalized additive models (GAMs) to identify and rank host-specific predictors (ecological, life history, taxonomic, and phylogenetic traits, and a control for research effort) of the number of total and zoonotic viruses in mammals (Methods; Supplementary Table 1).

The best-fit model for total viral richness per wild mammal species explained 49.2% of the total deviance, and included a per-species measure of disease-related research effort, phylogenetically corrected body mass, geographic range, mammal sympatry, and taxonomy (order) (Fig. 2a–e). Not surprisingly, research effort had the strongest effect on the total number of viruses per host, explaining 31.9% of the total deviance for this model (Extended Data Table 1). The remaining 17.3% can be explained by biological factors, a value greater than or comparable to studies examining much narrower groups of mammal hosts[10,12,15] (Supplementary Discussion). Mammal sympatry was the second most important predictor of total viral richness (Fig. 2d). Our model selection consistently identified mammal sympatry calculated at a $\geq$20% area overlap over other thresholds explored (Methods), providing insight into the minimum geographic overlap needed to facilitate viral sharing between hosts. Host geographic range was also significantly associated with increasing total viral richness, although the strength of this effect was low (Fig. 2c). Several

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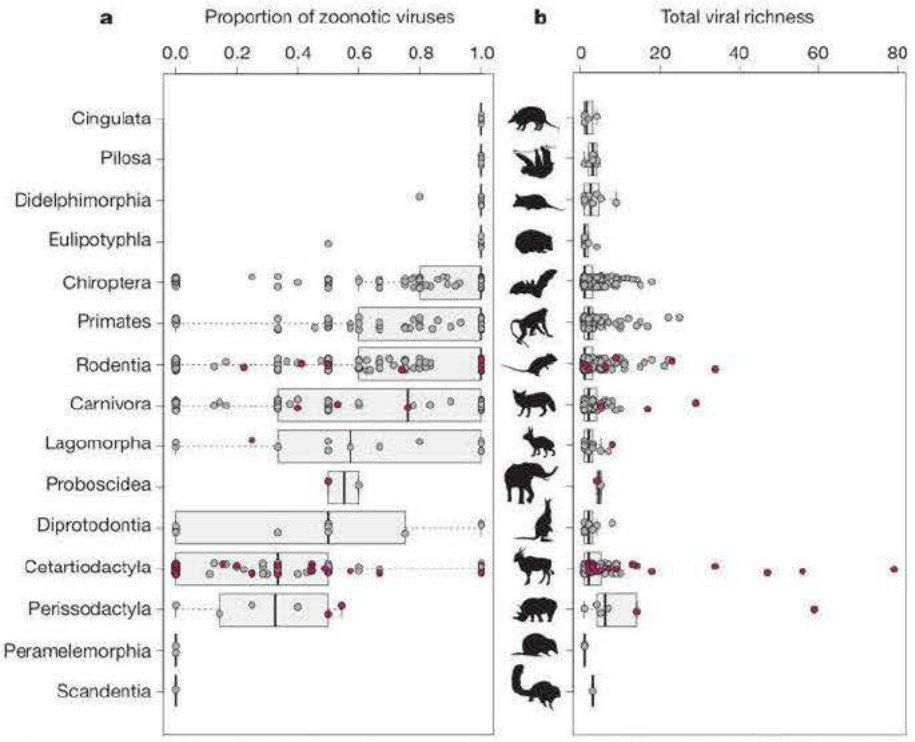

Figure 1 | Observed viral richness in mammals. **a**, **b**, Box plots of proportion of zoonotic viruses (**a**) and total viral richness per species (**b**), aggregated by order. Data points represent wild (light grey, $n = 721$) and domestic (dark red, $n = 32$) mammal species; lines represent median, boxes, interquartile range. Animal silhouettes from PhyloPic. Data based on 2,805 host–virus associations. See Methods for image credits and licensing.

mammalian orders, Chiroptera (bats), Rodentia (rodents), Primates, Cetartiodactyla (even-toed ungulates), and Perissodactyla (odd-toed ungulates) listed here in order of relative deviance explained, had a significantly greater mean viral richness than predicted by the other variables (Fig. 2e). This finding highlights these taxa as important targets for global viral discovery in wildlife[4], and suggests that traits not captured in our analysis (for example, immunological function, social structure, and other life-history variables) may underlie their capacity to harbour a greater number of viral species. Our models to predict total viral richness were comparable when excluding virus–host associations detected by serology, that is, using the 'stringent data', and were robust when validated with random cross-validation tests (Extended Data Table 1; Supplementary Table 2). However, we identified several regions that showed significant bias when cross-

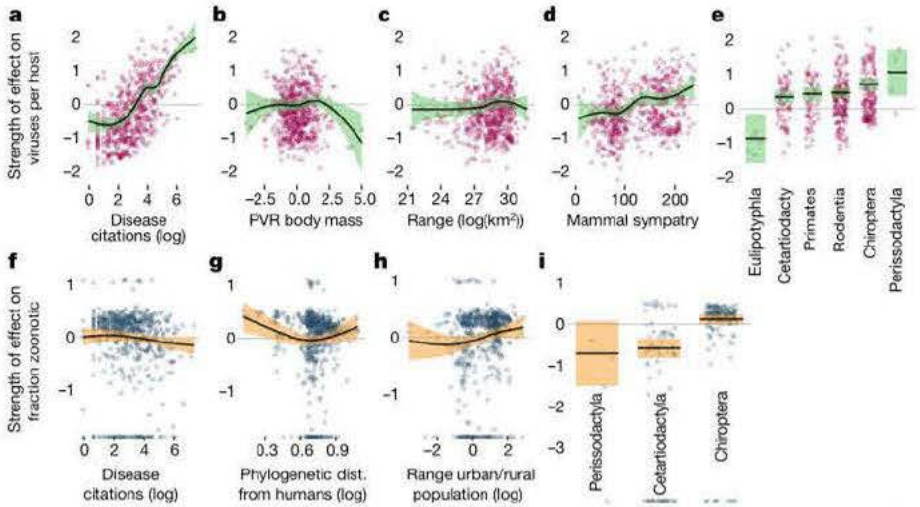

Figure 2 | Host traits that predict total viral richness (top row) and proportion of zoonotic viruses (bottom row) per wild mammal species. Partial effect plots show the relative effect of each variable included in the best-fit GAM, given the effect of the other variables. Shaded circles represent partial residuals; shaded areas, 95% confidence intervals around mean partial effect. **a**–**e**, Best model for total viral richness includes: **a**, number of disease-related citations per host species (research effort, log); **b**, phylogenetic eigenvector regression (PVR) of body mass (log); **c**, geographic range area of each species (log km^2); **d**, number of sympatric mammal species overlapping with at least 20% area of target species range; and **e**, mammalian orders. **f**–**i**, Best model for proportion of zoonoses includes: **f**, research effort (log); **g**, phylogenetic distance from humans (cytochrome *b* tree constrained to the topology of the mammal supertree[28]); **h**, ratio of urban to rural human population within species range; and **i**, three mammalian orders. Bats are the only order with a significantly larger proportion of zoonotic viruses than would be predicted by the other variables in the all-data model. Three additional mammalian orders, and whether or not a species is hunted, improved the overall predictive power of the best zoonotic virus model but were non-significant and are not shown (see Extended Data Table 1).

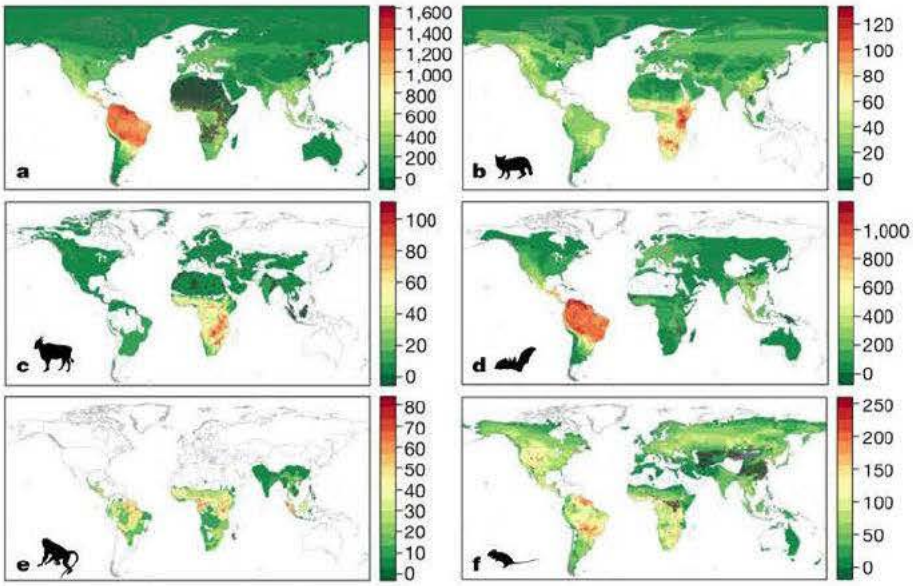

Figure 3 | Global distribution of the predicted number of 'missing zoonoses' by order. Warmer colours highlight areas predicted to be of greatest value for discovering novel zoonotic viruses. **a**, All wild mammals ($n = 584$ spp. included in the best-fit model). **b**, Carnivores (order Carnivora, $n = 55$). **c**, Even-toed ungulates (order Cetartiodactyla, $n = 70$). **d**, Bats (order Chiroptera, $n = 157$). **e**, Primates (order Primates, $n = 73$). **f**, Rodents (order Rodentia, $n = 183$). Hatched regions represent areas where model predictions deviate systematically for the assemblage of species in that grid cell (approximately 18 km × 18 km, see Methods). Animal silhouettes from PhyloPic.

validated by excluding mammals from zoogeographic areas, suggesting that there are location-specific factors that remain unexplained in our models (Methods; Supplementary Table 3).

Our best model to predict the number of zoonotic viruses per wild mammal species explained 82% of the deviance, and included phylogenetic distance from humans, the ratio of urban to rural human population across a species range, host order, whether or not a species is hunted, disease-related research effort, and total viral richness (Extended Data Table 1). A large fraction of the deviance explained is driven by the observed total viral richness per host, supporting the biological assumption that the number of viruses that infect humans scales positively with the size of the potential 'zoonotic pool'[19] in each reservoir host. Removing this contribution by including observed total viral richness per host as an offset, the model explains 33% of the total deviance in the proportion of viruses that are zoonotic (Methods), with 30% of total deviance explained by biological factors (Fig. 2f–i). Some mammalian orders had a significant positive (bats) or negative (two ungulate orders) effect on the proportion of zoonotic viruses (Fig. 2i). A number of previous studies have proposed that bats are special among mammals as reservoir hosts of a large number of recently emerging high-profile zoonoses (for example, SARS, Ebola virus, MERS)[12,13,20]. Our study tests this hypothesis in the context of all known mammalian viruses and hosts. While other mammalian orders have relatively high proportions of observed zoonoses and others have been poorly studied (Fig. 1a), our model results show that bats are host to a significantly higher proportion of zoonoses than all other mammalian orders after controlling for reporting effort and other predictor variables.

We found that the proportion of zoonotic viruses per species increases with host phylogenetic proximity to humans, and that this relationship is significant even when we removed 'reverse zoonoses' primarily associated with transmission from humans to primates (Methods). This is the first time this relationship has been demonstrated using data for all mammals and specifically as a determinant of zoonotic spillover, and is supported by previous taxon-specific studies that have examined host relatedness and parasite/pathogen sharing in primates[9,10], bats[14] and plants[21]. The proportion of zoonotic viruses shows some upward drift for mammals that are very phylogenetically distant from humans (Fig. 2g) that may represent an artefact of preferentially screening marsupials for human viruses. While primate species largely drive the phylogenetic effect, our best-fit model excluded the effect of the order Primates as a discrete variable (Fig. 2i), suggesting that continuous variation in phylogenetic distance across primate species is more important, and is significant even when all mammals are included. This finding highlights the need to uncover the mechanism by which phylogeny affects spillover risk, for example, evolutionarily related species sharing host cell receptors and viral binding affinities[22,23] and specific viral mutations that may expand host range in related mammal species[24].

We tested several measures to estimate human–wildlife contact at a global scale for the 721 wild mammals in our dataset, but only the ratio of urban to rural human population (all data model), the change in human population density, and the change in urban to rural population ratio from 1970–2005 across a species range (stringent data model) were included (Extended Data Table 1). The response curve for urban to rural population suggests that increasing urbanization raises the risk of zoonotic spillover (Fig. 2h), as does increasing human population density and the change in urban to rural population ratio over time. A single global metric of human–wildlife ecological contact did not emerge across models. However, the alternate inclusion of these related variables points to the importance of human–animal contact in defining per-species spillover risk globally, and the need for controlled field experiments and human behavioural risk studies to uncover the mechanisms underlying this risk. Overall, the strength of the effect of phylogenetic proximity was stronger than our proxies for animal–human contact in predicting proportion of zoonoses (30–44% stronger explanatory factor), but both remained significant after controlling for research effort (Extended Data Table 1).

The predominance of zoonoses of wildlife origin in emerging diseases has led to a series of programs to sample wildlife, discover novel viruses, and assess their zoonotic potential[4,23,25,26]. To inform their scale and scope we calculate the expected number of as-yet undiscovered viruses and zoonoses per host species using our best-fit GAMs and a scenario of increased research effort (Methods, Supplementary Table 4). We then project these 'missing viruses' and 'missing zoonoses' geographically (Fig. 3, Extended Data Figs 3–8) to identify regions of the world where targeted, future surveillance to find new viruses and zoonoses will be most effective. In the process of translating our non-spatial, species-level predictions to geographic space, we identified several regions where our model predictions of the number of total

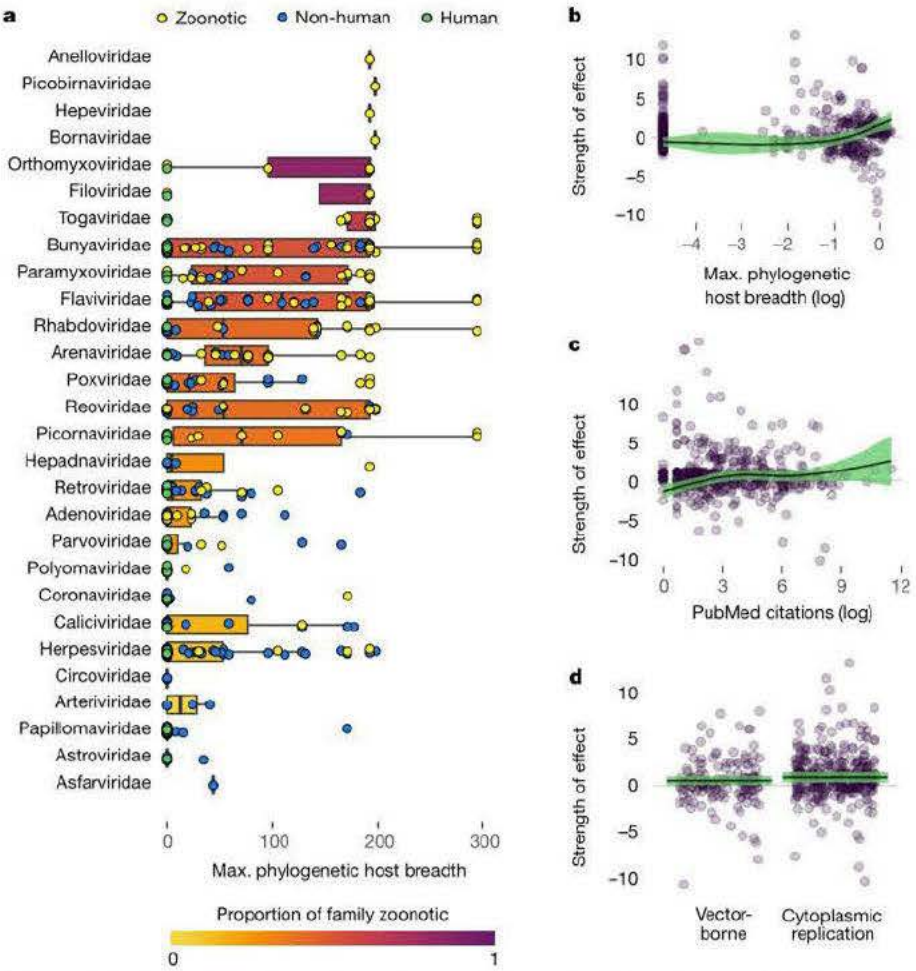

Figure 4 | Traits that predict zoonotic potential of a virus. **a**, Box plot of maximum phylogenetic host breadth per virus (PHB, see methods) for each of 586 mammalian viruses, aggregated by 28 viral families. Individual points represent viral species, colour-coded by zoonotic status. Box plots coloured and sorted by the proportion of zoonoses in each viral family. **b**–**d**, Partial effect plots for the best-fit GAM to predict the zoonotic potential of a virus. **b**, Maximum PHB. Viruses that infect a phylogenetically broader range of hosts are more likely to be zoonotic. **c**, Research effort (log, number of PubMed citations per viral species). **d**, Whether or not a virus replicates in the cytoplasm or is vector-borne. Viral genome length and whether or not a virus is enveloped improved the overall predictive power but were non-significant and are not shown (see Extended Data Table 1).

and zoonotic viruses were systematically biased (hatched regions in Fig. 3 and Extended Data Figs 3–8; Methods). Local factors contributing to this bias may include geographic variation in the detection probability of human and/or wildlife viruses, indicating areas where additional research and capacity strengthening for viral detection are most needed. Our model predictions were not systematically biased or clustered across host phylogeny (Extended Data Fig. 9).

Geographic hotspots of 'missing zoonoses' vary by host taxonomic order, with foci for carnivores and even-toed ungulates in eastern and southern Africa, bats in South and Central America and parts of Asia, primates in specific tropical regions in Central America, Africa, and southeast Asia; and rodents in pockets of North and South America and Central Africa. Areas where 'missing zoonoses' predictions were systematically biased varied by taxonomic order, but included large parts of Africa for the all-mammal dataset (Fig. 3a, Extended Data Figs 3–8f). By contrast, the distribution of bias in predicting the 'missing viruses' for all mammals was limited to patches of northeastern Asia, Greenland, peninsular Malaysia, and scattered grid cells in western Asia and Patagonia (Extended Data Fig. 3c). We also identify geographic regions with large numbers of mammal species currently lacking any information regarding their viral diversity (Extended Data Figs 3i–8i). In combination, these maps can be used for cost-effective allocation of resources for viral discovery programs, such as the Global Virome Project (D. Carroll *et al.*, submitted).

Finally, a significant challenge to preventing future disease emergence is estimating the zoonotic potential of a newly discovered viral species or strain based on viral traits[4–6,27]. The best model for determining whether or not a known virus ($n = 586$ mammalian viruses) has been observed as zoonotic explained 27.2% of total deviance and included maximum phylogenetic host breadth (PHB—a virus-specific trait that measures the phylogenetic range of known hosts, excluding humans), research effort, whether or not a virus replicates in the cytoplasm, is vector-borne, or is enveloped, and average genome length (Fig. 4). Using the 'stringent' dataset to define whether a virus is zoonotic resulted in a reduced model that excluded enveloped status and genome length (Extended Data Table 1). Our findings confirm a positive relationship between zoonotic potential and ability to replicate in the cytoplasm[7], and that viruses with arthropod vectors may be able to infect a wider range of mammalian hosts[5]. Our phylogenetically explicit measure of host breadth, PHB, can be used at various hierarchical taxonomic levels to quantify and rank viruses from specialist to generalist, and was the strongest predictor of zoonotic potential (12.4% of total deviance explained). This highlights the value of field programs to identify the natural host range of newly discovered pathogens in order to develop early proxies for their zoonotic potential[4]. Significant variation in PHB across viral families is suggestive of intrinsic differences in the ability of a virus to infect diverse hosts, and this relates to the proportion of observed zoonoses in each family (Fig. 4a).

We acknowledge several important caveats in this study. First, our estimates of missing viruses and missing zoonoses per species are based on the current maximum observed research effort from the literature, and these estimates should be viewed as relative, not absolute. The true size of the undiscovered mammalian virome will probably increase with new genetic tools for unbiased viral discovery and in-depth studies that repeatedly sample wildlife populations over time[25]. Second, our ecological and biological predictor variables only explain a portion of the total variation in viral richness per host and zoonotic potential based on viral traits, although this is greater than that reported in comparable order-specific studies[10,12]. Third, while we control for research effort we cannot account for viruses or host associations that have completely evaded human detection to date, nor those identified but not published. Additional resources to support better data sharing and on-the-ground viral surveillance in the species and regions we identify would help validate predictive models to identify zoonotic viral hotspots, and streamline costly efforts to develop measures to prevent their future emergence.

The analyses reported herein have broad potential to assist in expediting viral discovery programs for public health. Our host-specific analyses and estimates of missing zoonoses allow us to identify which species and regions should be preferentially targeted to characterize the global mammalian virome. Our viral trait framework then allows prioritization of newly discovered wildlife viruses for detailed characterization (for example, by sequencing receptor-binding domains, and conducting *in vitro* and *in vivo* infection experiments[23]) to assess their potential to threaten human health.

Online Content Methods, along with any additional Extended Data display items and Source Data, are available in the online version of the paper; references unique to these sections appear only in the online paper.

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METHODS

No statistical methods were used to predetermine sample size. The experiments were not randomized and the investigators were not blinded to allocation during experiments and outcome assessment.

Database. To construct the mammal–virus association database we initially extracted all viruses listed as occurring in any mammal from the International Committee on Taxonomy of Viruses database (ICTVdb), and further individually went through each virus listed in the ICTV 8th edition master list and searched the literature for mammalian hosts. All viral species names were synonymized to ICTV 8th edition, which was the global authority on viral taxonomy at the start of our data collection in 2010 (ref. 16). From 2010–15 the authors and a team of research assistants and interns at EcoHealth Alliance compiled mammal species associations for each of 586 unique viruses published in the literature between 1940–2015 initially by using the virus name and synonyms as the search keywords in the major online reference databases (Web of Science, PubMed, and Google Scholar) in addition to searching in books, reviews, and literature cited in sources we had already obtained. To narrow the search for hosts for well-researched viruses, we additionally included the terms 'host(s)', 'reservoir', 'wildlife', 'animals', 'surveillance', and other relevant terms to find publications related to host range. Associations were cross-checked for completeness with the Global Mammal Parasite Database for primate, carnivore and ungulate viruses, version as of Nov 2006 (GMPD, http://www.mammalparasites.org)[29] and other published reviews specific to bats and rodents[12,30,31]. We excluded all records without species-level host information, and those where we could not track down the primary references. Records of mammal–virus associations from experimental infection studies, zoological parks or captive breeding facilities, or cell culture discoveries were excluded. Host species were defined as domestic or wild following the list of domestic animal species from the Food and Agriculture Organization (FAO)[32], and we removed the black rat (*Rattus rattus*) and domestic mouse (*Mus musculus*) from the domesticated list as these two species make up their own 'peri-domestic' category. Host species were categorized as either occurring in human modified habitats or being hunted by humans—both estimates for human contact—according to the IUCN Red List species descriptions[33].

To control for the fact that some detection methods are more reliable than others in identifying the pathogen of interest, we recorded the detection method used for each host–virus association and scored these as 0, 1, or 2 according to the reliability of detection method used. Viral isolation and PCR detection with sequence confirmation were scored as a 2 (=stringent data); and serological methods were scored as a 0 or 1, with viral or serum neutralization tests (=1), and enzyme-linked immunoassays (ELISA), antigen detection assays, and other serological assays scored as (=0). 'Stringent data' were analysed separately to remove potential uncertainty owing to cross-reactivity with related viruses. We exhaustively searched the literature to identify a stringent detection for each mammal–virus pair, and only included the serological finding for that pair if no molecular or viral isolation studies were available. We partitioned data and conducted separate analyses for the entire data set (0 + 1 + 2 detection quality) and the stringent data (score of 2) to reduce the noise from potential serological cross-reactivity. Full list of host–virus associations, detection methods, and associated references are provided in our data and code repository at http://doi.org/10.5281/zenodo.596810.

Our operational definition of a zoonotic virus includes any virus that was detected in humans and at least one other mammalian host in at least one primary publication, and does not imply directionality. Our complete dataset of mammalian viral associations demonstrates evidence of past or current viral infection which we believe is a reasonable proxy for measuring spillover, and our stringent dataset specifically is more robust to exclude species that may have been exposed to a given virus versus those that show some evidence for replication within the host species. Our bi-directional definition of spillover follows a proposal by the WHO that defines a zoonosis as "any disease or infection that is naturally transmissible from vertebrate animals to humans and vice-versa" (http://www.who.int/zoonoses/en/) and excludes any human pathogens that recently evolved from nonhuman pathogens (for example, HIV in primates), as per Woolhouse and Gowtage-Sequeria (2005) (ref. 1).

In order to address influence of transmission from humans to wildlife in our models, we also ran our GAM model fitting and selection procedure (see below) on a subset of data that excluded any probable 'reverse zoonotic' viruses. We first searched our entire dataset and removed any clear instances of transmission from humans to primates, for example, including records from zoological parks and wildlife rehabilitation centres (as previously noted). We then additionally removed several human viruses most commonly transmitted from humans back to non-human primates to create a subset of data without the most common reverse zoonotic viruses (adeno-associated virus-2; human adenovirus D; human herpesvirus 4; human metapneumovirus; human respiratory syncytial virus; measles virus; mumps virus)[34,35]. We present these additional analyses excluding reverse zoonoses and associated code at http://doi.org/10.5281/zenodo.596810.

Total viral richness was calculated as the number of unique ICTV-recognized viruses found in a given host species, and zoonotic viral richness was defined as the number of unique ICTV-recognized viruses in a given host species that were also detected in humans in our database.

To assess research bias for both host and virus, we searched ISI Web of Knowledge, including Web of Science and Zoological Record, and PubMed for the number of research publications for a given host or pathogen. We recorded two values for the number of research papers for a host. The first was a simple search by scientific binomial in Zoological Abstracts where we recorded the number of papers published between 1940–2013 for each host species. We also recorded the number of disease-related publications for each species using the scientific binomial AND topic keyword: disease* OR virus* OR pathogen* OR parasit*. The * operator was used in our search criteria to capture all words that begin with each term, for example, 'parasit*' would return hits for 'parasite', 'parasites', and 'parasitic'. These search criteria broadly included papers that examined disease or diseases, virus or viruses, pathogen or pathogens, parasite parasites, or parasitology, for each species. Only one measure of per-host research effort was included at a time in model selection. As these metrics are highly correlated and the number of disease related citations per host outperformed the total number of publications per host in all but one model (all-data zoonoses), we decided to use disease-related publications as our per-species research effort measure for all models to improve interpretability. We also recorded the number of publications for each of 586 virus species using a keyword search by virus name in PubMed and Web of Science. Only one measure of per virus research effort was included at a time in model selection.

We used a phylogenetically corrected measure of body mass (see details below under 'Phylogenetic signal') as our main life history predictor variable, because it was the only one for which a nearly complete dataset existed for the species in our dataset. We used the body mass recorded in the PanTHERIA database[36] for 709 species. For 3 species, we used the second choice option, body mass recorded in the AnAge database[37]. For 11 species, we used the third choice option of the extrapolated body mass recorded in PanTHERIA, which is based on body length or forearm length, depending on species. For 36 species, we used the average body mass for members of the genus that had a recorded body mass. We explored other life-history variables related to longevity[38], reproductive success, and basal metabolic rate but these were ultimately excluded owing to the high number of missing records.

Phylogenetic signal. We address the issue of non-independence of host species traits owing to shared ancestry[39] in our analyses by first quantifying the phylogenetic signal for each variable in our model using Blomberg's K[40]. Blomberg's K measures phylogenetic signal in a given trait by quantifying trait variance relative to an expectation under a Brownian motion null model of evolution using a phylogenetic tree with varying branch lengths. Blomberg's K-values are scaled from 0 to infinity, with a value of 0 equal to no phylogenetic signal and values greater than 1 equal to strong phylogenetic signal for closely related species that share more similar trait values. While there is no clearly defined K value cut-off in which to apply phylogenetic comparative methods, non-significant value of <1, or more conservatively <0.5, are typical for traits that are phylogenetically independent. The only host variables we examined with significant K values >0.5 were host body mass, and our direct measure of phylogenetic distance to humans. While there are several tools available to control for phylogeny in multivariate analyses, for example, using phylogenetic generalized least square models (for example, PGLS)[41], there is currently no modelling approach to control for phylogeny using GAMs. More importantly, a wholesale effort to control for phylogeny across all variables in our analysis was not appropriate here, as we are explicitly testing the relative importance of phylogenetic distance to humans versus other host traits including measures of human–wildlife contact to predict the proportion of zoonotic viruses for a given host species. This left body mass as the only variable in our models, excluding our direct measures of phylogenetic distance, with a significant Blomberg K value that was greater than 1. We controlled for the significant effect of shared evolutionary history using a phylogenetic eigenvector regression (PVR)[42,43] on body mass. The PVR approach allowed us to remove phylogenetic signal for any phylogenetically non-independent variables and then include the corrected values back in our GAMs, while retaining predictor variables like phylogenetic distance to humans as unmodified. We calculated PVR for body mass using the R package PVR and our custom-build maximum likelihood host phylogeny using cytochrome *b* sequences constrained to the order-level topology of the mammalian supertree[28,44]. Our new variable for body mass that controls for phylogenetic signal (PVRcytb_resid) removed most of the phylogenetic signal, with $K = 3.5$ unadjusted, and $K < 0.5$ after PVR correction. Our new metric of body mass scales in the same way, with larger values equal to

species with larger body mass. PVR body mass was included in our GAM model selection for the total viral richness and zoonotic virus models.

Host phylogenetic analysis and phylogenetic host breadth. We used two different mammal phylogenetic trees in our analyses and used a model selection framework to determine which best explained our observed association with zoonotic viral richness. First the mammal supertree was pruned in R (package ape, function drop.tips) to include only synonymous species for the 753 species in our database[28,45]. We synonymized all host species names between the mammal supertree and the host associations in our database using the IUCN Red List[33]. If the species was listed as 'cattle' it was assumed to be *Bos taurus*, all other records were excluded if there was ambiguity as to the scientific name for the host species. Second, a maximum likelihood cytochrome *b* tree was generated using the constraint of a multifurcating tree with taxa constrained to their respective orders and the order-level topology matching that of the mammal supertree[6], as per this Newick tree file: (MONOTREMATA,((DIDELPHIMORPHIA,(DIPROTODONTIA,PERAMELEMORPHIA)),(PROBOSCIDEA,((PILOSA,CINGULATA),((((RODENTIA,LAGOMORPHA),(PRIMATES,SCANDENTIA)),((((CETARTIODACTYLA,PERISSODACTYLA),CARNIVORA),CHIROPTERA),EULIPOTYPHLA)))))). This generated a higher-resolution species-level mammal tree using cytochrome *b* data, with more reliable positioning of the higher-level taxonomic relationships than was obtained in exploratory phylogenetic analyses using cytochrome *b* data alone. GenBank accession numbers and cytochrome *b* sequence lengths for each species are provided in in our data and code repository. Cytochrome *b* gene fragments ranged from 143 to 1,140 bp, with >1,000 bp available for 558/665 (84%) of the taxa. Data derived from the cytochrome *b* tree constrained to the topology of the mammal supertree was selected as the best option in all best-fit GAMs.

Sequences were aligned using MUSCLE with default setting in Geneious R6, and checked visually for errors[46]. The best maximum likelihood tree with and without the constraint tree were generated using RAxML-HPC2 on XSEDE via the CIPRES Science Gateway server v.3.1 (ref. 47) using a GTR model with parsimony seed, 1,000 bootstrap replicates, and the following, specific parameters (raxmlHPC-HYBRID -s infile -n result -x 12345 -g constraint.tre -N 1000 -c 25 -p 12345 -f a -m GTRCAT).

Matrices of pairwise patristic distances between all species, including *Homo sapiens*, were calculated from the two phylogenies using the 'cophenetic' function in the R package ape[45]. Phylogenetic trees (Newick format for pruned supertree and cytochrome *b* tree) and matrices of phylogenetic distance from humans are provided in the data and code repository.

We calculated mean, median, max., min., IQR, and standard deviation (represented as generic function F in equation (1) of phylogenetic host breadth (PHB) from all known mammalian hosts for each virus using the pairwise patristic distances ($d_{i,j}$) for each mammal–mammal association for all hosts of a given virus excluding humans, where i indexes each mammal in the database, as does j, and J represents the total mammals in the database. We aggregated these PHB values using mean, median, or maximum values at a viral species, genus and viral family level to generate higher-level taxonomic variables of host breadth per viral group. Our measure is similar to those developed by previous studies to understand parasite host specificity[48–50], but here we create a generalizable variable to measure viral host breadth that can be aggregated at different viral taxonomic levels.

$$PHB_i = F^{J}_{j=0}\, d_{i,j} \quad (1)$$

To make Extended Data Fig. 9, taxon names and terminal branches of cytochrome *b* tree constrained to supertree were colour-coded using residual from the best-fit zoonotic virus GAM (predicted minus observed zoonotic viral richness) for wildlife species, and plotted using the plot.phylo function in the R package ape[45]. Symbols (circles) at terminal taxa additionally added to better visualize residual value colours were added using willeerd.nodelabels function (http://dx.doi.org/10.5281/zenodo.10855). All marine mammals, domestic animals, and other taxa with missing data were coded as grey for missing data.

Viral richness heat map (Extended Data Fig. 2) was generated using the R package pheatmap, and the 'complete' hierarchical clustering algorithm to sort cells across rows and columns by similar values of viral richness. All box plots, histograms and all other figures generated in R v.3.3.0 (ref. 51). R code for primary figure generation is provided in the code repository.

GAM fitting and selection. We fit a set of generalized additive models (GAMs) that included all of our selected potential variables explaining the number of total viruses or number of zoonoses in hosts, as well as whether viruses were zoonotic (for conceptual framework and summary of each GAM see Extended Data Fig. 1; for full variable list and data sources see Supplementary Table 1). Our use of GAMs, an incorporation of smooth spline predictor functions into the generalized linear model (GLM) framework, allowed us to examine the functional form of our predictor variables (for example, Figs 2 and 4). Categorical and binary variables (for example, host order, IUCN status of hunted or not, and certain viral traits) were fit as random effects of each variable level. We used automated term selection by double penalty smoothing[52] to eliminate variables from the models. This method removes variables with little to no predictive power and has been shown to be comparable or superior to comparing alternate models with and without variables. We did use the model comparison method for domestic animals, where the sample size was not sufficient for fitting all variables. In this case dropping variables by double penalty smoothing still allowed pruning the model list to eliminate redundant models. Where there were competing variables measuring the same mechanistic effect, we fit alternate GAMs using only one of each of these variables (as specified in below and in the Extended Data Fig. 1). These included phylogenetic variables, citation counts from alternate databases, and different measures of human population/host overlap. For example, to capture host phylogeny we used phylogenetic distance based on either the mammal supertree[20] or a purpose-built cytochrome *b* constrained by the topology of the mammal supertree, but never both in the same model. For human population variables, we looked at either variables measuring overlap of species range with human-occupied areas, or human population in those areas, as area- and population-based measures were highly co-linear. For citation variables, we looked at either all citations or the number of disease-related citations for each host species, not both, and similarly citations in either PubMed or Web of Knowledge. We used a binomial GAM to analyse the 586 mammalian viruses in our database and identify viral traits that may serve as predictors of zoonotic potential. Co-linearity was not a major issue among variables included in the same model.

We inspected models within 2 AIC units of the model with the lowest AIC, and present the outputs of the best-fit and all other top models (<2 ΔAIC) in our data and code repository. In general, variable effects retained the same functional form and effect size across models within 2 ΔAIC—differences were limited to the adding or dropping of very weak, insignificant effects, or switching between highly correlated competing variables such as citation counts from different databases.

For our model of number of zoonoses per host, we used the total number of observed viruses per host as an offset, effectively fitting a model of proportion of zoonotic viruses per host. We found this variable had a coefficient near to one when it was used as a linear predictor, indicating its appropriateness as an offset.

We repeated the model selection process for all models using the more stringent set of data that used only virus identified in mammal hosts using viral isolation, PCR, or other methods of nucleic acid sequence confirmation, that is, that excluded all associations detected via serology.

All models were fit using the MGCV package for R (version 1.8-12.). We used the model with the lowest AIC to predict the number of expected zoonotic viruses for each host species, using all the data from our database that had complete observations for the best model. Our top models consistently outperform the alternatives by wide margins, as measured by AIC. We used standard methods in the R package MGCV to calculate deviance explained, which is defined as (D_null – D_model)/D_null. In this formula, D_null is the deviance (−2 × likelihood) of an intercept-only, (or, in the case of the zoonoses model, offset-only), model, while D_model is the deviance of our best-fit model.

Analyses were limited to terrestrial mammal species as defined by the IUCN Red List (marine mammals were excluded) and we ran separate analyses for wild and domestic animals. As domestic animals made up a much smaller dataset ($n = 32$ species) with a unique set of explanatory variables that differed from the wild species analyses, these models were fit separately. Domestic species results are also discussed separately (see Supplementary Discussion) as they are tangential to the primary findings.

Model cross-validation. We used k-fold cross-validation to evaluate goodness of fit for all models. The data was divided into ten folds, selected randomly. For each fold, the model was re-fit based on the other nine folds, and goodness of fit was assessed by conducting a nonparametric permutation test comparing the predicted values versus the real values for the kth fold, where a non-significant result indicates that predictions are unbiased. Poisson models goodness-of-fit may be compared via a parametric χ^2 permutation test on deviance values, but this test is inappropriate in the case of models with low mean values, as is our case for some of our GAMs[53]. The k-fold cross-validation confirmed the robustness of our model predictions for wild mammals, code and outputs from these tests for each best-fit GAM are provided in Supplementary Table 2.

In addition to randomly selected k-fold cross-validation, we evaluated the robustness of our models via a non-random geographic cross-validation, code and summary document provided in our code and data repository. In order to meaningfully organize species in our dataset by geographic areas, we used the 34 zoogeographic regions for terrestrial mammals recently redefined by Holt *et al.*[54]. Using QGIS[55], a mammal-specific zoogeographical shapefile provided by Holt's group

at the University of Copenhagen (http://macroecology.ku.dk/resources/wallace) was intersected (using QGIS Vector > Geoprocessing Tools > Intersect) with a shapefile of IUCN's host ranges for all mammals in our database. Areas of these intersections were then calculated using an equal-area projection (Mollweide), and each host was assigned to only the region that contained the greatest proportion of its range. We systematically removed all observations (species) from each given zoogeographical region, re-fit the model using all observations from outside the region, then performed a non-parametric permutation test comparing the predicted values to the observed values for that region. Non-significant results indicate that model predictions are unbiased. Significant results for a given zoogeographic region suggest that there are location-specific biases that remain unexplained. This systematic zoogeographic cross-validation supported the overall robustness of our model predictions for several models, that is, all-data zoonoses, all-data total viral richness, and stringent-data total viral richness models. For these models, even though a majority of zoogeographic regions were unbiased, we still identified several zoogeographic regions that showed significant bias. Our zoogeographic cross-validation was equivocal for the stringent-data zoonoses model, with eight regions that showed evidence of bias and seven regions which showed no evidence of bias (Supplementary Table 3).

The presence of biased regions in our zoogeographic cross-validation suggested the possibility that there is a systematic bias associated with geography not captured by the predictor variables in our models. To further investigate this, we added zoogeographical region as a categorical random effect to each of our best-fit models. For three of our best-fit GAMs (all-data total viruses, stringent-data total viruses, and stringent-data zoonoses) the addition of zoogeographical region as a categorical random effect decreased the model AIC and increased the total deviance explained by 3–5%. The all-data zoonoses model, which was used to create the series of maps in the main manuscript, does not improve with the inclusion of zoogeographical region. However, the improved predictive power of models using region-specific terms is offset by the increase in degrees of freedom (that is, if we included 31 zoogeographic regions as separate terms) and, more importantly, a decreased interpretability of our models—especially when compared to the geographical variables we used, such as host area or species range overlap with human modified habitat. We opted not to include these random effects in our final GAMs in favour of keeping only variables interpretable in the context of our host trait-specific framework. Instead, we indicate areas of geographic bias directly on our spatially mapped outputs. (See 'Calculating and visualizing missing viruses and missing zoonoses', below.) Summaries of these models, along with changes in relative deviance explained for the other explanatory variables when zoogeographic region is added as a random effect, are provided in our code and data repository.

Spatial variables. For all the wildlife hosts we used the geographic range information obtained from the IUCN spatial database version 2015.2. Wildlife host species shapefiles needed to replicate analysis are hosted on our Amazon S3 storage (https://s3.amazonaws.com/hp3-shapefiles/Mammals_Terrestrial.zip)[33]. IUCN depict species' range distributions as polygons based on the extent of occurrence (EOO), which is defined as the area contained within a minimum convex hull around species' observations or records. This convex hull or polygon is further improved by including areas known to be suitable or by removing unsuitable or unoccupied areas based on expert knowledge. To accurately calculate the area in km^2 of each host species we projected the polygons to an equal area projection (Mollweide).

We calculated various thresholds of mammal sympatry based on percentage of range overlap for each wild species in our database using IUCN shape files for all mammals globally. We define mammal sympatry as the number of mammalian species that overlap with the target species' geographic range. We calculated mammal sympatry for each wild species in our database at six different thresholds based on the percentage area overlap with the target species geographic range, that is, the number of other wild mammal species with any (>0%), ≥20%, ≥40%, ≥50%, ≥80%, or 100% range overlap. The six different thresholds for mammal sympatry were included as competing terms in our model selection for the total viral richness models.

We derived and tested several global measures to estimate the level of human contact with each wild species in our database. To estimate the area of host geographic range covered by crops, pastures, rural and urban areas—as measures of global human contact with a given wildlife species—each species polygon was intersected (overlapped) with spatial data representing those land cover types. Additionally, we calculated the total number of people within each host geographic range using data from HYDE database[56], and also separately totalled the number of people in rural and urban populations. We obtained data on the distribution of cropland, pastures, rural and urban areas also from the HYDE database[56] for the years 1970, 1980, 1990, 2000 and 2005 with a spatial resolution of 5 × 5 arc minutes, equivalent to 10 km by 10 km at the equator. These datasets were created by combining information from satellite imagery and sub-national crop and pasture statistics[56]. In our GAMs, we used several transformations of these variables as competing proxies for human–wildlife contact: the log-transformed area of host range that overlapped each type of human-modified land cover, log-transformed human population in the host range, log-transformed human population density in the host range, and the log-ratio of urban and rural human populations in the host range. For each of these, we also included as a variable the change in value from 1970 to 2005. Human–wildlife contact variables that significantly covaried were excluded (set as competing terms) during the model selection process. The ratio of urban to rural human population was used to disentangle variables of human–wildlife contact that significantly covaried. For example, the total area of a species range that overlapped with urban and rural areas was highly correlated with the total geographic area variables we examined (for example, total area, and area in crop, pasture, rural, and urban). The ratio of urban to rural population allowed us to separate these signals and best represent this proxy of per-species human–wildlife contact. All spatial analyses were performed in R (3.3.2)[51], using the following R libraries: raster[57], rgdal[58], and sp[58].

Calculating and visualizing missing viruses and missing zoonoses. We used each respective best-fit, all-data GAM from the total viral richness and proportion zoonoses models to calculate the estimated number of viruses that would be observed if the research effort variable for each species was equal to that of the most-studied wild species in our database (*Vulpes vulpes* with 4,433 total publications and 1,477 disease-related publications). We used the prediction of the total virus richness GAM as the offset for the zoonoses GAM. We then calculated the missing viruses and missing zoonoses by subtracting the observed number of viruses and zoonoses from the predictions based on maximum research for each wild mammalian species.

We used geographic range maps from the IUCN spatial database (2015.2) to visualize the spatial distribution of observed host–virus associations, observed host–zoonoses associations, these associations as predicted under maximum research, and the maximum predicted minus the observed viruses, or the missing viruses and missing zoonoses (for example, Fig. 3; Extended Data Figs 3–8; Supplementary Table 4). We also generated maps comparing species richness of all species in the IUCN database against those with viral associations in our database. For each species, the distribution range was converted to a grid system with cells 1/6 of a geographic degree (approximately 18 km × 18 km at the equator line). Each grid cell was assigned a value of one to indicate presence. We repeated this process and assigned the observed and predicted-under-maximum-effort number of zoonotic viruses to their correspondent grid cells. Viral and host species richness maps, and both the missing viruses and missing zoonoses maps were calculated by overlying individual grids. Each richness map represents the sum of all values for a given grid cell. We repeated the process for all the host species in our database and created viral and species richness maps for the following orders: Carnivora, Cetartiodactyla, Chiroptera, Primates and Rodentia. These taxa were selected because they represent 681/736 (92.5%) of wild mammal species in our database.

In the process of translating our non-spatial, species-level predictions to geographic space (that is, layered raster maps), we identified several geographic areas where our model predictions of the number of total and zoonotic viruses were systematically biased, that is, $P < 0.05$ (Supplementary Table 3). In order to visualize the geographic biases of our non-spatial model predictions in our maps (see above regarding zoogeographic cross-validation), we demarcate regions with significant bias with hatching. Hatched regions represent areas where model predictions of total or zoonotic viral richness deviate systematically for the collection of species in that grid cell. For each grid cell we calculated whether the bias exceeded that expected from a random sampling of hosts. This was accomplished by summing the residuals from 100,000 random draws of species in our dataset that was equal to the number of species present in that grid cell, then identifying grid cells where the observed bias was outside the middle 95% of the randomly drawn distribution. We calculated this for all mammals, and separately for each order across all grid cells. Areas with observed bias (outside of 95% of the randomly drawn distribution) are shown with hatched regions on each missing virus and missing zoonoses map.

Animal images used in figures. Animal silhouettes added to Figs 1 and 3 and Extended Data Figs 1 and 2 to visually represent each mammalian order were downloaded from PhyloPic (http://www.phylopic.org). Images used to represent the orders Chiroptera, Cingulata, Diprotodontia, Lagomorpha, Peramelemorphia and Primates were available for use under the Public Domain Dedication license. Images used to represent the orders Carnivora and Rodentia (by R. Groom), Didelphimorphia, Pilosa, and Probscidea (by S. Werning), Eulipotyphyla (by C. Rebler), Certartiodactyla and Perissodactyla (by J. A. Venter, H. H. T. Prins, D. A. Balfour & R. Slotow and vectorized by T. M. Keesey) were provided under a Creative Commons license (https://creativecommons.org/licenses/by/3.0/). We created the silhouette used to represent the order Scandentia.

Data availability. All datasets (host traits, viral traits, full list of host–virus associations and associated references, phylogenetic trees, and phylogenetic distance matrices) needed to fully replicate and evaluate these analyses are provided at http://doi.org/10.5281/zenodo.596810. The top-level README.txt file in the directory details the file structure and metadata provided.

Code availability. All R code and R package dependencies needed to fully replicate and evaluate these analyses are provided at http://doi.org/10.5281/zenodo.596810.

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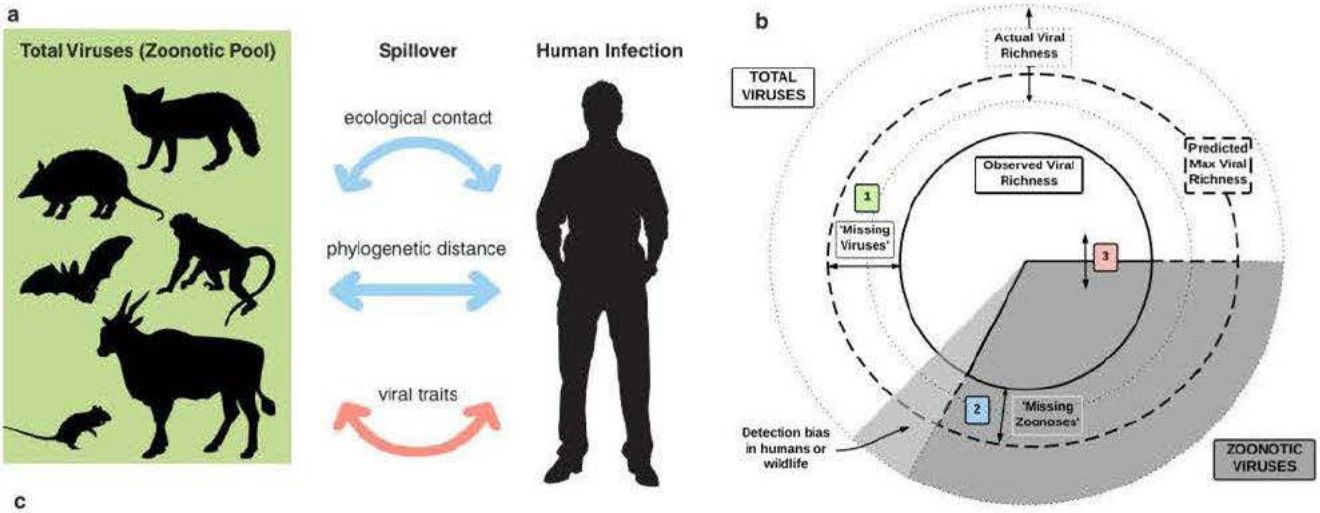


c

Host Species GAMs

1 Total Viruses Per Host Species

host order*

host range area*

change in host range area (1970 - 2005)

mammal sympatry (any, **20***, 40, 50, 80, or 100%)

body mass (phylogenetically corrected)*

disease-related citations per host*

age of domestication (domestic only)

continents inhabitated (domestic only)

production type (domestic only)*

Data subsets:
- all observed wild host-virus associations
- stringent observed wild host-virus associations
- all observed domestic host-virus associations
- stringent observed domestic host-virus associations

2 Zoonotic Viruses Per Host Species

% host habitat range urban, crop, or pasture

change in % host habitat range urban, crop, or pasture (1970 - 2005)

urban to rural human population ratio in host range* or human population density in host range

change in urban to rural human population ratio in host range or change in human population density in host range or total human population in host range (1970 - 2005)

host order*

phylogenetic distance from humans (CytB* or Supertree)

IUCN artificial habitat use

IUCN hunted

disease-related citations per host*

age of domestication (domestic only)

continents inhabitated (domestic only)

production type (domestic only)*

+ Offset Variable: Observed total viral richness per host species

Proportion of zoonotic viruses per host = predicted number of zoonoses ÷ total viral richness (offset)

Data subsets:
- all observed wild host-zoonotic virus associations
- stringent observed wild host-zoonotic virus associations
- all observed wild host-zoonotic virus associations without reverse zoonoses
- all observed domestic host-virus associations
- stringent observed domestic host-virus associations

Viral Traits GAMs

3 Probability of a Virus Being Zoonotic

PubMed or **Web of Science citations per virus**

vector-borne*

enveloped

average genome length

nucleic acid type (RNA vs DNA) or strand count

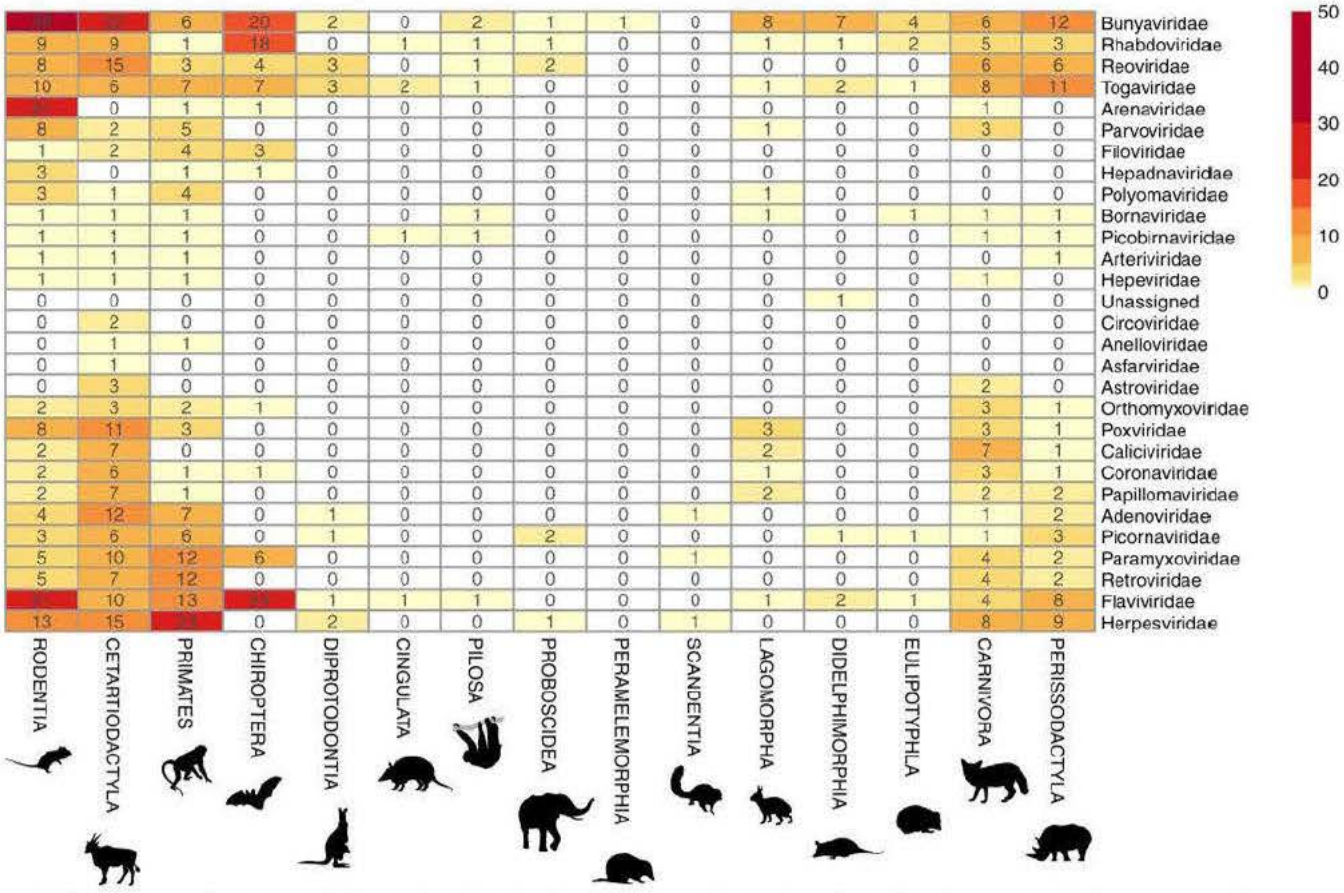
replication in cytoplasm*

median, mean, or **max*** **non-human phylogenetic host breadth** calculated from Supertree or **cytB**

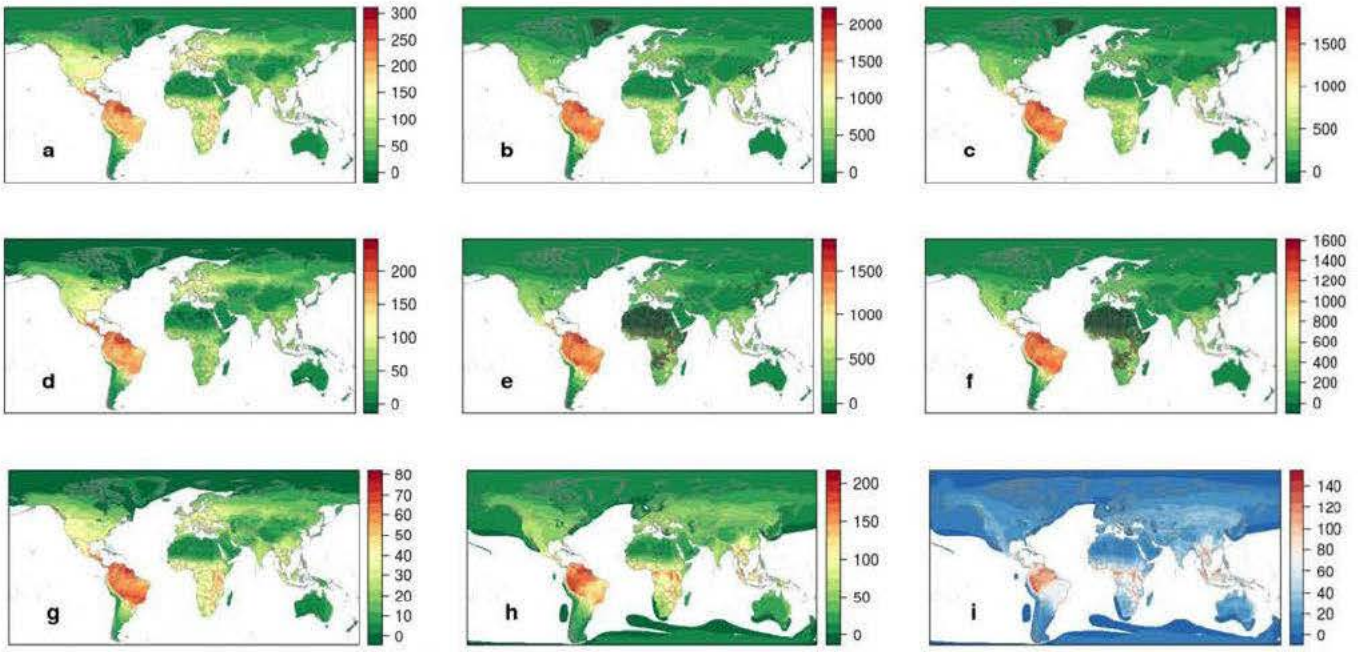
Data subsets:
- observed host-viral associations
- stringent observed host-viral associations

Extended Data Figure 1 | See next page for caption.

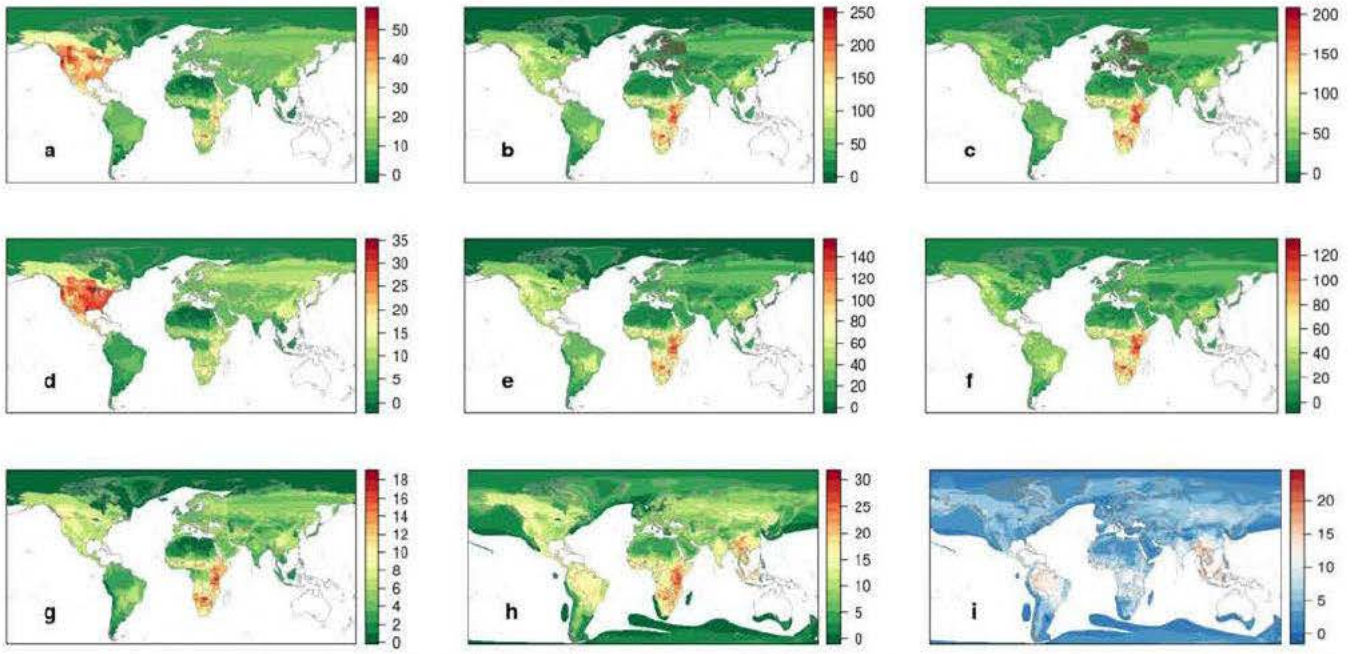
Extended Data Figure 1 | Conceptual model of zoonotic spillover, viral richness, and summary of models. a, Conceptual model of zoonotic spillover showing primary risk factors examined, colour-coded according to generalized additive models used. **b**, Conceptual model of observed, predicted, and actual viral richness in mammals. **c**, GAMs used in our study to address specific components of **a** and **b**, colour-coded by model. Variables listed with 'or' under each GAM covaried and were provided as competing terms in model selection, and those in bold were included in the best-fit model using all host–virus associations. Significant variables from each best-fit GAM are noted with an asterisk. Zoonotic viral spillover first depends on the underlying total viral richness in mammal populations and the ecological, taxonomic, and life-history traits that govern this diversity (GAM 1). Second, host- and virus-specific factors may facilitate viral spillover. We examine the relative importance of host phylogenetic distance to humans, ecological opportunity for contact, or other species-specific life-history and taxonomic traits (GAM 2), and identify viral traits associated with a higher likelihood of an observed virus being zoonotic (GAM 3). We estimate the total and zoonotic viral richness per host species using GAMs 1 and 2, and calculate the missing viruses and missing zoonoses under a scenario of increased research effort (**b**, Methods). Owing to imperfect surveillance in both humans and wildlife and biases in viral detection, there may be uncertainty in the exact proportion of viruses that are zoonotic (**b**, light grey), and also between the actual, or true, viral richness (dotted lines) and the predicted maximum viral richness per host (dashed line).



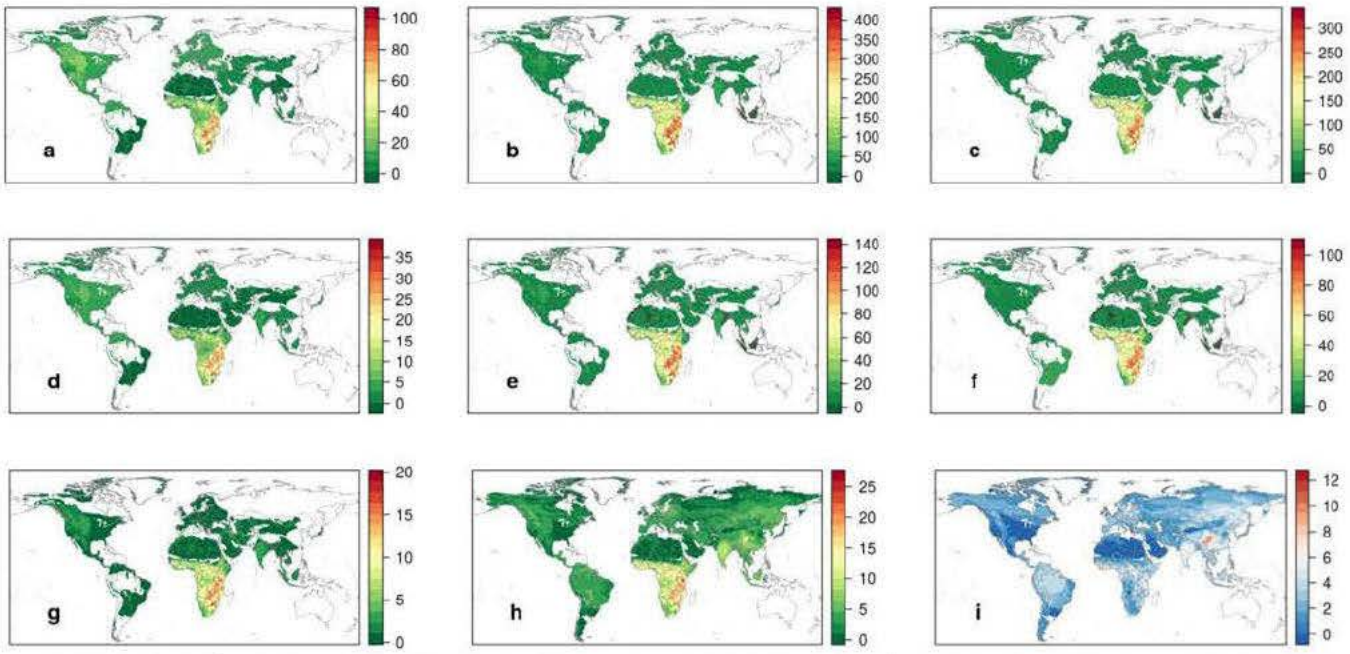
Extended Data Figure 2 | Heat map of observed total viral richness by mammalian order and viral family. Dataset includes 754 mammalian species and 586 unique ICTV recognized viral species. Heat map aggregated by rows and columns to group taxa with similar levels of observed viral richness.



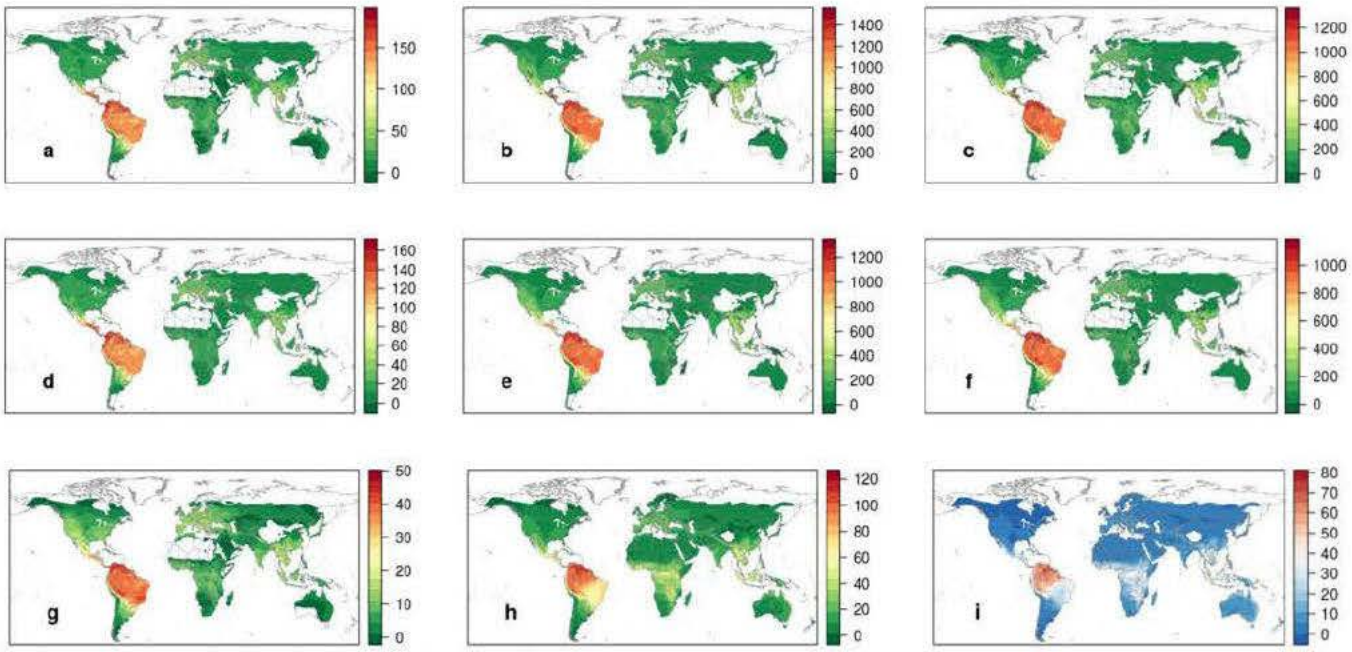
Extended Data Figure 3 | Global distribution of viral and host species richness for all wild mammals. a, Observed total viral richness (for $n = 576$ host spp.); **b**, predicted total viral richness given maximum research effort; **c**, missing viruses or predicted minus observed total viral richness; **d**, observed zoonotic viral richness ($n = 584$); **e**, predicted zoonotic viral richness given maximum research effort; **f**, missing zoonoses or predicted minus observed zoonotic viral richness (same as included in Fig. 3a); **g**, global mammal species richness ($n = 5{,}290$); **h**, mammal richness for species in our database ($n = 753$); **i**, mammal species with no described viruses in the literature. Warmer colours (larger values) in panels **c** and **f** highlight areas predicted to be of greatest value for discovering novel viruses or novel viral zoonoses, respectively, in mammals. Red/pink colours in panel **i** highlight areas with poor viral surveillance in mammal species to date. Hatched regions represent areas where model predictions deviate systematically for the collection of species in that grid cell (see Methods).



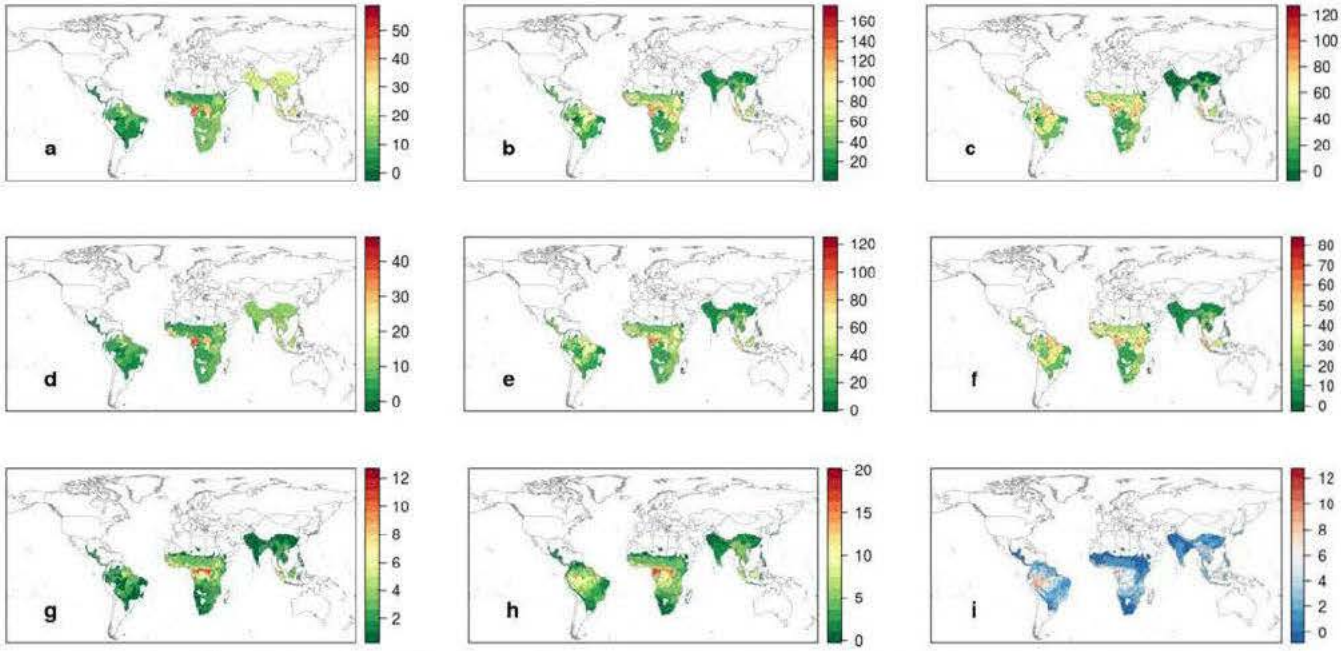
Extended Data Figure 4 | Global distribution of viral and host species richness for wild carnivores (order Carnivora). **a**, Observed total viral richness (for $n = 55$ host spp.); **b**, predicted total viral richness given maximum research effort; **c**, missing viruses or predicted minus observed total viral richness; **d**, observed zoonotic viral richness ($n = 55$); **e**, predicted zoonotic viral richness given maximum research effort; **f**, missing zoonoses or predicted minus observed zoonotic viral richness (same as included in Fig. 3b); **g**, global host species richness for Carnivora ($n = 276$); **h**, host species richness for Carnivora in our database ($n = 79$); **i**, species of the order Carnivora with no described viruses in the literature. Warmer colours (larger values) in **c** and **f** highlight areas predicted to be of greatest value for discovering novel viruses or novel viral zoonoses, respectively, in carnivores. Red/pink colours in panel **i** highlight areas with poor viral surveillance in carnivore species to date. Hatched regions represent areas where model predictions deviate systematically for the collection of species in that grid cell (see Methods).



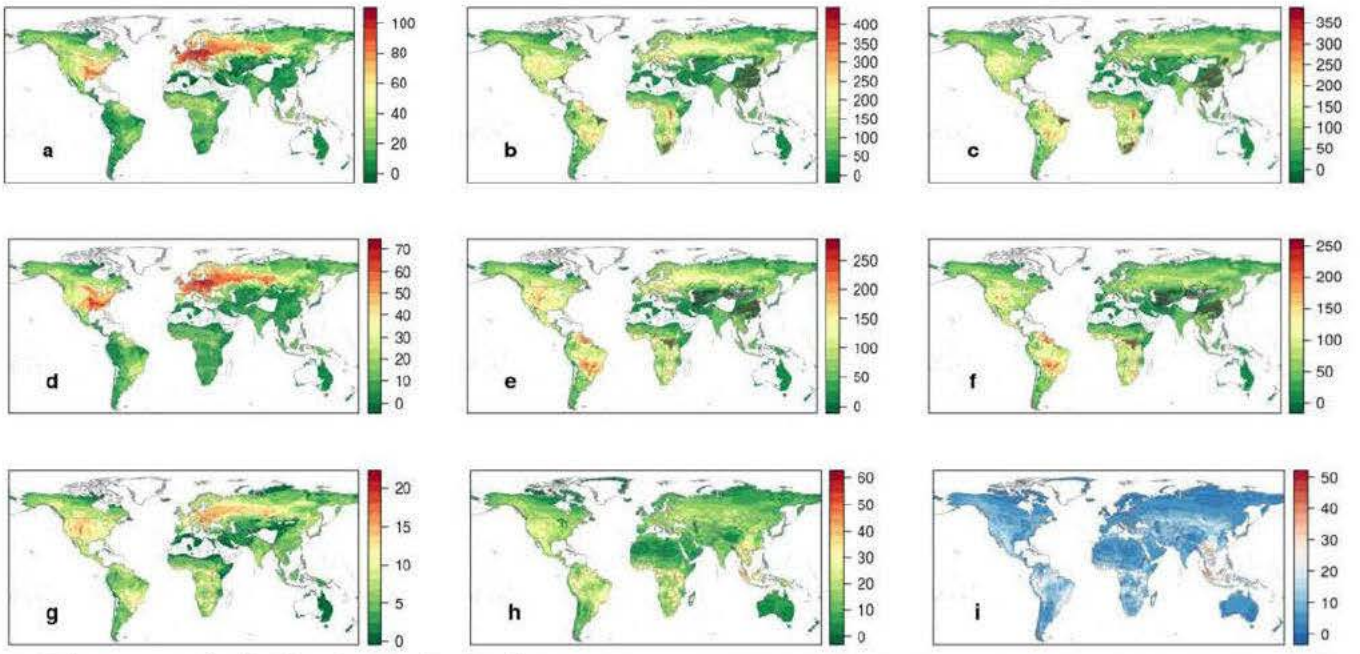
Extended Data Figure 5 | Global distribution of viral and host species richness for wild even-toed ungulates (order Cetartiodactyla). **a**, Observed total viral richness (for $n = 70$ host spp.); **b**, predicted total viral richness given maximum research effort; **c**, missing viruses or predicted minus observed total viral richness; **d**, observed zoonotic viral richness ($n = 70$); **e**, predicted zoonotic viral richness given maximum research effort; **f**, missing zoonoses or predicted minus observed zoonotic viral richness (same as included in Fig. 3c); **g**, global host species richness for Cetartiodactyla ($n = 229$); **h**, host species richness for Cetartiodactyla in our database ($n = 105$); **i**, species of the order Cetartiodactyla with no described viruses in the literature. Warmer colours (larger values) in **c** and **f** highlight areas predicted to be of greatest value for discovering novel viruses or novel viral zoonoses, respectively, in even-toed ungulates. Red/pink colours in panel **i** highlight areas with poor viral surveillance in even-toed ungulates species to date. Hatched regions represent areas where model predictions deviate systematically for the collection of species in that grid cell (see Methods).



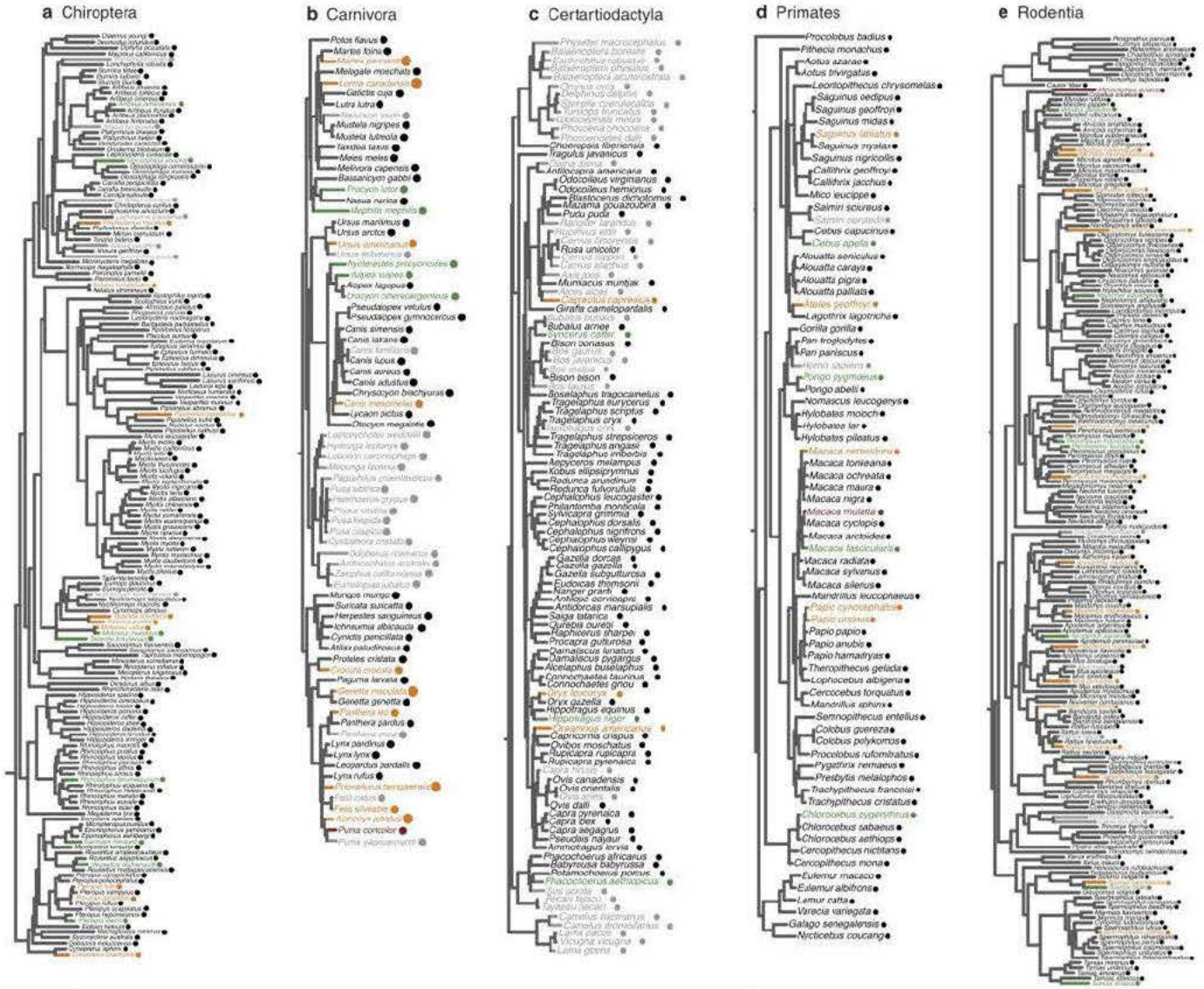
Extended Data Figure 6 | Global distribution of viral and host species richness for bats (order Chiroptera). **a**, Observed total viral richness (for $n = 156$ host spp.); **b**, predicted total viral richness given maximum research effort; **c**, missing viruses or predicted minus observed total viral richness; **d**, observed zoonotic viral richness ($n = 157$); **e**, predicted zoonotic viral richness given maximum research effort; **f**, missing zoonoses or predicted minus observed zoonotic viral richness (same as included in Fig. 3d); **g**, global host species richness for Chiroptera ($n = 1117$); **h**, host species richness for Chiroptera in our database ($n = 192$); **i**, species of the order Chiroptera with no described viruses in the literature. Warmer colours (larger values) in **c** and **f** highlight areas predicted to be of greatest value for discovering novel viruses or novel viral zoonoses, respectively, in bats. Red/pink colours in panel **i** highlight areas with poor viral surveillance in bat species to date. Hatched regions represent areas where model predictions deviate systematically for the collection of species in that grid cell (see Methods).



Extended Data Figure 7 | Global distribution of viral and host species richness for primates (order Primates). **a**, Observed total viral richness (for $n = 71$ host spp.); **b**, predicted total viral richness given maximum research effort; **c**, missing viruses or predicted minus observed total viral richness; **d**, observed zoonotic viral richness ($n = 73$); **e**, predicted zoonotic viral richness given maximum research effort; **f**, missing zoonoses or predicted minus observed zoonotic viral richness (same as included in Fig. 3e); **g**, global host species richness for Primates ($n = 400$); **h**, host species richness for Primates in our database ($n = 98$); **i**, primate species with no described viruses in the literature. Warmer colours (larger values) in **c** and **f** highlight areas predicted to be of greatest value for discovering novel viruses or novel viral zoonoses, respectively, in primates. Red/pink colours in panel **i** highlight areas with poor viral surveillance in primate species to date. Hatched regions represent areas where model predictions deviate systematically for the collection of species in that grid cell (see Methods).



Extended Data Figure 8 | Global distribution of viral and host species richness for rodents (order Rodentia). a, Observed total viral richness (for $n = 178$ host spp.); **b**, predicted total viral richness given maximum research effort; **c**, missing viruses or predicted minus observed total viral richness; **d**, observed zoonotic viral richness ($n = 183$); **e**, predicted zoonotic viral richness given maximum research effort; **f**, missing zoonoses or predicted minus observed zoonotic viral richness (same as included in Fig. 3f); **g**, global host species richness for Rodentia ($n = 2206$); **h**, host species richness for Rodentia in our database ($n = 221$); **i**, rodent species with no described viruses in the literature. Warmer colours (larger values) in **c** and **f** highlight areas predicted to be of greatest value for discovering novel viruses or novel viral zoonoses, respectively, in wild rodents. Red/pink colours in panel **i** highlight areas with poor viral surveillance in rodent species to date. Hatched regions represent areas where model predictions deviate systematically for the collection of species in that grid cell (see Methods).



Extended Data Figure 9 | Order-level phylogenies showing residuals from zoonoses model. a–e, Subtrees from cytochrome *b* maximum likelihood phylogeny for 558 mammal species (constrained to order-level topology of mammal supertree) for bats (**a**), carnivores (**b**), even-toed ungulates (**c**), rodents (**d**) and primates (**e**). Species included have at least one described virus association and available genetic data. Wildlife species names and terminal branches are colour-coded by the residuals (predicted minus observed) from the best-fit GAM to predict the number of zoonotic viruses using all data. Species with residual values between −1 and 1 (black) are accurately predicted within one virus. Warm colours represent species with positive residuals (orange >1 to 3; red >3). Cool colours represent species with negative residuals (green <−1 to −3; blue <−3). Marine mammals, domestic animals, and species with missing data and not included in the best-fit models are shown in grey.

Extended Data Table 1 | Summary of best-fit GAMs for total and zoonotic viral richness per wild mammal species, and probability of a virus being zoonotic

Term	Value	Z statistic	Chi-sq statistic	P-value	Effective Degrees of Freedom	Total Dev. Explained	Relative Dev. Explained
Total Viral Richness Model (all data, n=576 species)						**49.2%**	
Intercept	0.52	7.43		**<0.001**			
Disease-related publications (log)			1846.57	**<0.001**	5.55		64.8%
Mammal sympatry (>20% range overlap)			301.38	**<0.001**	5.16		10.1%
Order CHIROPTERA			155.12	**<0.001**	1		9.9%
Order RODENTIA			95.49	**<0.001**	1		4.8%
Order PRIMATES			34.4	**<0.001**	0.94		2.5%
Phylogenetically-corrected body mass			216.42	**0.009**	3.82		1.9%
Order CETARTIODACTYLA			24.37	**<0.001**	0.94		1.8%
Geographic range (log)			18.93	**0.025**	3.58		1.6%
Order PERISSODACTYLA			9.95	**0.001**	1		1.4%
Order EULIPOTYPHLA			5.87	**0.009**	0.85		1.1%
Total Viral Richness Model (stringent data, n=575 species)						**35.8%**	
Intercept	-0.47	-5.31		**<0.001**			
Disease-related publications (log)			923.02	**<0.001**	4.98		53.6%
Order RODENTIA			129.28	**<0.001**	0.98		12.6%
Order CHIROPTERA			109.23	**<0.001**	1		12.2%
Order PRIMATES			85.12	**<0.001**	1		11.8%
Mammal sympatry (>20% range overlap)			44.96	**<0.001**	4.69		3.9%
Phylogenetically-corrected body mass			9.65	**0.036**	3.51		2.8%
Geographic range (log)			11.14	0.079	2.66		1.5%
Order CINGULATA			0.87	0.286	0.76		0.6%
Order EULIPOTYPHLA			1.21	0.151	0.59		0.4%
Order PERAMELEMORPHIA			0.74	0.307	0.7		0.4%
Order SCANDENTIA			0.94	0.13	0.41		0.3%
Proportion Zoonoses Model (all data, n=584 species)						**82.0%** (*number* of zoonoses) **33.0%** (*proportion*, w/offset)	
Intercept	-0.34	-8.57		**<0.001**			
Order CETARTIODACTYLA			27	**<0.001**	0.88		36.3%
Phylog. dist. from humans (log, cytb tree)			12.7	**0.002**	1.88		17.0%
Urban to rural human population ratio in species range (log)			10.01	**0.002**	1.25		13.0%
Disease-related publications (log)			5.81	**0.017**	1.2		7.7%
Order CHIROPTERA			4.43	**0.015**	0.71		6.5%
Order PERISSODACTYLA			3.28	**0.039**	0.76		6.4%
Order SCANDENTIA			0.81	0.311	0.79		5.3%
Order PERAMELEMORPHIA			0.76	0.323	0.78		4.8%
Order DIPROTODONTIA			0.72	0.194	0.43		1.7%
Hunted species, IUCN			0.75	0.167	0.36		1.3%
Proportion Zoonoses Model (stringent data, n=576 species)						**23.6%**	
Intercept	-1.35	-22.66		**<0.001**			
Phylog. dist. from humans (log, cytb tree)			56.13	**<0.001**	2.36		34.5%
Order CETARTIODACTYLA			22.93	**<0.001**	0.94		28.0%
Urban to rural human population ratio change, 1970-2005			16.88	**0.002**	4.05		19.6%
Order PERISSODACTYLA			0.86	0.308	0.83		5.0%
Change in human population density in range, 1970-2005			3.16	0.132	1.47		4.3%
Disease-related publications (log)			5.03	**0.014**	1.21		3.8%
Order DIPROTODONTIA			2.39	0.066	0.71		2.8%
Phylogenetically-corrected body mass			0.12	0.294	0.12		1.1%
Order LAGOMORPHA			0.7	0.196	0.42		0.9%
Order PRIMATES			0.62	0.097	0.28		0.1%
Viral Traits Model (all data, n=464 viruses)						**27.2%**	
Intercept	-1.59	-5.69		**<0.001**			
Max phylogenetic host breadth w/out humans, (log, cytb tree)			44.91	**<0.001**	2.94		45.6%
Number of publications (log)			35.83	**<0.001**	3.28		37.4%
Cytoplasmic replication			10.96	**<0.001**	0.86		9.2%
Vector-borne			4.9	**0.014**	0.75		4.6%
Envelope			0.88	0.166	0.46		2.3%
Average genome length (log)			0.12	0.266	0.09		0.9%
Viral Traits Model (stringent data, n=408 viruses)						**21.1%**	
Intercept	-2.23	-7.51		**<0.001**			
Number of publications (log)			29.51	**<0.001**	2.64		53.1%
Max phylogenetic host breadth w/out humans, (log, cytb tree)			15.75	**<0.001**	2.53		25.5%
Cytoplasmic replication			10.33	**0.001**	0.88		17.5%
Vector-borne			1.87	0.085	0.6		3.9%

Models were selected separately using the entire dataset and a stringent dataset that excluded host-virus associations detected by serology. Variables are sorted by relative per cent deviance explained with in each model.

From: Bernabe, Gayle (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]
Cc: Bernabe, Gayle (NIH/NIAID) [E]
Subject: Re: FACTS: Project for BURMA on queue for SDC: R01AI110964-03; DASZAK, PETER (Approved by Embassy)
Date: Monday, May 8, 2017 10:25:29 AM

Dear Erik and Philip:
This is to inform you that the U.S. Embassy Assistance Working Group in Burma approved/cleared this project.
Thank you and kind regards,
Gayle

From: "Bernabe, Gayle (NIH/NIAID) [E]" (b) (6)
Date: Tuesday, April 18, 2017 at 11:01 AM
To: "Stemmy, Erik (NIH/NIAID) [E]" (b) (6)
Cc: "Smith, Philip (NIH/NIAID) [E]" (b) (6)
Subject: RE: FACTS: Project for BURMA on queue for SDC: R01AI110964-03; DASZAK, PETER
Thanks very much Erik for contacting the PI and for obtaining the additional information requested by Post in Burma. These are appreciated.
I will let you know if they have any further questions.
Thanks again and kind regards,
Gayle

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, April 18, 2017 7:53 AM
To: Bernabe, Gayle (NIH/NIAID) [E] (b) (6)
Cc: Smith, Philip (NIH/NIAID) [E] (b) (6)
Subject: RE: FACTS: Project for BURMA on queue for SDC: R01AI110964-03; DASZAK, PETER
Hi Gayle,
Sorry for the delay; the PI has been out of the country. The work from this grant will supplement and collaborate the PREDICT work, but not duplicate any efforts. See response from the PI pasted below. Let me know if they need any more information.
Thank you!
Erik
From the PI:
The work is planned to supplement that done by PREDICT and hopefully to collaborate with the PREDICT team if possible. The aim is for the Co-investigator (Zhengli Shi) and her field team to coordinate with the PREDICT Myanmar field team and co-leads to ensure that there is no duplication of effort (the NIAID group will not use the PREDICT protocols), and that there is the opportunity for cross-training. Samples will be collected from bats and tested by PCR for SARS-like Coronaviruses, then for positive samples, to do a series of further characterization of the viruses using the techniques Zhengli has developed in her lab (spike protein binding assays etc.).
Samples collected will also be made available to the Myanmar lab so that the PREDICT protocols can be run in-country.

From: Bernabe, Gayle (NIH/NIAID) [E]

Sent: Wednesday, April 12, 2017 6:52 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Smith, Philip (NIH/NIAID) [E] (b) (6)
Subject: FW: FACTS: Project for BURMA on queue for SDC: R01AI110964-03; DASZAK, PETER

Dear Erik:

Post in Burma is requesting additional information:

"could you ask the PI to clarify how they are working with the USAID funded PREDICT Project – it is our understanding that ECO-Health is a partner in PREDICT and the sampling methods, etc. described are similar to activities in PREDICT (it may be that the PR is going to be doing additional testing on already collected samples, but that is not clear from the information provided)."

Thank you and kind regards,

Gayle

Gayle Bernabe, MPH
Regional Program Officer-East/SE Asia and the Pacific
Office of Global Research (OGR)
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services
5601 Fishers Ln Rm 1E MSC 9802
Bethesda, MD 20892-9802 [For courier deliveries: 20852]
Phone: (b) (6)
Fax: (301) 480-2954
Email: (b) (6)

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 8, 2017 6:09:18 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-04	DASZAK	2017-06-01	2017-04-12	Y	35	Normil
R01AI089728-07	Li	2017-06-01	2017-04-14	Y	35	Clarke
R21AI126300-02	Frieman	2017-06-01	2017-04-13	Y	35	Clarke
R01AI085089-08	Baker	2017-07-01	Not Recvd	N	35	Hartman

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 1, 2017 6:03:02 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

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Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-04	DASZAK	2017-06-01	2017-04-12	Y	35	Normil
R01AI089728-07	Li	2017-06-01	2017-04-14	Y	35	Clarke
R21AI126300-02	Frieman	2017-06-01	2017-04-13	Y	35	Clarke

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 24, 2017 6:00:44 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-04	DASZAK	2017-06-01	2017-04-12	Y	35	Normil
R21AI126300-02	Frieman	2017-06-01	2017-04-13	Y	35	Clarke
R01AI089728-07	Li	2017-06-01	2017-04-14	Y	35	Clarke

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 17, 2017 6:00:53 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R21AI126300-02	Frieman	2017-06-01	2017-04-13	Y	35	Clarke
R01AI089728-07	Li	2017-06-01	2017-04-14	Y	35	Clarke
R01AI110964-04	DASZAK	2017-06-01	2017-04-12	Y	35	Normil

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]; Normil, Carine (NIH/NIAID) [C]; NIAID GM I2 Notifications
Subject: eRA Commons: RPPR for Grant R01AI110964-04 Received by Agency
Date: Wednesday, April 12, 2017 7:10:19 PM

RPPR for grant R01AI110964-04 associated with Program Director/Principal Investigator PETER DASZAK has been received electronically through the eRA Commons. You may view the progress report through one of the IMPAC II modules by going to the Grant Folder and selecting the e-Application.

Program Class Code:	M51C
Program Officer:	Stemmy, Erik J.
Grants Management Specialist:	Normil, Carine

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact. Please access Commons at http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 10, 2017 6:01:07 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

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Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R21AI126300-02	Frieman	2017-06-01	Not Recvd	N	35	Clarke
R01AI110964-04	DASZAK	2017-06-01	Not Recvd	N	35	Normil
R01AI089728-07	Li	2017-06-01	Not Recvd	N	35	Clarke

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 3, 2017 6:01:11 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

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Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI114657-03	Makino	2017-05-01	2017-02-24	Y	35	Briggs
R21AI126300-02	Frieman	2017-06-01	Not Recvd	N	35	Clarke
R01AI110964-04	DASZAK	2017-06-01	Not Recvd	N	35	Normil
R01AI089728-07	Li	2017-06-01	Not Recvd	N	35	Clarke

From: Bateman, Karen (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; DMID GrantOps
Subject: RE: PO checklists still needed
Date: Tuesday, July 19, 2016 2:43:34 PM

Thanks for the update, Erik!

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, July 19, 2016 7:38 AM
To: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: RE: PO checklists still needed
Hi GrantOps,
Grants Management finally approved the GoF term of award that I've been waiting on so I completed the checklist for the Daszak award listed below.
Erik

From: DMID GrantOps
Sent: Monday, July 18, 2016 5:45 PM
To: Challberg, Mark (NIH/NIAID) [E] (b) (6); Eichelberg, Katrin (NIH/NIAID) [E] (b) (6); Sizemore, Christine (NIH/NIAID) [E] (b) (6); Wali, Tonu (NIH/NIAID) [E] (b) (6); Hiltke, Thomas (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Degrace, Marciela (NIH/NIAID) [E] (b) (6); Brown, Liliana (NIH/NIAID) [E] (b) (6); Gezmu, Misrak (NIH/NIAID) [E] (b) (6); Kraigsley, Alison (NIH/NIAID) [E] (b) (6)
Cc: DMID GrantOps (b) (6)
Subject: FW: PO checklists still needed
Dear all:
As of this morning, the GMO reported as incomplete the following Type 5 checklists which were due on 7/10. If you have not already, would you please complete your checklist(s) by tomorrow and reply to GrantOps and the assigned GMS with a status update?
Note: The report below is supplied by the GMO and we recognize that it may not take into account your most recent actions or correspondence with the GMS regarding these grants.
If one of your Type 5s is not yet received, please assist by contacting your PI. Future funding may be impacted by their delayed PR submission.
Thank you for your assistance!
Karen
DMID GrantOps

From: Connors, Victoria (NIH/NIAID) [E]
Sent: Monday, July 18, 2016 9:54 AM
To: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: PO checklists still needed
Please see the list below
Thanks!

DMID Start Date	PO Signature	T5 Received	T	Grant Number	PCC	STATUS	PI	GMS	PO
8/1/16		6/22/16	5	R01AI106307-04	M32A	35	LUO	Vily,Aytaj	Challberg
8/1/16		6/3/16	5	U19AI111211-03	M33AB	35	BLUMBERG	Machuca,Jorge	Eichelberg
7/1/16		7/6/16	5	R01AI099603-05	M33BBR	35	Stoltz	Cooper,Kim	Sizemore
8/1/16		6/15/16	5	R01AI107588-04	M44B	35	Gause	Halary,Azita	Wali

8/1/16	7/15/16	5	R01AI044033-15	M48	35	Maurelli	Normil,Carine	Hiltke
6/1/16	5/13/16	5	R01AI110964-03	M51C	35	DASZAK	Greer,Jenny	Stemmy
8/1/16	6/14/16	5	R01AI108993-03	M51JB	35	Gray	Hartman,Jeffrey	DeGrace
8/1/16	6/14/16	5	R01AI108888-03	M63E	35	Ye	Saletta,Jill	Brown
8/1/16	6/20/16	5	R01AI107721-03	M71	35	Kulldorff	Rodriguez,Cynthia	Gezmu

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, July 18, 2016 6:02:22 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, July 11, 2016 6:03:02 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

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Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer

From: Greer, Jenny (NIH/NIAID) [E]
To: (b) (6); (b) (6)
Cc: Stemmy, Erik (NIH/NIAID) [E]; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Thursday, July 7, 2016 10:00:17 AM
Attachments: 110964 Daszak GoF Determination Letter 7-7-2016.pdf

---

Aleksei and Peter,

Please find attached a determination regarding your grant.

As always, don't hesitate to contact us with any questions.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 7, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is not subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

From: Ford, Andrew (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Ford, Andrew (NIH/NIAID) [E]
Subject: RE: Daszak GoF Term
Date: Wednesday, July 6, 2016 4:00:12 PM
Attachments: GoF PAUSE letter - R01AI110964 NIAID Response AQF.docx

---

Hey Erik,
Incorporated into the attached version are a few edits and comments; most of the edits were to bring the language in line with that which appears in the letter from EcoHealth Alliance and the draft term-of-award. (b) (5)

Let me know what you would like to do and if any changes are needed to the term-of-award I can make those and resend it to the group.
Let me know if you have any questions.
Thanks,
Andrew

Andrew Q. Ford, Ph.D.
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane Room 7G64
Rockville, MD 20892
(b) (6)
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, July 06, 2016 11:29 AM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Daszak GoF Term
Hi Andrew,
Attached is the draft response letter. Can you please review and let me know if you have any comments? If it looks good I can get it to the GMS to send out.
Thanks!
Erik

From: Ford, Andrew (NIH/NIAID) [E]
Sent: Tuesday, July 5, 2016 1:00 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: RE: Daszak GoF Term
Thanks
Andrew Q. Ford, Ph.D.

Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane Room 7G64
Rockville, MD 20892
(b) (6)
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, July 05, 2016 12:51 PM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Daszak GoF Term

I've just finished the draft and sent it to the RDB folks for comments. I'll send that to you as soon as I hear back.

From: Ford, Andrew (NIH/NIAID) [E]
Sent: Tuesday, July 05, 2016 11:23 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: RE: Daszak GoF Term

That could work. Do you think you will have a draft of the letter today?

Andrew Q. Ford, Ph.D.
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane Room 7G64
Rockville, MD 20892
(b) (6)
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, July 05, 2016 11:08 AM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Daszak GoF Term

I needed to be sure that the group didn't have any issues with the IBC oversight before drafting the letter, so I'm working on that now. The only other award I had that we determined not to have GoF was from way back in 2014 and we didn't put any terms on it so I didn't think about terms for this one until this morning. (b) (5)

(b) (5)

From: Ford, Andrew (NIH/NIAID) [E]
Sent: Tuesday, July 05, 2016 11:00 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: RE: Daszak GoF Term

Do you not plan to send the letter before the funds are released?

Andrew Q. Ford, Ph.D.
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane Room 7G64
Rockville, MD 20892
(b) (6)
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, July 05, 2016 10:42 AM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Daszak GoF Term

Only comment is that the final determination letter hasn't gone back yet so that's why I referenced the June 8th letter from the PI. Does that make a difference?

From: Ford, Andrew (NIH/NIAID) [E]
Sent: Tuesday, July 05, 2016 10:37 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Daszak GoF Term

Hey Erik,

I will send the draft terms to Mary/Victoria/Jenny. However, to keep them in line with the others we had them review, I would make the proposed changes (see red font); most of the edits simply reinforces language EcoAlliance used in their response. Do you have any problems with these edits?

Thanks,

Andrew

Andrew Q. Ford, Ph.D.
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane Room 7G64
Rockville, MD 20892
(b) (6)
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, July 05, 2016 9:56 AM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: Daszak GoF Term

Hi Andrew,

I hadn't thought about adding GoF terms to the Daszak award since we determined it wasn't GoF. But in talking with Teresa this morning she put the general term on a recent award of hers. If I use the same language does this still need to be cleared by Mary Kirker? Here's what I'd put in the checklist:

(b) (5)

Let me know if it's ok to complete the checklist.

Thanks!

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: (b) (6)
Email: (b) (6)

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

****

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

(b) (5)

[redacted]

(b) (5)

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, July 4, 2016 6:03:22 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, June 27, 2016 6:03:00 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

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Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, June 20, 2016 6:03:41 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

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Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer
R44AI114023-03	WYCOFF	2016-08-01	2016-06-15	Y	35	Lundgren
R01AI108197-05	DENISON	2016-08-01	2016-06-15	Y	35	Wolcott

From: Bateman, Karen (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]; DMID GrantOps
Subject: RE: ACTION: PO Checklists due on June 10
Date: Wednesday, June 15, 2016 3:53:58 PM

Hi Erik,
Thanks for your response. These soft assignments create lots of problems for the reasons you state both here and in GMP. In the future, please bring issues to GrantOps. We can work with GMP team leads to help move things along. They expect to hear from us and vice versa, so don't hesitate to work through us as division coordinators.
Karen

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, June 15, 2016 6:54 AM
To: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: RE: ACTION: PO Checklists due on June 10
Hi GrantOps,
My two below are in progress. The Daszak award may have GoF and I've been in touch with the GMS for a while now. For the Gambotto award there was an issue with the animal section (species change) that wasn't submitted for prior approval. I had been emailing the GMS listed in IMPAC for about a month but never received a reply until yesterday when Grants Management sent out another reminder and I replied to several people. It seems there were several soft reassignments for the award and no one was responding. Do you know if there is a way to keep track of who is actually responsible for processing awards for soft reassignments? Similarly, is there a GM contact we should CC if we find a GMS unresponsive? Not sure if I'm the only one who has trouble figuring out which GMS is handling things for my awards.
Thanks for your help!
Erik

From: DMID GrantOps
Sent: Tuesday, June 14, 2016 5:49 PM
To: NIAID DMID Program Branches <NIAIDDMIDProgramBranches@niaid.nih.gov>
Cc: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: ACTION: PO Checklists due on June 10
Importance: High
Dear POs,
DMID has an unusually high number of incomplete checklists which were due on June 10. If you have not already, please complete the overdue checklist(s) below, or reply to GrantOps and the assigned GMS regarding the need for continued delay.
The report below is supplied by the GMO and we recognize that it may not take into account your most recent actions or correspondence with the GMS regarding these grants. Note: If one of your Type 5s is not yet received, please contact your PI and warn that future funding may be impacted by their delayed submission.
Thank you for your prompt attention to this!
DMID GrantOps
On Jun 14, 2016, at 10:19 AM, Connors, Victoria (NIH/NIAID) [E] (b) (6) wrote:

> Could we get some help with these late PO checklists? Unfortunately, there is still a large amount for the DMID grants.
> Thank you

DMID Start Date	PO Signature	T5 Received	T	Grant Number	PCC	STATUS	PI	GMS	PO
7/1/16		5/13/16	5	R44AI120250-02	M30CBR	35	Zeng	Galczynski,Anneliese	Xu
7/1/16		5/19/16	5	R44AI106235-04	M30D	35	MUTZ	Lyons,Kelvin	Franceschi
7/1/16		5/9/16	5	R21AI114833-02	M32A	35	DEVAUX	Girma,Tseday	Challberg
7/1/16		5/2/16	5	P01AI106695-02	M32DB	35	Harris	Powell,Tamia	Challberg
7/1/16		5/23/16	5	R01AI073450-08	M32DB	35	Fernandez-Sesma	Dalmeida,Charline	Challberg
7/1/16		5/13/16	5	R33AI102239-05	M33CB	35	Elkington	Dalmeida,Charline	Lacourciere
7/1/16		5/13/16	5	K23AI099019-	M33F	35	Heysell	Bumbray-	Lacourciere

			05	B			Quarles,Devon	
7/1/16	5/20/16	5	R01AI105185-04	M33F BR	35	Valafar	Madoo,David	Lacourciere
7/1/16	4/29/16	5	P01AI112522-02	M34B	35	Abecassis	Kindbom,Jordan	Beisel
7/1/16	5/16/16	5	R01AI093614-05	M34C	35	Sawtell	Gratton,Shaun	Challberg
7/1/16	5/12/16	5	R21AI112382-02	M34C	35	Ishov	Mai,Qi	Challberg
7/1/16	5/17/16	5	R21AI112755-02	M34C B	35	HE	Girma,Tseday	Challberg
7/1/16	5/17/16	5	R01AI072683-10	M46C	35	CARLYON	Bumbray-Quarles,Devon	Perdue
6/1/16	5/13/16	5	R01AI110964-03	M51C	35	DASZAK	Greer,Jenny	Stemmy
7/1/16	5/19/16	5	R21AI114264-02	M51C B	35	GAMBOTTO	Nickerson,Lebrit	Stemmy
7/1/16	5/13/16	5	R01AI101028-04	M51J B	35	Xiao	Cooper,Kim	DeGrace
7/1/16	5/13/16	5	R01AI054423-13	M64F	35	SALAMA	Nwogu,Oneneeobari	Mills
7/1/16	6/8/16	5	R01AI078000-09	M64F	35	LUECKE	Brill,Clark	Mills
7/1/16	5/13/16	5	R01AI108713-03	M64F	35	SOLNICK	Nwogu,Oneneeobari	Mills
7/1/16	5/20/16	5	R21AI117345-02	M64F	35	OTTEMANN	Madoo,David	Mills
7/1/16	5/16/16	5	R01AI084928-07	M64F B	35	BAKARDJIEV	Brill,Clark	Mills
7/1/16	5/11/16	5	R01AI100934-06	M64F B	35	Way	Gratton,Shaun	Mills
7/1/16	4/28/16	5	R01AI108778-03	M64F B	35	SPILLER	Halary,Azita	Mills
7/1/16	6/10/16	5	R37AI036929-23	M64F B	35	THERIOT	Nwogu,Oneneeobari	Mills
7/1/16	5/19/16	5	R21AI115701-02	M71	35	Wertheim	Madoo,David	Gezmu

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, June 13, 2016 6:02:25 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer
R21AI114264-02	GAMBOTTO	2016-07-01	2016-05-19	Y	35	Nickerson
R44AI114023-03	WYCOFF	2016-08-01	Not Recvd	N	35	Lundgren
R01AI108197-05	DENISON	2016-08-01	Not Recvd	N	35	Wolcott

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, June 6, 2016 6:01:09 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer
R21AI114264-02	GAMBOTTO	2016-07-01	2016-05-19	Y	35	Nickerson
R01AI108197-05	DENISON	2016-08-01	Not Recvd	N	35	Wolcott
R44AI114023-03	WYCOFF	2016-08-01	Not Recvd	N	35	Halary

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 30, 2016 6:00:49 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer
R21AI114264-02	GAMBOTTO	2016-07-01	2016-05-19	Y	35	Nickerson
R21AI114920-02	Weiss	2016-07-01	2016-05-12	Y	35	Nickerson
R01AI085089-07	Baker	2016-07-01	2016-05-19	Y	35	Kindbom

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 23, 2016 6:00:56 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer
R21AI114920-02	Weiss	2016-07-01	2016-05-12	Y	35	Nickerson
R21AI114264-02	GAMBOTTO	2016-07-01	2016-05-19	Y	35	Nickerson
R01AI085089-07	Baker	2016-07-01	2016-05-19	Y	35	Kindbom

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 16, 2016 6:01:13 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	2016-05-13	Y	35	Greer
R01AI085089-07	Baker	2016-07-01	Not Recvd	N	35	Kindbom
R21AI114264-02	GAMBOTTO	2016-07-01	Not Recvd	N	35	Nickerson
R21AI114920-02	Weiss	2016-07-01	2016-05-12	Y	35	Nickerson

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]; Normil, Carine (NIH/NIAID) [C]; NIAID GM I2 Notifications
Subject: eRA Commons: RPPR for Grant R01AI110964-03 Received by Agency
Date: Friday, May 13, 2016 2:30:20 AM

RPPR for grant R01AI110964-03 associated with Program Director/Principal Investigator PETER DASZAK has been received electronically through the eRA Commons. You may view the progress report through one of the IMPAC II modules by going to the Grant Folder and selecting the e-Application.

Program Class Code:	M51C
Program Officer:	Stemmy, Erik J.
Grants Management Specialist:	Normil, Carine

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact. Please access Commons at http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

From: Bateman, Karen (NIH/NIAID) [E]
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: ACTION -- FW: VERY CONCERNED: PO checklist needed
Date: Wednesday, May 11, 2016 9:16:12 PM

Thanks very much, Erik. Let us know if the PI has trouble connecting with the new GMS.

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, May 11, 2016 10:56 AM
To: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: RE: ACTION -- FW: VERY CONCERNED: PO checklist needed

Hi GrantOps,

The M51C grant below (R01AI110964-03, PI: Daszak) is still missing the progress report. They'd been in touch with the previous GMS about a delayed submission, but it doesn't look like that information made it to the new GMS. They have said they'll have the progress report in by the 12th and I plan to do the checklist as soon as it's received.

Erik

From: DMID GrantOps
Sent: Wednesday, May 11, 2016 10:48 AM
To: Alarcon, Rodolfo (NIH/NIAID) [E] (b) (6); Alexander, William (NIH/NIAID) [E] (b) (6); Challberg, Mark (NIH/NIAID) [E] (b) (6); Eichelberg, Katrin (NIH/NIAID) [E] (b) (6); Ernst, Nancy (NIH/NIAID) [E] (b) (6); Franceschi, Francois (NIH/NIAID) [E] (b) (6); Huntley, Clayton (NIH/NIAID) [E] (b) (6); Ilias, Maliha (NIH/NIAID) [E] (b) (6); Koshy, Rajen (NIH/NIAID) [E] (b) (6); Krafft, Amy (NIH/NIAID) [E] (b) (6); Kraigsley, Alison (NIH/NIAID) [E] (b) (6); Meegan, James (NIH/NIAID) [E] (b) (6); Rao, Malla (NIH/NIAID) [E] (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Wali, Tonu (NIH/NIAID) [E] (b) (6); Xu, Zuoyu (NIH/NIAID) [E] (b) (6); Lacourciere, Karen (NIH/NIAID) [E] (b) (6); Kraigsley, Alison (NIH/NIAID) [E] (b) (6); David, Hagit (NIH/NIAID) [E] < (b) (6)
Cc: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: ACTION -- FW: VERY CONCERNED: PO checklist needed

Dear all:

We have been contacted by Mary Kirker regarding the unusually high number of incomplete T5 checklists in DMID (report attached and pasted below, sorted by PO). If you have not already, please complete your checklist(s) below, or reply to us and the assigned GMS today regarding the need for delay. The attached report is supplied by the GMO. We recognize that it may not take into account your most recent actions or correspondence with the GMS regarding these grants. If one of your Type 5s is not yet received, please contact your PI and warn that future funding may be impacted by their delayed submission.

Thanks for your assistance. We look forward to hearing from you, but note that it is not necessary to reply to all.

Karen

DMID GrantOps

Start Date	T5 Received	Grant Number	PCC	PI	GMS	PO
6/1/16	3/29/16	P01AI057788-12	M64E B	Estes	Briggs,Jenna	Alarcon
6/1/16	4/15/16	R01AI108695-02	M64E B	GILMAN	Graham,Adam	Alarcon
6/27/16	4/27/16	F31AI118220-02	M64D B	Chung	Wall,Cheryl	Alexander
6/1/16	4/13/16	R01AI073755-09	M32D B	Diamond	Girma,Tseday	Challberg
6/1/16	4/13/16	K23AI097267-05	M37A	Van Wagoner	Normil,Carine	David
6/1/16	4/15/16	R44AI063820-08	M37A	Yang	Mai,Qi	David
6/1/16	4/13/16	R21AI119327-02	M37A BR	RAM	Halary,Azita	David
6/1/16		R21AI106329-02	M52A B	Nilsen-Hamilton	Normil,Carine	Davis

6/1/16	4/15/16	K08AI119150-02	M33A B	Portal Celhay	Lyons,Kelvin	Eichelberg
6/1/16	4/15/16	R01AI113211-03	M36	Isberg	Mai,Qi	Ernst
6/1/16	4/7/16	R01AI093646-05	M36 B	Skerrett	Normil,Carine	Ernst
6/1/16	4/14/16	R01AI072219-08	M36 BR	BONOMO	Mpinja,Bora	Ernst
6/1/16	4/18/16	R21AI114508-02	M36 BR	BONOMO	Normil,Carine	Ernst
6/1/16	4/11/16	R01AI119554-02	M30D	Lopez-Ribot	Graham,Adam	Franceschi
6/1/16	4/12/16	R21AI118228-02	M46F B	ZENG	Hartman,Jeffrey	Franceschi
6/1/16	4/28/16	R01AI101371-04	M38 BR	Price	Mpinja,Bora	Huntley
6/1/16	4/1/16	F32AI118316-03	M35	Ramsey	Smith,Philip	Ilias
6/1/16	3/28/16	R01AI032223-21	M35	Weis	Mai,Qi	Ilias
6/1/16	4/4/16	R01AI101175-04	M35	STEERE	Mpinja,Bora	Ilias
6/1/16	4/15/16	R33AI100228-05	M35	Belisle	Halary,Azita	Ilias
6/1/16		R44AI091291-05	M35	KOvalenko	Smith,Philip	Ilias
6/1/16	4/15/16	R01AI087946-07	M35 B	Liu	Graham,Adam	Ilias
6/1/16	3/29/16	R21AI119532-02	M35 B	Blevins	Normil,Carine	Ilias
6/1/16	4/20/16	R21AI119572-02	M35 B	Lin	Hartman,Jeffrey	Ilias
6/1/16	4/4/16	R21AI119821-02	M35 B	SKARE	Hartman,Jeffrey	Ilias
6/1/16		R21AI107380-02	M35 B	Esteve-Gassent	Hartman,Jeffrey	Ilias
6/1/16	4/7/16	K08AI108629-03	M53A	Fusco	Lyons,Kelvin	Koshy
6/1/16	4/13/16	R21AI113394-02	M53B	TONG	Normil,Carine	Koshy
6/1/16	4/15/16	R21AI119481-02	M51F B	Demokritou	Halary,Azita	Krafft
6/1/16	4/11/16	R44AI093018-05	M51G B	CAI	Normil,Carine	Krafft
6/1/16	4/25/16	R21AI115091-03	M33D B	Prados-Rosales	Alford,Trevor	Kraigsley
6/1/16		R21AI119473-02	M33C B	Cangelosi	Graham,Adam	Lacourciere
6/1/16	4/4/16	U01AI108543-04	X82 B	Troedsson	Galczynski,Anneliese	Meegan
6/1/16		R01AI099623-05	M90 BR	Wilson	Greer,Jenny	Rao
6/1/16		R01AI110964-03	M51C	DASZAK	Normil,Carine	Stemmy
6/1/16		R44AI100471-04	M44 B	Levin	Girma,Tseday	Wali
6/1/16	5/4/16	R21AI119684-02	M30C	VOGEL	Graham,Adam	Xu

From: Kirker, Mary (NIH/NIAID) [E]
Sent: Wednesday, May 11, 2016 9:50 AM
To: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Cc: Connors, Victoria (NIH/NIAID) [E] (b) (6)
Subject: VERY CONCERNED: PO checklist needed

I am very concerned with the number of grants in the DMID program which has not as yet completed their RPPR checklist for June 1 grants. The number is much higher than we expected or we have seen. This is a critical time for us and delays are very problematic. I appreciate your looking into this matter and ensuring these are completed soon.

Thank you

Mary Kirker
Program Director, Grants Management Program
NIAID, NIH, DHHS
5601 Fishers Lane, Room 4E11 MCS 9833
Bethesda, Maryland 20892- 9824
Telephone Number: (240) 669-2944
Fax Number: (b) (6)
Email Address: (b) (6)

on behalf of the NIAID by one of its representatives.

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 9, 2016 6:02:02 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	Not Recvd	N	35	Normil
R01AI085089-07	Baker	2016-07-01	Not Recvd	N	35	Kindbom
R21AI114264-02	GAMBOTTO	2016-07-01	Not Recvd	N	35	Nickerson
R21AI114920-02	Weiss	2016-07-01	Not Recvd	N	35	Nickerson

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 2, 2016 6:02:24 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	Not Recvd	N	35	Normil
R01AI085089-07	Baker	2016-07-01	Not Recvd	N	35	Kindbom
R21AI114264-02	GAMBOTTO	2016-07-01	Not Recvd	N	35	Nickerson
R21AI114920-02	Weiss	2016-07-01	Not Recvd	N	35	Nickerson

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 25, 2016 6:01:00 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	Not Recvd	N	35	Normil

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 18, 2016 6:00:55 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	Not Recvd	N	35	Normil

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 11, 2016 6:01:08 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-03	DASZAK	2016-06-01	Not Recvd	N	35	Normil

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 4, 2016 6:01:14 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI114657-02	Makino	2016-05-01	2016-03-02	Y	35	Graham
R01AI110964-03	DASZAK	2016-06-01	Not Recvd	N	35	Normil

From: Aleksei Chmura
To: Pone, Laura (NIH/NIAID) [E]
Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject: Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER
Date: Wednesday, May 20, 2015 3:58:46 PM
Attachments: R01AI110964 IRB Approval Letter.pdf
ATT00001.htm

Dear Laura,

Attached is our IRB approval notice, which includes both our IRB protocol and our informed consent forms. The text (pages 4-5 in the PDF) details how we plan to recruit participants and ensure their privacy (consent forms in English and Chinese on pages 7-13 of the PDF).

We do not have formal plans to provide participants with information about minimizing risks of exposure to Coronavirus infection, but test-retest studies have shown that participants in surveys similar to ours do increase their knowledge about the survey topics. All participants will be allowed to ask questions and discuss any related topics.

Please call or email me anytime, if further information is required. We are still waiting on the FWA number from Wuhan University and I will keep you updated early next week with any progress.

Many thanks!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(b) (6) (mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

hummingbirdIRB

November 17, 2014

Peter Daszak Ph.D.
EcoHealth Alliance
460 West 34th St., 17th Floor
New York, NY 10001-2320

Protocol Title:	Understanding the Risk of Bat Coronavirus Emergence
Hummingbird IRB #:	2014-23
Grant Number:	1R01AI110964-01
Sponsor:	EcoHealth Alliance
Approval Period:	November 14, 2014 – November 13, 2015

Dear Dr. Daszak:

At the convened board meeting of November 14, 2014, Hummingbird IRB approved the above referenced study for one year.

The following document was approved:

Protocol Date: May 27, 2014

We wish to acknowledge the approval from Wuhan University's IRB which approved the portion of the study for which there was human subject intervention. Hummingbird IRB's approval extends only to the data analysis which will take place for anonymized data transferred to Dr. Daszak.

Any changes made to the protocol must be submitted to the Hummingbird IRB. Approval from Hummingbird IRB must be secured prior to initiation of the revision(s). You will receive a reminder to renew approval of the study approximately 3 months prior to the end of the approval period.

Attached, you will find a summary of investigator commitments with which the Board requires each investigator to adhere to during the approval period.

Sincerely,

(b) (6)

Isaac M. Colbert, Ph.D.
Chairman, Hummingbird IRB

Attachment
cc: Maureen Miller, EcoHealth Alliance
Hummingbird IRB File

Investigator Commitments

All Hummingbird IRB (HIRB) approved investigators are required to fulfill these commitments.

In granting approval to the investigator for the conduct of an investigational study, Hummingbird IRB requires the investigator to understand and agree to these commitments:

1. The investigator will conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol when necessary to protect the safety, rights, or welfare of subjects.

2. The investigator will personally conduct or supervise the described investigation(s).

3. The investigator will delegate tasks to only trained, experienced and appropriately credentialed individuals who are familiar with the protocol and understand the tasks required to conduct the study and protect human subjects during screening and while enrolled.

4. The investigator is obligated to inform Hummingbird IRB of any financial conflicts of interest which may exist through submitting appropriate forms on an annual basis. Should a conflict arise during the course of the study, this conflict will be promptly reported to the IRB.

5. The investigator will inform any patients involved in a study involving drugs, devices or biologics, or any persons used as controls, that the drugs, devices or biologics are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

6. The investigator will report to the sponsor and Hummingbird IRB (when applicable) adverse and unanticipated problems that occur in the course of the investigation(s). If after the study has concluded, new information is made available that is relevant to ongoing health or safety, the investigator will inform subjects of these results.

7. When applicable, the investigator will read and understand the information in the investigator's brochure, device manual and other scientific background that describes the potential risks and side effects of the drug, procedure or device.

8. The investigator will ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the commitments outlined in this document.

9. The investigator will maintain adequate and accurate records and make those records available for inspection.

10. The investigator will promptly report Hummingbird IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, the investigator will not make any changes in the research without Hummingbird IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
11. The investigator will have in place at his or her site, a process by which the HIRB approved consent form is compared to the executed contract to ensure that consistency exists between documents in terms of procedures, study visits, payment to subjects and compensation for injury as well as other conditions effecting human subjects. The investigator and sponsor will resolve any difference and notify HIRB of any changes impacting the consent.

12. The investigator will provide referrals to any subject for whom a condition or potentially adverse information is uncovered during the study. This may include, for example, learning of suicidality or a previously unknown disease. This does not pertain to results of genetic testing unless sharing this information is part of the protocol.

PROTOCOL: Understanding the Risk of Bat Coronavirus Emergence

Protocol #: R01AI110964

Version Date and Number: 6/5/13 updated 10/21/14 Version #1

The behavioral component of this multidisciplinary study has been designed directly in concert with the novel work of zoonotic viral detection and the identification and characterization of spillover and further transmission risk from wildlife. The approach is iterative and begins with rapid and focused qualitative research conducted in natural settings at biological and ecological surveillance sites. The research includes observation and mapping of public spaces, as well as focus groups and ethnographic interviews conducted with two groups of individuals: those involved with the wildlife value chain (from hunter through market to consumer) and those highly exposed exposure to wildlife, particularly bats (eg, cave dwellers). The focus is on the type and frequency of animal contact, as well as the range of wildlife observed. Participants will also be asked about observed environmental/ecological changes and impact; travel with animals, animal responsibilities and how these are divided by age and gender, and animal taboo; daily life, seasonal changes, times of shortage and other socioeconomic factors; and finally the frequency, types, causes and understanding of illness. This information provides a framework to gain rapid understanding of human-animal interactions and the actions/meanings surrounding these interactions, as well as for the exploration of unanticipated knowledge, such as the presence and rationale for taboos on certain human-animal interactions. These data will directly inform the development of detailed behavioral surveys. Alignment of the behavioral studies will coincide with animal biological surveillance to maximize the understanding of risk and reconcile information gathered on transmission risk with the actual presence of potentially zoonotic pathogens.

Consistent with the original proposal, we will recruit volunteers for the qualitative research by word of mouth or by referral from key informants or other participants from the two target groups (ie, wildlife value chain participants and those highly exposed to wildlife, particularly bats) in Guangdong, Guangxi, Yunnan, and Fujian provinces in cooperation with local Bureaus of Public Health and CDCs. To recruit participants, we will identify local individuals influential with the target population, introduce the study in public community fora and identify volunteers through these mechanisms. We will identify three sites in each province for a total of 12 sites representing the range of settings where the target population may be found (eg, bat caves, wet markets; formal and informal wildlife trade posts; animal transport/travel routes and mechanisms including transport storage and exchange centers, and wildlife value chain supporting industries such as guesthouses, restaurants, medicinal/magical/material animal parts and animal by-product preparers, vendors and purchasers). It is anticipated that eight focus groups (two per province) of approximately 8-10 individuals each (ie, a total of 48-80) and 144 ethnographic interviews (12 per site) will be conducted. Therefore, a total of 192 to 224 individuals will participate in qualitative research. With participant permission, qualitative interviews and focus groups will be recorded.

For the behavioral survey, in each of the four provinces in southern China we will aim to include 10 markets and survey 20 vendors per market; an additional 420 individuals will be selected based on the results of qualitative data analysis. In each province, 620 people will be surveyed for a total of 2480 individuals. A sampling frame and recruitment materials for this quantitative research will be developed in Year 2. Participants in the survey will be asked to provide blood (no more than 550ml), sputum, and stool samples. We will screen sera for antibodies to SARS-CoV, other alpha & beta coronaviruses including MERS-CoV,

and novel bat-CoVs. We will screen stool from CoV seropositive participants for CoV nucleic acid. We will also develop specific bat-CoV serological assays and share these with our Chinese collaborators.

In recognition of the time and expertise offered by study participants, each person will be offered a small token of practical, emotional or social significance. The token will not cost a lot of money, nor will it be money.

Only adults 18 years or older will be invited to participate. At least one of the focus groups and an estimated 35-40% of the interviews and surveys will be conducted with women. Subjects will be enrolled in this study without regard to ethnicity. The primary enrollment criteria are related to occupational exposure to wildlife and residence near wildlife.

We currently have no plans to pursue the substudy in Shanghai mentioned in the text. There are also no current plans for follow up of any study participants. In addition, if SARS virus is identified in any human sample, it will be immediately reported to public health authorities because we will have identified an outbreak.

The original sources of this information are on p112 section C1b and p120 Human subjects in the grant proposal.

On May 18, 2015, at 13:49, Pone, Laura (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,

OER has reviewed the original response to the summary statement concern and requested the following additional information. Please provide a response no later than **Wednesday, May 20th.**

-

- Please have the PI discuss the recruitment of participants.
- Please have the PI discuss how privacy is ensured, particularly with face-to-face interviews.
- Will participants be provided any information regarding minimizing their risks of Coronovirus infection?

NIH Instructions for Grant Applications may be found at:
http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerB.pdf, Part II onwards for requirements on the Protection of Human Subjects
Please also visit our public website for information on "Research Involving Human Subjects":
http://grants.nih.gov/grants/policy/hs/index.htm

Thank you,

Laura

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, May 4, 2015 6:05:32 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI110964-02	DASZAK	2015-06-01	2015-05-01	Y	35	Pone
P01AI060699-10	Perlman	2015-07-01	2015-04-30	Y	35	Early
R01AI095569-05	Frieman	2015-07-01	2015-05-01	Y	35	Tempchin
R01AI101028-03	Xiao	2015-07-01	Not Recvd	N	35	Shriner

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]; Pone, Laura (NIH/NIAID) [E]; NIAID GM I2 Notifications
Subject: eRA Commons: RPPR for Grant R01AI110964-02 Received at NIH
Date: Friday, May 1, 2015 2:49:17 PM

RPPR for grant R01AI110964-02 associated with Program Director/Principal Investigator PETER DASZAK has been received electronically through the eRA Commons. You may view the progress report through one of the IMPAC II modules by going to the Grant Folder and selecting the e-Application.

Program Class Code:	M51C
Program Officer:	Stemmy, Erik J.
Grants Management Specialist:	Pone, Laura A.

For any further questions about this email, call the eRA Help Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact.
For more information please visit http://era.nih.gov/.

Please access Commons at http://public.era.nih.gov/commons/.

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 27, 2015 6:05:22 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R21AI113206-02	Tseng	2015-06-01	2015-04-15	Y	35	Fato
R01AI110964-02	DASZAK	2015-06-01	Not Recvd	N	35	Pone
R01AI091322-05	Perlman	2015-06-01	2015-03-25	Y	35	Early

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 20, 2015 6:04:57 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI091322-05	Perlman	2015-06-01	2015-03-25	Y	35	Early
R21AI113206-02	Tseng	2015-06-01	2015-04-15	Y	35	Fato
R01AI110964-02	DASZAK	2015-06-01	Not Recvd	N	35	Pone

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 13, 2015 6:04:34 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R01AI091322-05	Perlman	2015-06-01	2015-03-25	Y	35	Early
R01AI110964-02	DASZAK	2015-06-01	Not Recvd	N	35	Pone
R21AI113206-02	Tseng	2015-06-01	Not Recvd	N	35	Fato

From: era-notify@mail.nih.gov
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: NIAID GM I2 Notifications
Subject: Review Needed for Type 5 Progress Reports
Date: Monday, April 6, 2015 6:03:31 AM

*** This is an automated notification - Please do not reply to this message. ***

Dear Program Official (Stemmy Erik J.),

Below is a listing of Type 5 progress reports assigned to you and not yet completed.

Please complete these reviews as soon as possible via the eRA Program Module.

Please keep in mind grantees have until the 15th of the due month to submit eSNAP applications via the NIH Commons.

Thanks - Grants Management Office

Grant Number	PI Last Name	Start Date	Received	Image	Status	Specialist
R21AI113206-02	Tseng	2015-06-01	Not Recvd	N	35	Fato
R01AI091322-05	Perlman	2015-06-01	2015-03-25	Y	35	Early
R01AI110964-02	DASZAK	2015-06-01	Not Recvd	N	35	Pone

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 October 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

I am following up on Mr. Krinsky's August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. ("EcoHealth") responding to NIH's suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no *current* connection to the Project or EcoHealth's research, and EcoHealth had not issued any subawards in connection with the Grant *at the time of the suspension*.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth's grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that "Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China." EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV's facilities, EcoHealth described WIV as China's premier institute for virological research" and touted WIV's "fully equipped biosafety level 3 laboratory" and "a newly opened BLS-4 laboratory." In support of the application, Dr. Zheng Li Shi's personal statement indicated that "My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains." The application stated that "Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3

lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations."

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV's work in the following annual amounts for years 1 through 5:

	-Yr 1	-Yr 2	-Yr 3	-Yr 4	-Yr 5
Total Direct Costs	$123,699	$128,718	$147,335	$147,335	$147,335
F&A Costs @ 8%	$9,896	$10,297	$11,787	$11,787	$11,787
TOTAL COSTS	$133,595	$139,015	$159,122	$159,122	$159,122

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) ("The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities."). Moreover, EcoHealth was required to "Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]" 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]." Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV's lab safety and EcoHealth's oversight of its subrecipient, and an inspection of WIV's laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this

project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that "NIAID is not authorized under 45 CFR§§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates."

These provisions are irrelevant to NIH's requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH's concerns. Moreover, as a granting agency, NIH is required to "manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]" 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to "make site visits as warranted by program needs." 45 C.F.R. § 75.342. As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH's authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV's facility to conduct an inspection. EcoHealth's responses have not satisfied NIH's concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:

1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)

From: Aleksei Chmura
To: Girma, Tseday (NIH/NIAID) [E]
Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER
Date: Wednesday, July 17, 2019 3:53:48 PM
Attachments: EHAL FY20 Prov Indirect Agmt Signed.pdf

Tseday,

Attached is our provisional rate of (b) (4) - signed today.

Many thanks!

-Aleksei

On Jul 17, 2019, at 15:38, Girma, Tseday (NIH/NIAID) [E] (b) (6) wrote:

Thank you.

Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E49
Rockville, MD 20852
Phone: (b) (6)
Email: (b) (6)
NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

From: Aleksei Chmura (b) (6)
Sent: Wednesday, July 17, 2019 3:11 PM
To: Girma, Tseday (NIH/NIAID) [E] (b) (6)
Cc: Peter Daszak (b) (6); Stemmy, Erik (NIH/NIAID) [E]

(b) (6)

Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Dear Tseday,

We are still waiting on our cognisant agency (DoD) to issue a provisional rate or other notice. We will do all possible to get this to you today or before 5pm tomorrow.

Cheers,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

(b) (6) (office)
(b) (6) (mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

On Jul 17, 2019, at 12:07, Girma, Tseday (NIH/NIAID) [E]
(b) (6) wrote:

Good afternoon,

The F&A rate agreement submitted in the JIT for ECHOHealth Alliance, Inc. dated 11/14/2018 has expired on 06/30/2017. Do you have any documentation that you can send us that shows you could use the expired rate. Pending the establishment of a negotiated facilities and administrative (F&A) rate, we will restrict the amount of F&A funds in excess of 10% salaries and wages exclusive of fringe benefits and may not be expended until the new F&A rate agreement is issued and you receive a revised Notice of award from NIH.

Please send us the requested information ASAP but no later than

07/18/2019.

Thanks,
Tseday

Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E49
Rockville, MD 20852
Phone: (b) (6)
Email: (b) (6)
NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

DEPARTMENT OF THE NAVY
OFFICE OF NAVAL RESEARCH
875 NORTH RANDOLPH STREET
SUITE 1425
ARLINGTON, VA 22203-1995

IN REPLY REFER TO:

Agreement Date: July 17, 2019

NEGOTIATION AGREEMENT

INSTITUTION: **ECOHEALTH ALLIANCE, INC.**
460 WEST 34TH ST. 17TH FLR
NEW YORK, NY 10001-2320

The Indirect Cost rate contained herein is for use on grants, contracts and/or other agreements issued or awarded to the EcoHealth Alliance, Inc. by all Federal Agencies of the United States of America, in accordance with the provisions and cost principles mandated by 2 CFR Part 200. The rate shall be used for forward pricing and billing purposes for the EcoHealth Alliance, Inc. Fiscal Year 2020. This rate agreement supersedes all previous rate agreements/determinations for Fiscal Year 2020.

Section I: RATES - TYPE: PROVISIONAL (PROV)

Indirect Rates:

TYPE	FROM	TO	RATE	BASE	APPLICABLE TO	LOCATION
Prov.	07/01/19	06/30/20	(b) (4)	(a)	All	All

DISTRIBUTION BASES

(a) Total direct costs excluding capital expenditures (buildings, individual items of equipment; alterations and renovations), the portion of each subaward in excess of $25,000, participant support costs, and flow-through funds.

SECTION II - GENERAL TERMS AND CONDITIONS

A. **LIMITATIONS:** Use of the rate set forth under Section I is subject to availability of funds and to any other statutory or administrative limitations. The rate is applicable to a given grant or contract or other agreement only to the extent that funds are available. Acceptance of the rate agreed to herein is predicated upon the following conditions: (1) that no costs other than those incurred by the organization were included in this indirect cost pool as finally accepted and that such costs are legal obligations of the organization and allowable under governing cost principles; (2) that the same costs that have been treated as indirect costs are not claimed as direct costs; (3) that similar types of costs have been accorded consistent accounting treatment; and (4) that the information provided by the organization which was used as a basis for acceptance of the rate agreed to herein, and expressly relied upon by the Government in negotiating and accepting the said rate is not subsequently found to be materially incomplete or inaccurate.

B. **ACCOUNTING CHANGES**: The rate contained in Section I of this agreement is based on the accounting system in effect at the time the agreement was negotiated. Changes to the method(s) of accounting for costs, which affect the amount of reimbursement resulting from the use of the rate require the prior written approval of the authorized representative of the cognizant agency for indirect costs. Such changes include but are not limited to changes in the charging of a particular type of cost from indirect to direct. Failure to obtain such approval may result in subsequent cost disallowances.

C. **PROVISIONAL RATES:** The provisional rate contained in this agreement is subject to unilateral amendment by the Government or bilateral amendment by the Contracting parties at any time.

D. **USE BY OTHER FEDERAL AGENCIES**: The rate set forth in Section I is negotiated in accordance with and under the authority set forth in 2 CFR Part 200. Accordingly, such rate shall be applied to the extent provided in such regulations to grants, contracts, and other agreements to which 2 CFR Part 200 applies, subject to any limitations in part A of this section. Copies of this document may be provided by either party to other federal agencies to provide such agencies with documentary notice of this agreement and its terms and conditions.

E. **SPECIAL REMARKS**: The Government's agreement with the rate set forth in Section I is not an acceptance of the EcoHealth Alliance, Inc.'s accounting practices or methodologies. Any reliance by the Government on cost data or methodologies submitted by EcoHealth Alliance, Inc. is on a non-precedence-setting basis and does not imply Government acceptance.

Accepted:

FOR ECOHEALTH ALLIANCE, INC.:

(b) (6)

ARMINE ARUSTAMYAN
Chief Financial Officer

07-17-19
Date

FOR THE U.S. GOVERNMENT:

WOOD.LINDA.MORGAN.1514688946

Digitally signed by WOOD.LINDA.MORGAN.1514688946
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USN, cn=WOOD.LINDA.MORGAN.1514688946
Date: 2019.07.17 15:42:35 -04'00'

LINDA MORGAN WOOD
Contracting Officer

7/17/19
Date

For information concerning this agreement contact:

Sharon Gales
Office of Naval Research
875 North Randolph Street
Arlington, VA 22203-1995

Phone: (b) (6)
E-mail: (b) (6)

From: Soto, Tiffani (NIH/OD) [C]
To: Aleksei Chmura; Girma, Tseday (NIH/NIAID) [E]
Cc: (b) (6) OLAW Division of Assurances (NIH/OD)
Subject: 2R01AI110964-06 EcoHealth Alliance, Inc.
Date: Friday, July 12, 2019 11:31:07 AM
Attachments: A7941-04.pdf

Good Morning Dr. Chmura,

Please find enclosed the approved Inter-institutional Assurance for the above mentioned grant.

Tseday, the above, mentioned grant has been added to the daily list that OLAW sends to eRA for assurance number updates. It usually takes 72 hours before the changes will reflect in the IMPAC II record.
Please contact me if you do not see the assurance update at that time.

Kind Regards,

Tiffani T. Soto
Program Assistant (Contractor)
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700 B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892
Phone: (b) (6) (Main)
Phone: (b) (6) (Direct)
Email: (b) (6)

Division of Assurances
E-Fax (301) 451-5672
Email: OLAWdoa@mail.nih.gov

Quote:
Tell me and I forget, Teach me and I remember, Involve me and I learn.
Benjamin Franklin

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Fax: (301) 451-5672

July 10, 2019

Grant#: 2-R01-AI110964-06
Project Title: Understanding the Risk of Bat Coronavirus Emergence
Principal Investigator: Dr. Peter Daszak
Animal Facility: The University of North Carolina at Chapel Hill

Dr. Aleksei Chmura
Authorized Organizational Reprehensive
EcoHealth Alliance, Inc.
460 West 34th Street, Suite 1701
New York, New York 10001

Dear Dr. Chmura:

The Division of Assurances, Office of Laboratory Animal Welfare (OLAW) has reviewed and approved the new Inter-institutional Assurance which was submitted by your Institution in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) revised August 2015.

This Assurance with identification ***A7941-04*** became effective on ***7/10/2019***. The Assurance is good for the current period of project support. Under your approved Assurance with ***The University of North Carolina at Chapel Hill***, their institutional Animal Care and Use Committee (IACUC) is authorized to conduct subsequent reviews of this project.

The Assurance is a key document in defining the relationship of your Institution to the PHS and the cooperating Institution's IACUC since they set forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals.

A copy of the approved Assurance is enclosed. If I can be of any further assistance, please feel free to contact me by phone or mail.

Sincerely,

(b) (6)

Venita Thornton, D.V.M., M.P.H.
Senior Assurance Officer, Division of Assurances
Office of Laboratory Animal Welfare (OLAW)

Enclosure
Cc:
Terry Magnuson, PhD
Roland Tisch, Ph.D.
Tseday Girma, NIAID

ScInterinstitutional Assurance

The Interinstitutional Assurance is used by U.S. institutions that receive Public Health Service (PHS) funds through a grant or contract award when the institution has neither its own animal care and use program, facilities to house animals, nor an Institutional Animal Care and Use Committee (IACUC) and will conduct the animal activity at an Assured institution (named as a performance site).

I. Awardee Institution

Name of Awardee Institution: EcoHealth Alliance
Address: *(street address, city, state, zip code)* 460 West 34th Street, Suite 1701, New York, NY 10001, USA
Project Title: *(from grant application/contract proposal)* Understanding the Risk of Bat Coronavirus Emergence
Grant/Contract Number: 2-R01-AI110946-06
Principal Investigator: Dr. Peter Daszak

A. Applicability

This Interinstitutional Assurance between the awardee institution and the Assured institution is applicable to research, research training, and biological testing involving live vertebrate animals supported by the PHS and conducted at the Assured institution.

B. Awardee and Assured Institutional Responsibilities

i. The institutions agree to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

ii. The institutions agree to be guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and comply with the PHS Policy on Humane Care and Use of Laboratory Animals (Policy).

iii. The institutions acknowledge and accept responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, the institutions will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

iv. The awardee institution acknowledges and accepts the authority of the IACUC of the Assured institution where the animal activity will be performed and agrees to abide by all conditions and determinations as set forth by that IACUC.

Name of Assured Institution: University of North Carolina at Chapel Hill
Office of Sponsored Research 104 Airport Dr. CB# 1350 Chapel Hill, NC 27599

II. Institutional Endorsement

By signing this document, the authorized official at the awardee institution and the Institutional Official and IACUC Chairperson at the Assured institution (performance site) provide their assurances that the project identified in Part I will be conducted in compliance with the PHS Policy and the Assurance of the Assured institution.

A. Endorsement of Awardee Institution	
Name of Awardee Institution: EcoHealth Alliance	
Authorized Official: Dr. Aleksei Chmura	
Signature: (b) (6)	Date: 21 June 2019
Title: Authorized Organizational Representative	
Address: *(street address, city, state, zip code)* 460 West 34th Street, Suite 1701, New York, NY 10001, USA	
Phone: (b) (6)	Fax: +1.212.380.4465
E-mail: (b) (6)	
B. Endorsement of Assured Institution	
Name of Assured Institution: University of North Carolina at Chapel Hill	
Institutional Official: Terry Magnuson, PhD	
Signature: (b) (6)	Date: 7/5/2019
Title: Vice Chancellor for Research	
Address: *(street address, city, state, zip code)* 312 South Bldg- Office of the VCR CB #4000 Chapel Hill NC, 27599-4000	
Phone: (b) (6)	Fax: 919-962-1476
E-mail: (b) (6)	
IACUC Chairperson: Roland Tisch, PhD	
Signature: (b) (6)	Date: 7/05/19
Title: IACUC Chair	
Address: *(street address, city, state, zip code)* UNC - Department of Microbiology and Immunology CB #7290 Chapel Hill, NC 27599-7290	
Phone: (b) (6)	Fax: 919-966-8429
E-mail: (b) (6)	
Date of IACUC Approval: *(within 3 years, pending not acceptable)* ~~9/29/19~~ 9/29/2017	

III. PHS Approval *(to be completed by OLAW)*

Signature of OLAW Official: (b) (6)	Date: 7/10/2019
Venita B. Thornton, D.V.M., M.P.H. Senior Assurance Officer, Division of Assurances Office of Laboratory Animal Welfare (OLAW) NIH/OD/OER 6700B Rockledge Drive, Suite 2500- MSC 20892 Bethesda, Maryland 20892	
Grant/Contract #: 2R01AI110964-06	Animal Welfare Assurance #: A7941-04
Effective Date: 7/10/2019	Expiration Date: *(duration of project, up to 5 years)*

From: Soto, Tiffani (NIH/OD) [C]
To: Aleksei Chmura; Girma, Tseday (NIH/NIAID) [E]
Cc: wangyy@wh.iov.cn; zhouxi@wh.iov.cn; OLAW Division of Assurances (NIH/OD)
Subject: 2R01AI110946-06 EcoHealth Alliance, Inc.
Date: Tuesday, June 25, 2019 7:35:36 AM
Attachments: 3209_001.pdf

Good Morning Dr. Chmura,

Please find enclosed the approved Inter-institutional Assurance between EcoHealth Alliance, Inc. & Wuhan Institute of Virology.

Kind Regards,

Tiffani T. Soto
Program Analyst (Contractor)
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700 B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892
Phone: (b) (6) (Main)
Phone: (b) (6) (Direct)
Email: (b) (6)

Division of Assurances
E-Fax (301) 451-5672
Email: OLAWdoa@mail.nih.gov

Quote:
Tell me and I forget, Teach me and I remember, Involve me and I learn.
Benjamin Franklin

From: OLAW-PTR5@nih.gov <OLAW-PTR5@nih.gov>
Sent: Tuesday, June 25, 2019 7:31 AM
To: Soto, Tiffani (NIH/OD) [C] (b) (6)
Subject: Attached Image

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Fax: (301) 451-5672

June 24, 2019

Grant #: 2-R01-AI110946-06
Project Title: Understanding the Risk of Bat Coronavirus Emergence
Principal Investigator: Dr. Peter Daszak
Animal Facility: Wuhan Institute of Virology

Dr. Aleksei Chmura
Authorized Organization Representative
EcoHealth Alliance, Inc.
460 West 34th Street, 17 Floor
New York, New York 10001

Dear Dr. Chmura:

The Division of Assurances, Office of Laboratory Animal Welfare (OLAW) has reviewed and approved the new Inter-institutional Assurance which was submitted by your Institution in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) revised August 2015.

This Assurance with identification ***A7941-03*** became effective on ***6/24/2019***. The Assurance is good for the current period of project support. Under your approved Assurance with ***Wuhan Institute of Virology,*** their institutional Animal Care and Use Committee (IACUC) is authorized to conduct subsequent reviews of this project.

The Assurance is a key document in defining the relationship of your Institution to the PHS and the cooperating Institution's IACUC since they set forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals.

A copy of the approved Assurance is enclosed. If I can be of any further assistance, please feel free to contact me by phone or mail.

Sincerely,

(b) (6)

Venita Thornton, D.V.M., M.P.H.
Senior Assurance Officer, Division of Assurances
Office of Laboratory Animal Welfare (OLAW)

Enclosure
Cc:
Dr. Yanyi Wang
Dr. Xi Zhou
Tseday Girma, NIAID

ScInterinstitutional Assurance

The Interinstitutional Assurance is used by U.S. institutions that receive Public Health Service (PHS) funds through a grant or contract award when the institution has neither its own animal care and use program, facilities to house animals, nor an Institutional Animal Care and Use Committee (IACUC) and will conduct the animal activity at an Assured institution (named as a performance site).

I. Awardee Institution

Name of Awardee Institution: EcoHealth Alliance
Address: *(street address, city, state, zip code)* 460 West 34th Street, 17th Floor New York, NY 10001, USA
Project Title: *(from grant application/contract proposal)* Understanding the Risk of Bat Coronavirus Emergence
Grant/Contract Number: 2-R01-AI110946-06
Principal Investigator: Dr. Peter Daszak

A. Applicability

This Interinstitutional Assurance between the awardee institution and the Assured institution is applicable to research, research training, and biological testing involving live vertebrate animals supported by the PHS and conducted at the Assured institution.

B. Awardee and Assured Institutional Responsibilities

i. The institutions agree to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

ii. The institutions agree to be guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and comply with the PHS Policy on Humane Care and Use of Laboratory Animals (Policy).

iii. The institutions acknowledge and accept responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, the institutions will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

iv. The awardee institution acknowledges and accepts the authority of the IACUC of the Assured institution where the animal activity will be performed and agrees to abide by all conditions and determinations as set forth by that IACUC.

Name of Assured Institution: Wuhan Institute of Virology, Chinese Academy of Sciences
Address: *(street address, city, state, zip code)* Xiao Hong Shan No. 44 Wuhan, Hubei Province, 430071 P.R. China

II. Institutional Endorsement

By signing this document, the authorized official at the awardee institution and the Institutional Official and IACUC Chairperson at the Assured institution (performance site) provide their assurances that the project identified in Part I will be conducted in compliance with the PHS Policy and the Assurance of the Assured institution.

A. Endorsement of Awardee Institution	
Name of Awardee Institution: EcoHealth Alliance	
Authorized Official: Dr. Aleksei Chmura	
Signature: (b) (6)	Date: June 21, 2019
Title: Authorized Organizational Representative	
Address: *(street address, city, state, zip code)* 460 West 34th Street, 17th Floor New York, NY 10001, USA	
Phone: (b) (6)	Fax: +1.212.380.4465
E-mail: (b) (6)	
B. Endorsement of Assured Institution	
Name of Assured Institution: Wuhan Institute of Virology, Chinese Academy of Sciences	
Institutional Official: Dr. Yanyi Wang	
Signature: (b) (6)	Date: June 28th 2019
Title: Director	
Address: *(street address, city, state, zip code)* Xiao Hong Shan No. 44 Wuhan, Hubei Province, 430071 P.R. China	
Phone: (b) (6)	Fax: +86.27.87198209
E-mail: (b) (6)	
IACUC Chairperson: Dr. Xi Zhou	
Signature: (b) (6)	Date: June 28th 2019
Title: Chairman of Institutional Animal Care and Use Committee, Wuhan Institute of Virology, Chinese Academy of Science	
Address: *(street address, city, state, zip code)* Xiao Hong Shan No. 44 Wuhan, Hubei Province, 430071 P.R. China	
Phone: (b) (6)	Fax: +86.27.87198209
E-mail: (b) (6)	
Date of IACUC Approval: *(within 3 years, pending not acceptable)* June 21st 2019	

III. PHS Approval *(to be completed by OLAW)*

Signature of OLAW Official: (b) (6)	Date: **6/24/2019**
Venita B. Thornton, D.V.M, M.P.H. **Senior Assurance Officer, Division of Assurances** **Office of Laboratory Animal Welfare (OLAW)** **NIH/OD/OER** **6700B Rockledge Drive** **Suite 2500-MSC 6910** **Bethesda, Maryland 20892**	
Grant/Contract #: **2R01AI110964-06**	Animal Welfare Assurance #: **A7941-03**
Effective Date: **6/24/2019**	Expiration Date: *(duration of project, up to 5 years)*

Just In Time Report

Report submitted on : 05/06/2019 11:01 PM

IRB Confirmation:

Human Subjects Assurance Number:

Human Subjects Education: No Human Subjects Education was provided

IACUC Confirmation:

t2R01AI110964 - Understanding the Risk of Bat Coronavirus Emergence (PI, Daszak)

6 May 2019

Dear NIAID Just-in-Time,

Please find Active and Pending Support information for ALL individuals designated in our application as Senior/Key Personnel. These individuals are as follows (below) and their respective active and pending support details are on the following pages. The order is kept identical to that in our proposal. If additional details are required, please contact me anytime.

Sincerely,

Peter Daszak
President, EcoHealth Alliance
460 West 34th Street – Ste. 1701
New York, NY 10001

Count	Role	Key Personnel	Institution	Page
1	Principal Investigator	Daszak, Peter	EcoHealth Alliance	1-2
2	Co-Investigator	Shi, Zhengli	Wuhan Institute of Virology	3
3	Co-Investigator	Olival, Kevin	EcoHealth Alliance	4-5
4	Co-Investigator	Baric, Ralph	University of North Carolina at Chapel Hill	6-9
5	Co-Investigator	Ross, Noam	EcoHealth Alliance	10
6	Research Scientist	Latinne, Alice	EcoHealth Alliance	11
7	Research Scientist	Li, Hongying	EcoHealth Alliance	12
8	Co-Investigator	Francisco, Leilani	EcoHealth Alliance	13
9	Co-Investigator	Sims, Amy	University of North Carolina at Chapel Hill	14-15
10	Research Scientist	Hagan, Emily	EcoHealth Alliance	16
11	Co-Investigator	Zhu, Guangjian	East China Normal University	17
12	Co-Investigator	Wang, Linfa	Duke-NUS Medical School	18
13	Co-Investigator	Ren, Lili	Institute of Pathogen Biology	19
14	Co-Investigator	Li, Guo	Institute of Pathogen Biology	20
15	Co-Investigator	Zhou, Peng	Wuhan Institute of Virology	21
16	Co-Investigator	Hu, Ben	Wuhan Institute of Virology	22
17	Research Scientist	Chmura, Aleksei	EcoHealth Alliance	23

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Peter Daszak | Other agencies (including NSF) to which this proposal

Support: ☐ Current ☐ Pending ☒ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: AccelNet: EpiDyn: Predicitng Disease and Popualtion Dynamics for Improved Resilience

Source of Support: NSF - EEID

Total Award Amount: $358,109 Total Award Period Covered: 09/01/2019-08/2020

Location of Project: EcoHealth Alliance, subcontract from UC Davis (prime)

Person-Months Per Year Committed to the Project. 0.0 ~~Cal:~~ (b) (4), (b) (6) Acad: 0.0 Sumr: 0.0

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: PREDICT-2

Source of Support: USAID Emerging Pandemic Threats

Total Award Amount: $38,000,000 Total Award Period Covered: 10/01/2014- 09/2019

Location of Project: EcoHealth Alliance, subcontract from UC Davis (prime)

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence R01AI110964

Source of Support: NIAID

Total Award Amount: $3,086,735 Total Award Period Covered: 06/01/2014-05/31/2019

Location of Project: EcoHealth Alliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Optimal Strategies of Land Use in Southeast Asia's Tropical Forests

Source of Support: NSF – Division of Social and Economic Sciences

Total Award Amount: $497,667 Total Award Period Covered: TBD

Location of Project: EcoHealth Alliance and Malaysia

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Alliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

---

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (10/99) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Peter Daszak	Other agencies (including NSF) to which this proposal

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: AccelNet: A network of networks linking ecology, conservation, and disease emergence

Source of Support: NSF

Total Award Amount: $748,847 Total Award Period Covered: 10/01/019 – 09/30/22

Location of Project: US and International

Person-Months Per Year Committed to the Project. 0.0 Cal: (b) (4), (b) (6) Acad: 0.0 Sumr: 0.0

NSF Form 1239 (10/99) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Zhengli Shi | Other agencies (including NSF) to which this proposal

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Geographical distribution and genetic variation of pathogens in Africa

Source of Support: SAJC201605 Sino-Africa Joint Research Center, Chinese Academy of Sciences

Total Award Amount: $ 447,760 Total Award Period Covered: 01/01/2016-12/31/2020

Location of Project: Wuhan Insitute of Virology & Sino-Africa Joint Research Center, Chinese Academy of Sciences

Person-Months Per Year Committed to the Project. 0.0 Cal: (b) (4), (b) (6) Acad: 0.0 Sumr: 0.0

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Evolution mechanism of the adaption of bat SARS-related coronaviruses to host receptor

Source of Support: 31770175 National Natural Science Foundation of China

Total Award Amount: $ 98,507 Total Award Period Covered: 01/01/2018-12/31/2021

Location of Project: Wuhan Insitute of Virology, Chinese Academy of Sciences

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence
R01AI110964

Source of Support: NIAID

Total Award Amount: $3,086,735 Total Award Period Covered: 06/01/2014-05/31/2019

Location of Project: Wuhan Insitute of Virology, Chinese Academy of Sciences

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Genetic evolution and transmission mechanism of important bat-borne viruses

Source of Support: XDB29010000 The strategic Priority research Program of CAS

Total Award Amount: $1,305,970 Total Award Period Covered: 07/01/2018-06/30/2023

Location of Project: Wuhan Institute of Virology, Chinese Academy of Sciences

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

---

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (10/99) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Kevin Olival	Other agencies (including NSF) to which this proposal has

Support: ☐ Current ☐ Pending ☒ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: AccelNet: Integrating Mammalian Ecology, Conservation Biology, and Zoonotic Disease Research

Source of Support: NSF

Total Award Amount: $749,138 Total Award Period Covered: 10/01/19 – 9/30/22

Location of Project: Global

Person-Months Per Year Committed to the Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Strengthening biosurveillance and early detection capabilities for MERS-CoV and Other coronaviruses in USCENTCOM and USEUCOM

Source of Support: GHERI

Total Award Amount: $2,849,106 Total Award Period Covered: 11/01/19 – 10/31/22

Location of Project: USA, Georgia, Jordan

Person-Months Per Year Committed to the Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ Transfer of Support

Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIH

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/19 – 05/31/24

Location of Project: US and China

Person-Months Per Year Committed to the Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Drivers of Nipah virus spillover across Bangladesh

Source of Support: NIH NIAID

Total Award Amount: $3,035,541 Total Award Period Covered: 09/01/2019 – 08/31/2024

Location of Project: USA, Global

Person-Months Per Year Committed to the Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title: Understanding the Risk of Bat-Borne Zoonotic Disease Emergence in Western Asia

Source of Support: DTRA

Total Award Amount: $4,391,444 Total Award Period Covered: 10/02/2017 – 10/01/2022

Location of Project: USA, Western Asia

Person-Months Per Year Committed to the Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Support:	☒ Current	☐ Pending	☐ Submission Planned in Near Future	☐ *Transfer of Support

Project/Proposal Title: Understanding the Risk of Coronavirus Emergence

Source of Support: NIH NIAID
Total Award Amount: $3,086,735 Total Award Period Covered: 09/01/2016 – 08/31/2021
Location of Project: USA, Global
Person-Months Per Year Committed to the Cal: (b) (4), (b) (6) Acad: Sumr:

Support:	☒ Current	Pending	☐ Submission Planned in Near Future	☐ *Transfer of Support

Project/Proposal Title: Emerging Pandemic Threats: PREDICT2

Source of Support: USAID
Total Award Amount: $21,000,000 Total Award Period Covered: 10/01/2014 – 09/30/2019
Location of Project: Global
Person-Months Per Year Committed to the Cal: (b) (4), (b) (6) Acad: Sumr:

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Ralph Baric	Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Natural history, immunity, and transmission patterns of sapovirus in a Nicaraguan birth cohort
Source of Support: NIH
Total Award Amount: $500,513 Total Award Period Covered: 09/27/16-08/31/21
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Nicaraguan Emerging and Endemic Diseases (NEED)
Source of Support: NIH
Total Award Amount: $230,000 Total Award Period Covered: 05/10/18-02/28/23
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ Transfer of Support
Project/Proposal Title:

Molecular Characterization of Functional RNA Structures in the ZikV genome
Source of Support: NIH
Total Award Amount: $150,000 Total Award Period Covered 02/05/18-01/31/20
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence
Source of Support: NIAID
Total Award Amount $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024
Location of Project: EcoHealth Alliance and International Field and Lab Locations
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Antiviral Drug Discovery and Development Center
Source of Support: NIH/NIAID
Total Award Amount: $304,371 Total Award Period Covered: 03/01/19-02/28/20
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Ralph Baric	Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Systems Immunogenetics of Biodefense Pathogens in the Collaborative Cross
Source of Support: NIH/NIAID
Total Award Amount: $2,662,979 Total Award Period Covered: 08/05/12-08/31/22
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Diagnostic and Prognostic Biomarkers for Viral Severe Lung Disease
Source of Support: NIH/NIAID
Total Award Amount: $584,891 Total Award Period Covered: 03/01/14-02/28/20
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ Transfer of Support
Project/Proposal Title:

Preclinical Assays To Predict Tetravalent Dengue Vaccine Efficacy
Source of Support: NIH/NIAID
Total Award Amount: $848,808 Total Award Period Covered 05/04/16-04/30/21
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Mechanisms of MERS-CoV Entry, Cross-species Transmission and Pathogenesis
Source of Support: NIH/NIAID
Total Award Amount $605,933 Total Award Period Covered: 04/20/15-03/31/20
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Molecular Analysis of Serum Antibody Constituents in Zika Virus Infection
Source of Support: NIH/NIAID
Total Award Amount: $191,625 Total Award Period Covered: 02/01/18-1/31/20
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Ralph Baric	Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Determinants of Coronavirus Fidelity in Replication and Pathogenesis
Source of Support: NIH/NIAID
Total Award Amount: $532,971 Total Award Period Covered: 03/01/18-02/28/23
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Broad-spectrum antiviral GS-5734 to treat MERS-CoV and related emerging CoV
Source of Support: NIH
Total Award Amount: $919,427 Total Award Period Covered: 08/09/17-07/31/22
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ Transfer of Support
Project/Proposal Title:

Receptor recognition and cell entry of coronaviruses
Source of Support: NIH
Total Award Amount: $120,384 Total Award Period Covered: 06/07/16-05/31/21
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Molecular Basis of Dengue Virus Neutralization by Human Antibodies
Source of Support: NIH/NIAID
Total Award Amount $421,235 Total Award Period Covered: 08/05/13-08/31/23
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

The Development of Norovirus Immunity in Early Childhood and Implications for Norovirus Vaccines
Source of Support: NIH/NIAID
Total Award Amount: $157,100 Total Award Period Covered: 12/06/18-11/30/23
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Ralph Baric	Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Respiratory Virus Vaccine and Adjuvant Exploration

Source of Support: NIH/NIAID

Total Award Amount: $3,220,355 Total Award Period Covered: 03/01/19-02/29/24

Location of Project: UNC Chapel Hill

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Noam Ross

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

R01AI110964

Source of Support: NIAID

Total Award Amount: $3,086,735 Total Award Period Covered: 06/01/14 - 05/31/19

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: 1.0 Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Alice Latinne

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,7 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Alliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

R01AI110964

Source of Support: NIAID

Total Award Amount: $3,086,735 Total Award Period Covered: 06/01/14 - 05/31/19

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (7/95) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Hongying Li | Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:
Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID
Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024
Location of Project: EcoHealth Alliance and International Field and Lab Locations
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ~~☒ Current~~ ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:
Understanding the Risk of Bat Coronavirus Emergence
R01AI110964
Source of Support: NIAID
Total Award Amount: $3,086,735 Total Award Period Covered: 06/01/14 - 05/31/19
Location of Project: EcoHealth Alliance and International Field and Lab Locations
Person-Months Per Year Committed to the Project. ~~Cal:~~ (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Source of Support:
Total Award Amount: $ Total Award Period Covered:
Location of Project:
Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Source of Support:
Total Award Amount: $ Total Award Period Covered:
Location of Project:
Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Source of Support:
Total Award Amount: $ Total Award Period Covered:
Location of Project:
Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (7/95) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Leilani Francisco

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ ~~Pending~~ ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

CNH-L: Land-use change and microbial spillover as a coupled natural-human system

Source of Support: NSF CNH

Total Award Amount: $1,599,991 Total Award Period Covered: 07/1/2018-07/1/2021

Location of Project: EcoHealth Alliance, Uganda and Malaysia

Person-Months Per Year Committed to the Project. ~~Cal:~~ (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

PREDICT-2

Source of Support: USAID Emerging Pandemic Threats

Total Award Amount: $6,000,000 Total Award Period Covered: 10/1/2017 – 9/30/2018

Location of Project: EcoHealth Alliance, subcontract from UC Davis (prime)

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Alliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

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*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Amy Sims

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence
Source of Support: NIAID
Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024
Location of Project: EcoHealth Aliance and International Field and Lab Locations
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Mechanisms of MERS-CoV Entry, Cross-Species Transmission and Pathogenesis
Source of Support: NIH/NIAID
Total Award Amount: $605,933 Total Award Period Covered: 04/20/15 - 03/31/2020
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ Transfer of Support
Project/Proposal Title:

MERS-CoV Supplement for OMICs Proposal
Source of Support: NIH
Total Award Amount: $87,000 Total Award Period Covered ~~06/01/13-05/31/19~~
Location of Project: University of Wisconsin
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Antiviral Drug Discovery and Development Center
Source of Support: NIH/NIAID
Total Award Amount $2,250,000 Total Award Period Covered: 03/01/19-02/28/24
Location of Project: EcoHealth Alliance and International Field and Lab Locations
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Diagnostic and Prognostic Biomarkers for Viral Severe Lung Disease
Source of Support: NIH/NIAID
Total Award Amount: $889,074 Total Award Period Covered: 03/01/14-02/28/20
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Amy Sims	Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Mechanisms of MERS-CoV Entry, Cross-species Transmission and Pathogenesis
Source of Support: NIH/NIAID
Total Award Amount: $605,933 Total Award Period Covered: 04/20/15-03/31/20
Location of Project: EcoHealth Aliance and International Field and Lab Locations
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

Broad-spectrum antiviral GS-5734 to treat MERS-CoV and related emerging CoV
Source of Support: NIH
Total Award Amount: $919,427 Total Award Period Covered: 08/09/17 - 07/31/22
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ Transfer of Support
Project/Proposal Title:

How MERS-CoV Regulates Innate Immunity in Primary Human Lung Cells
Source of Support: NIH
Total Award Amount: $250,000 Total Award Period Covered 07/01/19-06/30/21
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support
Project/Proposal Title:

How MERS-CoV Regulates Innate Immunity in Primary Human Lung Cells
Source of Support: NIH
Total Award Amount $275,000 Total Award Period Covered: 03/01/19-02/28/24
Location of Project: UNC Chapel Hill
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Emily Hagan

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

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Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Guangjian Zhu

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

1R01AI110964

Source of Support: NIAID

Total Award Amount: $2,500,000 Total Award Period Covered: 06/01/~~2014~~ - 5/31/2019

Location of Project: EcoHealth Alliance

Person-Months Per Year Committed to the Project. ~~Cal:~~ (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: 0.0 Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (7/95) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Linfa Wang	Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:
Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ Transfer of Support

Project/Proposal Title:

Combating the next SARS-or MERS-like emerging infectious disease outbreak by active surveillance

Source of Support: National Research Foundation, Singapore

Total Award Amount: SGD$416,421 Total Award Period Covered: 01/01/2017 - 31/12/2019

Location of Project: Duke-NUS Medical School, Singapore

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Investigating Febrile Deaths in Tanzania (INDITE)

Source of Support: NIH

Total Award Amount: USD$464,645 Total Award Period Covered: 01/01/2016 - 31/12/2020

Location of Project: Duke-NUS Medical School, Singapore

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (10/99) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Lili Ren

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Key Project of Infectious Diseases

Etiology of respiratory tract infections and viral variations

Source of Support: Ministry of Science and Technology of China

Total Award Amount: $812,000 Total Award Period Covered: 01/01/2017 - 12/31/2020

Location of Project: China

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Key Project of Infectious Diseases

Techniques for pathogens indentification of respiratory tract infections

Source of Support: Ministry of Science and Technology of China

Total Award Amount: $222,300 Total Award Period Covered: 1/01/2018 - 12/31/2020

Location of Project: China

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (7/95) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Guo Li | Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Key technologies for the identification and identification of important respiratory viruses and establishment of reference libraries

Source of Support: Ministry of Science and Technology of China

Total Award Amount: $255,401 Total Award Period Covered: 01/01/2018 - 12/31/2020

Location of Project: China

Person-Months Per Year Committed to the Project. 6 Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (7/95) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Peng Zhou

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:
Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID
Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024
Location of Project: EcoHealth Aliance and International Field and Lab Locations
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:
Combating the next SARS- or MERS-like emerging infectious disease outbreak by improving active surveillance
Source of Support: National Natural Science Foundation of China
Total Award Amount: $ 358,210 Total Award Period Covered: 01/01/2017-12/31/2019
Location of Project: Wuhan Institute of Virology, CAS and Duke-NUS
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:
Interferon responses in SARS-Like Coronavirus infected Bat cells

Source of Support: National Basic Research program of China
Total Award Amount: $100,298 Total Award Period Covered: 01/01/2018-12/31/2022
Location of Project: Wuhan Institute of Virology, CAS
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:
Bat Virology

Source of Support: National Natural Science Foundation of China
Total Award Amount: $232,836 Total Award Period Covered: 01/01/2019-12/31/2021
Location of Project: Wuhan Institute of Virology
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:
Understanding the Risk of Bat Coronavirus Emergence
R01AI110964
Source of Support: NIAID
Total Award Amount: $3,086,735 Total Award Period Covered: 06/01/14 - 05/31/19
Location of Project: EcoHealth Aliance and International Field and Lab Locations
Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (7/95) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Ben Hu

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence this grant

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Pathogenicity studies of two novel bat SARSr-CoVs on transgenic mice expressing human ACE2

Source of Support: National Natural Science Foundation of China

Total Award Amount: $ 44,776 Total Award Period Covered: 01/01/2019-12/31/2021

Location of Project: Wuhan Institute of Virology, CAS

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

R01AI110964

Source of Support: NIAID

Total Award Amount: $3,086,735 Total Award Period Covered: ~~06/01/14 - 05/31/19~~

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Bat Virology

Source of Support: National Natural Science Foundation of China

Total Award Amount: $232,836 Total Award Period Covered: 01/01/2019-12/31/2021

Location of Project: Wuhan Institute of Virology, CAS

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

PREDICT-2

Source of Support: USAID

Total Award Amount: $38,000,000 Total Award Period Covered: 10/01/2014- 09/2019

Location of Project: EcoHealth Alliance, subcontract from UC Davis (prime)

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (7/95) USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator: Aleksei Chmura

Other agencies (including NSF) to which this proposal has been/will be submitted.

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

U.S.-China Collab: Spillover, co-infection and control of bat-origin livestock coranavirusese

Source of Support: NSF

Total Award Amount: $2,497,738 Total Award Period Covered: 07/01/2019 - 6/30/2024

Location of Project: US International Field and Laboratory Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☒ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

R01AI110964

Source of Support: NIAID

Total Award Amount: $3,086,735 Total Award Period Covered: ~~06/01/14 - 05/31/19~~

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☒ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Understanding the Risk of Bat Coronavirus Emergence

Source of Support: NIAID

Total Award Amount: $3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024

Location of Project: EcoHealth Alliance and International Field and Lab Locat

Person-Months Per Year Committed to the Project. Cal: (b) (4), (b) (6) Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support: ☐ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support

Project/Proposal Title:

Source of Support:

Total Award Amount: $ Total Award Period Covered:

Location of Project:

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

NSF Form 1239 (7/95) USE ADDITIONAL SHEETS AS NECESSARY

EcoHealth Alliance

06 May 2019

Tseday Girma
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E24
Rockville, MD 20852

Dear Tseday,

Please find below our responses to the requested Just-in-Time information requested in your email dated 30 April 2019 for our proposal (2R01AI110964) titled *Understanding the Risk of Bat Coronavirus Emergence* (PI, Daszak).

1) **Current Other Support:** Our AOR/SRO has uploaded the other current support information for all senior/key personnel on our proposal via the eRA Commons JIT page.

2) **IRB Approval Date:** Our current (1R01AI110964) NIAID human subject research IRB approvals from Hummingbird IRB and the Medical Ethics Review Board at the School of Health Sciences of Wuhan University are still valid until October 1, 2019. The human subject research study under our proposal (2R01AI110964) will be reviewed for approval by both US and Chinese IRBs through Hummingbird IRB (IORG0007741, IRB00009289, US) and the Medical Ethics Review Board of the Institute of Pathogen Biology of the Chinese Academy of Medical Sciences (FWA00016236, China). Our new human subject research protocol will be submitted to both IRBs by the deadline of 01 June 2019 with review and approvals expected no later than the Meeting and Approval Date of 31 July 2019. We will inform NIAID immediately upon confirmation and provide the date in eRA Commons.

3) **Dissemination Plan required for NIH-funded clinical trial:** No clinical trials are planned under our proposed work. We have human subjects and have provided both the Study Population Criteria and Protection & Monitoring Plan in our proposal.

4) **Documentation of the Required Education in the Protection of Human Subject Research Participants:** All key personnel involved with human subject research have passed the Collaborative Institutional Training Initiative (CITI) Program Human Subjects Research Course. All details have been uploaded via the eRA Commons JIT page.

5) **IACUC:** Our current (1R01AI110964) NIAID protocol IACUC approval is from Tufts University (#G2017-32) through our inter-institutional agreement with them and this expires on 29 February 2020. The OLAW Assurance number listed in eRA Commons (**A4059-01)** is correct. We will submit our amended protocol for IACUC review by the pre-review deadline of 15th May 2019. The Tufts IACUC Meeting and Approval Date will be on 5th June 2019, we will inform NIAID immediately upon confirmation and provide the date in eRA Commons.

6) **Other**:

   a. EcoHealth Alliance's EIN number is 31-1726494
   b. The latest F&A rate agreement for the University of North Carolina Chapel Hill dated 23 November 2016 with a rate of 55% is attached
   c. EcoHealth Alliance's latest F&A rate agreement dated 14 November 2018 with a rate of 32.74% is attached

If you have any other questions, please contact me anytime. We are very appreciative of your consideration and look forward to further details.

Yours sincerely,

Dr. Peter Daszak
EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001, USA
(b) (6)
(b) (6)

COLLEGES AND UNIVERSITIES RATE AGREEMENT

EIN: 566001393A1

DATE:11/23/2016

ORGANIZATION:

University of North Carolina at Chapel Hill

2114 Administrative Office Building
CB # 1350
Chapel Hill, NC 27599-1350

FILING REF.: The preceding agreement was dated 05/16/2012

The rates approved in this agreement are for use on grants, contracts and other agreements with the Federal Government, subject to the conditions in Section III.

SECTION I: Facilities And Administrative Cost Rates

RATE TYPES: FIXED FINAL PROV. (PROVISIONAL) PRED. (PREDETERMINED)

	EFFECTIVE PERIOD				
TYPE	**FROM**	**TO**	**RATE(%)**	**LOCATION**	**APPLICABLE TO**
PRED.	07/01/2016	06/30/2017	52.00	On-Campus	Organized Research
PRED.	07/01/2017	06/30/2020	55.50	On-Campus	Organized Research
PRED.	07/01/2016	06/30/2020	28.00	Off-Campus (A)	Organized Research
PRED.	07/01/2016	06/30/2020	26.00	Off-Campus (B)	Organized Research
PRED.	07/01/2016	06/30/2020	50.00	On-Campus	Instruction
PRED.	07/01/2016	06/30/2020	28.00	Off-Campus (A)	Instruction
PRED.	07/01/2016	06/30/2020	26.00	Off-Campus (B)	Instruction
PRED.	07/01/2016	06/30/2020	36.00	On-Campus	Other Sponsored Activities
PRED.	07/01/2016	06/30/2020	28.00	Off-Campus (A)	Other Sponsored Activities
PRED.	07/01/2016	06/30/2020	26.00	Off-Campus (B)	Other Sponsored Activities

TYPE	FROM	TO	RATE(%)	LOCATION	APPLICABLE TO
PROV.	07/01/2020	Until Amended			Use same rates and conditions as those cited for fiscal year ending June 30, 2020.

(A) Off-Campus, Adjacent -- Activites performed within the commuting area of Chapel Hill, N.C.
(B) Off-Campus, Remote -- Activities performed outside the commuting area of Chapel Hill, N.C.

*BASE

Modified total direct costs, consisting of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.

SECTION II: SPECIAL REMARKS

TREATMENT OF FRINGE BENEFITS:

The fringe benefits are specifically identified to each employee and are charged individually as direct costs. The directly claimed fringe benefits are listed below.

TREATMENT OF PAID ABSENCES

Vacation, holiday, sick leave pay and other paid absences are included in salaries and wages and are claimed on grants, contracts and other agreements as part of the normal cost for salaries and wages. Separate claims are not made for the cost of these paid absences.

OFF-CAMPUS DEFINITION: For all activities performed in facilities not owned by the institution or to which rent is directly allocated to the project(s) the off-campus rate will apply. Grants or contracts will not be subject to more than one F&A cost rate. If more than 50% of a project is performed off-campus, the off-campus rate will apply to the entire project.

Treatment of Transit Service and Network Infrastructure:
These costs are based on an annual fixed fee assessed on salaries and wages identified to each employee. Costs are subject to the same principles and definitions described in Sections II and III of this agreement.

Fringe Benefits include: Pension/Retirement, FICA/Medicare, Workers' Compensation, Unemployment Insurance, Health Insurance, Short-Term Disability, and State Severance Pay Plan.

Supplemental Fringe Benefits for members of the Physicians and Associates Practice Plan include: Supplemental Health Insurance, Dental Insurance, Supplemental Retirement, Group Life Insurance, Long-Term Disability, Accidental Death & Dismemberment, and Vision.

Equipment means an article of nonexpendable tangible personal property having a useful life of more than one year, and an acquisition cost of $5,000 or more per unit.

SECTION III: GENERAL

A. LIMITATIONS:

The rates in this Agreement are subject to any statutory or administrative limitations and apply to a given grant, contract or other agreement only to the extent that funds are available. Acceptance of the rates is subject to the following conditions: (1) Only costs incurred by the organization were included in its facilities and administrative cost pools as finally accepted: such costs are legal obligations of the organization and are allowable under the governing cost principles; (2) The same costs that have been treated as facilities and administrative costs are not claimed as direct costs; (3) Similar types of costs have been accorded consistent accounting treatment; and (4) The information provided by the organization which was used to establish the rates is not later found to be materially incomplete or inaccurate by the Federal Government. In such situations the rate(s) would be subject to renegotiation at the discretion of the Federal Government.

B. ACCOUNTING CHANGES:

This Agreement is based on the accounting system purported by the organization to be in effect during the Agreement period. Changes to the method of accounting for costs which affect the amount of reimbursement resulting from the use of this Agreement require prior approval of the authorized representative of the cognizant agency. Such changes include, but are not limited to, changes in the charging of a particular type of cost from facilities and administrative to direct. Failure to obtain approval may result in cost disallowances.

C. FIXED RATES:

If a fixed rate is in this Agreement, it is based on an estimate of the costs for the period covered by the rate. When the actual costs for this period are determined, an adjustment will be made to a rate of a future year(s) to compensate for the difference between the costs used to establish the fixed rate and actual costs.

D. USE BY OTHER FEDERAL AGENCIES:

The rates in this Agreement were approved in accordance with the authority in Title 2 of the Code of Federal Regulations, Part 200 (2 CFR 200), and should be applied to grants, contracts and other agreements covered by 2 CFR 200, subject to any limitations in A above. The organization may provide copies of the Agreement to other Federal Agencies to give them early notification of the Agreement.

E. OTHER:

If any Federal contract, grant or other agreement is reimbursing facilities and administrative costs by a means other than the approved rate(s) in this Agreement, the organization should (1) credit such costs to the affected programs, and (2) apply the approved rate(s) to the appropriate base to identify the proper amount of facilities and administrative costs allocable to these programs.

BY THE INSTITUTION:

University of North Carolina at Chapel Hill

(INSTITUTION)

(b) (6)

(SIGNATURE)

(b) (6)

(NAME)

(b) (6)

(TITLE)

1/4/17

(DATE)

ON BEHALF OF THE FEDERAL GOVERNMENT:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

(AGENCY)

Darryl W. Mayes - A

Digitally signed by Darryl W. Mayes -A
DN: c=US, o=U.S. Government, ou=HHS, ou=PSC, ou=People, 0.9.2342.19200300.100.1.1=2000131869, cn=Darryl W. Mayes -A
Date: 2016.12.20 21:12:34 -05'00'

(SIGNATURE)

Darryl W. Mayes

(NAME)

Deputy Director, Cost Allocation Services

(TITLE)

11/23/2016

(DATE) 0309

HHS REPRESENTATIVE: Steven Zuraf

Telephone: (b) (6)

DEPARTMENT OF THE NAVY
OFFICE OF NAVAL RESEARCH
875 NORTH RANDOLPH STREET
SUITE 1425
ARLINGTON, VA 22203-1995

IN REPLY REFER TO:

Agreement Date: November 14, 2018
[Supersedes Agreement Dated: June 30, 2016]

NEGOTIATION AGREEMENT

INSTITUTION: **ECOHEALTH ALLIANCE, INC.**
460 WEST 34TH ST. 17TH FLR
NEW YORK, NY 10001-2320

The Indirect Cost and Fringe Benefits rates contained herein are for use on grants, contracts and other agreements with all Federal Agencies of the United States of America, in accordance with the provisions and cost principles mandated by 2 CFR Part 200. These rates shall be used for final billing purposes for EcoHealth Alliance, Inc. for Fiscal Year 2017. This rate agreement supersedes all previous rate agreements/determinations for Fiscal Year 2017.

Section I: RATES - TYPE: FINAL (FINAL)

Indirect Rates:

TYPE	FROM	TO	RATE	BASE	APPLICABLE TO	LOCATION
FINAL	07/01/16	06/30/17	(b) (4)	(a)	All	All

Fringe Benefits Rates:

TYPE	FROM	TO	RATE	BASE	APPLICABLE TO	LOCATION
FINAL	07/01/16	06/30/17	(b) (4)	(b)	All	All

DISTRIBUTION BASES

(a) Modified Total Direct Costs (MTDC) means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

(b) Total Salaries and Wages less Donated Services.

SECTION II - GENERAL TERMS AND CONDITIONS

A. **LIMITATIONS:** Use of the rates set forth under Section I is subject to any statutory or administrative limitations and is applicable to a given grant, contract, or other agreement only to the extent that funds are available. Acceptance of the rates agreed to herein is predicated upon the following conditions: (1) that no costs other than those incurred by the recipient/contractor were included in this indirect cost pool as finally accepted and that such costs are legal obligations of the recipient/contractor and allowable under governing cost principles; (2) that the same costs that have

been treated as indirect costs are not claimed as direct costs; (3) that similar types of costs have been accorded consistent accounting treatment; and (4) that the information provided by the recipient/contractor which was used as a basis for acceptance of the rates agreed to herein, and expressly relied upon by the Government in negotiating and accepting the said rates is not subsequently found to be materially incomplete or inaccurate.

B. **ACCOUNTING CHANGES**: The rates contained in Section I of this agreement are based on the accounting system in effect at the time the agreement was negotiated. Changes to the method(s) of accounting for costs, which affect the amount of reimbursement resulting from the use of these rates require the prior approval of the authorized representative of the cognizant negotiation agency. Such changes include but are not limited to changes in the charging of a particular type of cost from indirect to direct. Failure to obtain such approval may result in subsequent cost disallowances.

C. **USE BY OTHER FEDERAL AGENCIES**: The rates set forth in Section I are negotiated in accordance with and under the authority set forth in 2 CFR Part 200. Accordingly, such rates shall be applied to the extent provided in such regulations to grants, contracts, and other agreements to which 2 CFR Part 200 applies, subject to any limitations in part A of this section. Copies of this document may be provided by either party to other federal agencies to provide such agencies with documentary notice of this agreement and its terms and conditions.

D. **SPECIAL REMARKS**: The Government's agreement with the rates set forth in Section I is not an acceptance of the EcoHealth Alliance, Inc.'s accounting practices or methodologies. Any reliance by the Government on cost data or methodologies submitted by EcoHealth Alliance, Inc. is on a non-precedence-setting basis and does not imply Government acceptance.

Accepted:

FOR ECOHEALTH ALLIANCE, INC.:

(b) (6)

ARMINE ARUSTAMYAN
Chief Financial Officer

11-15-2018
Date

FOR THE U.S. GOVERNMENT:

KERSEY.SHEA.DELORES.1049331149

Digitally signed by KERSEY.SHEA.DELORES.1049331149
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USN, cn=KERSEY.SHEA.DELORES.1049331149
Date: 2018.11.21 12:27:47 -05'00'

SHEA D. KERSEY
Contracting Officer

November 21, 2018
Date

For information concerning this agreement contact:
Shea Kersey
Office of Naval Research

Phone: (b) (6)
E-mail: (b) (6)

2R01AI110964 - Understanding the Risk of Bat Coronavirus Emergence (PI, Daszak)

6 May 2019

Dear NIAID Just-in-Time,

Please find details on the Collaborative Institutional Training Initiative (CITI) Program Human Subjects Research Training for *all* individuals designated in our application who will be involved in human subject research. These individuals are as follows (below). The order is kept identical to that in our proposal. *All* individuals have taken and passed the following courses on the dates (below):

- Social and Behavioral Research Best Practices for Clinical Research
- Social and Behavioral Responsible Conduct of Research
- Biomedical Researchers and staff
- Public Health Researchers
- Social-Behavioral-Education Researchers

CITI Program URL: https://www.citiprogram.org

If additional details and certificates are required, please contact me anytime.

Sincerely,

(b) (6)

Peter Daszak
President, EcoHealth Alliance
460 West 34th Street – Ste. 1701
New York, NY 10001

Last	First	Role	Training	Date of Training
Daszak	Peter	PD/PI	Collaborative Institutional Training initiative (CITI)	30-Jan-19
Shi	Zhengli	Co-Investigator	Collaborative Institutional Training initiative (CITI)	3-May-19
Olival	Kevin	Co-Investigator	Collaborative Institutional Training initiative (CITI)	18-Jan-16
Ross	Noam	Co-Investigator	Collaborative Institutional Training initiative (CITI)	29-Jan-19
Latinne	Alice	Co-Investigator	Collaborative Institutional Training initiative (CITI)	22-Jan-19
Li	Hongying	Co-Investigator	Collaborative Institutional Training initiative (CITI)	20-Dec-18
Francisco	Leilani	Co-Investigator	Collaborative Institutional Training initiative (CITI)	28-Feb-17
Hagan	Emily	Co-Investigator	Collaborative Institutional Training initiative (CITI)	9-May-17
Zhu	Guangjian	Co-Investigator	Collaborative Institutional Training initiative (CITI)	3-May-19
Ren	Lili	Co-Investigator	Collaborative Institutional Training initiative (CITI)	2-May-19
Li	Guo	Co-Investigator	Collaborative Institutional Training initiative (CITI)	2-May-19
Chmura	Aleksei	Co-Investigator	Collaborative Institutional Training initiative (CITI)	25-Jan-19

From: Girma, Tseday (NIH/NIAID) [E]
To: Aleksei Chmura
Cc: Peter Daszak; 李泓萤; Alison Andre
Subject: RE: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER
Date: Thursday, May 2, 2019 2:02:00 PM

Good afternoon,

Thank you for your email. Please see my responses to your questions below:

- IRB review of the research protocol is required prior to award, please submit the approval date with the JIT.
- Regarding the IACUC approval, the Grants Policy statement says "It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC." http://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm#Animal Please provide the IACUC approval date with the JIT – which **confirms** that the research described in the application is congruent with any corresponding protocols approved by the IACUC.
- If you are not conducting clinical trials, just respond in the JIT stating the same. You don't need to extract the section from the application.

If you are unable to provide the IRB and IACUC approval dates as described above by the JIT submission deadline, please let me know when you will be to submit it.

Hope this answers your questions.

Thanks,
Tseday

From: Aleksei Chmura (b) (6)
Sent: Thursday, May 2, 2019 9:11 AM
To: Girma, Tseday (NIH/NIAID) [E] (b) (6)
Cc: Peter Daszak (b) (6); 李泓萤 (b) (6); Alison Andre (b) (6)
Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Dear Tseday,

I confirm receipt of your email on behalf of the PI Dr. Peter Daszak. We will get these items or information submitted via eRA Commons by the 6th.

A two quick questions in advance:

- We have not yet IACUC nor IRB review and approval of our proposed protocols. If we receive notification of award, then we would be ready to rapidly submit these for review for the next cycle of each committee. Is this (dates and institution names) all that we would be required to provide presently for the JIT?

- We will not conduct clinical trials, but we have human subjects. We have provided both the Study Population Criteria and Protection & Monitoring Plan in our proposal. Should we extract these to include for JIT and state that we are not conducting clinical trials?

Many thanks!

-Aleksei

Aleksei Chmura, PhD
Chief of Staff

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

(b) (6) (office)
(mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

From: Girma, Tseday (NIH/NIAID) [E] (b) (6)
Sent: Tuesday, April 30, 2019 11:00 AM
To: Peter Daszak; Peter Daszak
Cc: Stemmy, Erik (NIH/NIAID) [E]
Subject: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

<image002.jpg>

April 30, 2019

GRANT NUMBER - 2R01AI110964 - 06 PI Name: DASZAK, PETER

The above referenced application is being considered for funding by the National Institute of Allergy and Infectious Diseases. Please note that this request is not a guarantee of funding. Official notification of funding is only made by issuance of a Notice of Award (NoA).

The following Just-In-Time information (JIT) identified is requested:

___X___ 1) Current Other Support - Provide active and pending support information for ALL individuals designated in an application as key personnel.
*There is no form page for providing other support, although a sample format page is available at*https://grants.nih.gov/grants/forms/othersupport.htm

___X___ 2) IRB approval date *(NIH does not require a copy of the IRB certification/approval).* See NOT-OD-19-055. Pending or out-of-date approvals are not acceptable. **If IRB has not met, provide anticipated meeting date.** *Information regarding the Federal Wide Assurance website:* http://grants.nih.gov/grants/policy/hs/faqs_aps_assurances.htm

___X___ 3) Dissemination Plan required for NIH-funded clinical trial that addresses how the expectations of NOT-OD-16-149will be met. Additional guidance at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.7

___X___ *4)* Documentation of the required education in the Protection of Human Subject Research Participants for all key personnel involved in HS research.

___X___ 5) IACUC approval date *(NIH does not require a copy of the IACUC certification/approval).* Pending or out-of-date approvals are not acceptable.
If IACUC has not met, provide anticipated meeting date.

Information regarding IACUCs can be found at http://grants.nih.gov/grants/olaw/faqs.htm

___X___ 6) Other

i. Confirm institution's Entity Identification Number (EIN) is 1311726494A1.

ii. Confirm the latest F&A agreement for University of North Carolina Chapel Hill is dated 11/23/2016 and the F&A rate is 55.5%. **If this is not correct, send a copy of your latest F&A rate agreement with your JIT response.**

iii. Submit your latest F&A Agreement for ECOHEALTH ALLIANCE, INC

The requested Just In Time (JIT) information must be submitted via eRA Commons (NIH Guide Notice NOT-OD-12-101) by Monday, May 6th, 2019. If unable to submit the requested information through eRA Commons, please contact your Grants Management Specialist. Timely submission of the above information will enable us to expedite the issuance of an award should the application be identified for funding.

Sincerely,

Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E24
Rockville, MD 20852
Phone: (b) (6)
Email: (b) (6)
NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

From: Aleksei Chmura
To: Graham, Adam (NIH/NIAID) [E]
Subject: Fwd: Grant Number: 5R01AI110964 - 05 PI Name: DASZAK, PETER
Date: Thursday, June 14, 2018 11:15:57 PM
Importance: High

Dear Adam,

I am resending the email, below. Apologies if it did not go through earlier for any reason. Please confirm receipt. If I do not hear back from you, I will try calling you tomorrow (Friday) morning.

Cheers!

-Aleksei

Begin forwarded message:

From: Aleksei Chmura [redacted (b) (6)]
Subject: Re: Grant Number: 5R01AI110964 - 05 PI Name: DASZAK, PETER
Date: June 13, 2018 at 22:45:47 GMT+8
To: "Graham, Adam (NIH/NIAID) [E]" [redacted (b) (6)]
Cc: "Dr. Peter Daszak" [redacted (b) (6)], "Stemmy, Erik (NIH/NIAID) [E]" [redacted (b) (6)]

Adam,

Thanks again for your help with this! Please find the details with updates as per section G9, below.

As per last year, we will not be subcontracting any funds to the intuitions in these countries. All efforts expended in these countries will be from collaborating partners and not funded by our award. PI, Co-Investigators or other team members may conduct short field trips to assess markets, identify wildlife in them, and arrange for shipment of samples of bats and other high-risk host species in countries that neighbor China (Burma, Vietnam, Cambodia, Laos) and that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia).

If you need any additional information, email, text, or call me anytime [redacted (b) (6)] and I will provide it as rapidly as possible.

Cheers,

-Aleksei

Organisation Name: San Pya Clinic
Country: BURMA
Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: Institut Pasteur du Cambodge
Country: CAMBODIA
Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: Primate Research Center at Bogor Agricultural University
Country: INDONESIA
Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: Conservation Medicine, Ltd.
Country: MALAYSIA
Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: King Chulalongkorn Memorial Hospital
Country: THAILAND
Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: Hanoi Agricultural University
Country: VIETNAM
Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: National Animal Health Laboratory
Country: LAOS
Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

From: Aleksei Chmura
To: Normil, Carine (NIH/NIAID) [C]
Cc: Stemmy, Erik (NIH/NIAID) [E]; Dr. Peter Daszak; Smith, Philip (NIH/NIAID) [E]; Alison Andre
Subject: Re: Publication compliance for Grant Number: 5R01AI110964 - 04 PI Name: DASZAK, PETER
Date: Wednesday, May 31, 2017 10:59:35 AM
Attachments: bib.pdf
Importance: High

Dear Carine,

Please find the attached documentation of this publication being in compliance with NIH Public Access Policy.

Many thanks most,

Sincerely,

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

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On 23 May 2017, at 13:12, Normil, Carine (NIH/NIAID) [C] (b) (6) wrote:

Good afternoon:

Your progress report for the above referenced award has a non-compliant publication. Please take the necessary steps to bring (b) (4)
(b) (4)
(b) (4) into compliance with the NIH Public Access Policy.

To comply with the policy, please reply to this email and provide a PDF generated report from My NCBI that includes evidence of compliance (PMCID number) for this

publication. If you believe the above referenced publication does not fall under the Public Access Policy, please provide a brief explanation. A response is appreciated by **June 15, 2017**.

If you have questions about the Policy, feel free to contact me via email at (b) (6) or send a note to PublicAccess@nih.gov.

Best regards,
Carine

Carine Normil

Grants Management Specialist (Contractor)

Grants Management Program, DEA, NIAID, NIH, HHS
5601 fishers Lane, Rm 4G46, Bethesda , Maryland 20892

Phone: (b) (6)

Fax: (301)-493-0597
Email: (b) (6)

Publications Reported for this Reporting Period

NIH Public Access Compliance	Citation
Complete	(b) (4)

From: Normil, Carine (NIH/NIAID) [C]
To: Smith, Philip (NIH/NIAID) [E]
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Tuesday, May 23, 2017 12:24:00 PM

Thank you Philip! I will add Laos to the foreign consortium term.

Best,
Carine

Carine Normil

Grants Management Specialist (Contractor)

Grants Management Program, DEA, NIAID, NIH, HHS
5601 fishers Lane, Rm 4G46, Bethesda , Maryland 20892

Phone: (b) (6)

Fax: (301)-493-0597
Email: (b) (6)

National Institute of Allergy and Infectious Diseases

From: Smith, Philip (NIH/NIAID) [E]
Sent: Tuesday, May 23, 2017 11:38 AM
To: Normil, Carine (NIH/NIAID) [C] (b) (6)
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Yes, this site was approved. I forgot to add it to the NoA issued on 5/5/2017 adding new foreign sites. You can just add it to the year 4 NoA and I don't think year 3 needs to be revised since it is basically over.

Philip Smith
☎: (b) (6)
✉: (b) (6)

From: Normil, Carine (NIH/NIAID) [C]
Sent: Tuesday, May 23, 2017 11:09 AM
To: Smith, Philip (NIH/NIAID) [E] (b) (6)
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Philip,

I have completed my review of this grant, but I noticed the National Animal Health Laboratory in

Laos was not included in year three's Notice of Award. Was this site approved for this award?

Thanks,
Carine

Carine Normil

Grants Management Specialist (Contractor)

Grants Management Program, DEA, NIAID, NIH, HHS
5601 fishers Lane, Rm 4G46, Bethesda , Maryland 20892

Phone: (b) (6)

Fax: (301)-493-0597
Email: (b) (6)

National Institute of Allergy and Infectious Diseases

From: Smith, Philip (NIH/NIAID) [E]
Sent: Friday, May 05, 2017 1:58 PM
To: Normil, Carine (NIH/NIAID) [C] (b) (6)
Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

FYI

Just added new sites to this one on year 3 file. You are assigned to yr-04, so you won't see them on the RPPR since it is after the submission.

Thanks,

Philip Smith
Grants Management Specialist
Grants Management Program, DEA, NIAID, NIH
5601 Fishers Lane, Rm 4E48, MSC 9833 GMP
Rockville, Maryland 20892-9824
☎: (b) (6)
✉: (b) (6)

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

From: Aleksei MacDurian
To: Smith, Philip (NIH/NIAID) [E]
Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Wednesday, May 03, 2017 4:10:18 PM

Dear Philip,

Sincere apologies for my tardy reply. I was out-of-office the past two days unexpectedly and am just catching up with emails.

There are no planned in-country costs associated with these foreign sites. All testing costs will be at the Wuhan Institute of Virology in China - our current, approved partner under our award.

Many thanks!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

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On Fri, Apr 28, 2017 at 5:29 PM, Smith, Philip (NIH/NIAID) [E] (b) (6) wrote:

> Hi Aleksei,
>
> Can you provide the direct and indirect costs for the foreign sites we are adding (Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Thailand, Vietnam)? Once this is received we can issue a revised NOA approving these sites.
>
> Thanks,

Philip Smith

Grants Management Specialist

Grants Management Program, DEA, NIAID, NIH

5601 Fishers Lane, Rm 4E48, MSC 9833 GMP

Rockville, Maryland 20892-9824

☎: (b) (6)

✉: (b) (6)

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From: Thakur, Neil (NIH/OD) [E]
To: EPMC Principals
Subject: Fwd: NIH Manuscript Submission (NIHMS) Technical Issues
Date: Thursday, March 02, 2017 1:30:55 PM

Hi folks. Please see the note about Public Access compliance to GMAC. No action from you should be required, although it might be good to share with your program staff.
Neil

Sent from my iPhone

Begin forwarded message:

From: "Ashe, Samuel (NIH/OD) [E]" (b) (6)
Date: March 2, 2017 at 1:22:39 PM EST
To: GMAC Principals (b) (6)
Cc: "Thakur, Neil (NIH/OD) [E]" (b) (6)
Subject: NIH Manuscript Submission (NIHMS) Technical Issues

GMAC Principles -

The NIH Manuscript Submission (NIHMS) system is used to convert awardee papers to the PubMed Central format, and is necessary to bring most NIH awards into compliance with the public access policy. The NIHMS is experiencing technical issues, and is not able to process papers. Therefore, some awardees will not be able to bring their awards into compliance with the public access policy. We are not sure when we will be able to bring the NIHMS back online. To address this situation:

- Staff should continue to fill out the program check list for public access questions as they normally do.
- Until further notice, please do not delay processing of RPPRs for public access compliance. We are effectively suspending the compliance approach outlined in NOT-OD-12-160 until this situation is resolved.
- Please place a copy of this letter in the grant folder of any RPPR that you fund that has a public access compliance issue.

We will let you know when the NIHMS is operational again and we can resume our normal procedures.

To minimize confusion for our awardees, we do not plan to make a broad announcement. Please forward any staff or awardee questions to the public access helpdesk at publicaccess@nih.gov.

Regards,

Sam

Samuel Ashe
Director, Division of Grants Policy
Office of Policy for Extramural Research Administration, OER
National Institutes of Health, HHS
6705 Rockledge Drive, Suite 350/MSC 7974
Bethesda, MD 20892-7974
Phone: (b) (6)
Fax: (301) 435-3059
Email: (b) (6)

From: Aleksei Chmura
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Greer, Jenny (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER
Date: Friday, February 17, 2017 10:19:33 PM
Attachments: NIH-NIAID_5R01AI110964 Additional Site Q and A.pdf

---

Dear Erik,

Please find our responses in the attached PDF. If you need any additional details, please let me know.

Many thanks!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

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On Feb 15, 2017, at 08:52, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,
I know you said nothing will be changing from your currently approved animal studies, but it would be helpful for me in preparing the foreign clearance request if you could write a few concise sentences about the new animal work addressing the following points:

- Kind or species of animal and number to be used
- Location of the source of the animals, if known
- A brief description of the sampling (blood draw, swab, etc)
- Location from where the animals will be obtained (source)
- If possible, what will be done with the animals after the project ends (e.g., euthanized)

Let me know if you have any questions.
Thanks!
Erik

From: Aleksei Chmura (b) (6)
Sent: Monday, February 13, 2017 4:23 PM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Cc: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Smith, Philip (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Super! Thanks, Jenny.

Erik and Philip - please let me know, if you have any questions or require additional details. We look forward to your responses.

Sincerely,

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

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> On Feb 13, 2017, at 16:18, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:
>
> Aleksei,
>
> Thank you for your email. I am copying Erik on this response so he can make sure he has everything needed to initiate a request for each of these foreign sites. I am also copying Philip Smith, the grants management specialist assigned to this grant for this fiscal year. Please don't hesitate to contact either of them with any questions you may have.

Please note that this response does not constitute approval and it will take at least 3 weeks for a final determination to be made.

Thanks again! And have a great afternoon!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

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From: Aleksei Chmura (b) (6)
Sent: Friday, February 10, 2017 2:54 PM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Dear Jenny,

I am just following up with item 1 and 1a from your email below. As per Peter's email (also below), we would like to request prior approval for collecting non-human animal samples in 7 countries: Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam.

No new animals will be introduced nor any new field procedures, we have submitted IACUC protocol modification - for geographic locations only - and will provide approval dates as soon as they are available.

No work will be conducted until we have your approval and IACUC approval.

Testing would be conducted locally and if any samples were to be transferred to China these would be only extracted viral DNA - and not the original sample material.

Samples will be collected by either our current China field team personnel working directly with our collaborators in these countries or by respective in-country personnel and require no more than 10% budget modification total (from already budgeted China fieldwork) for any non-China in-country work.

Here is the list of our local in-country contacts and institutions:

Cambodia
Veasna Duong
Institut Pasteur du Cambodge
No. 5 Monivong Boulevard
P.O Box. 983, Phnom Penh, Cambodia
(b) (6)

Indonesia
Joko Pamungkas
Primate Research Center at Bogor Agricultural University
JalanLodayaII/5,Bogor16151, Indonesia
(b) (6)

Lao People's Democratic Republic
Watthana Theppangna
National Animal Health Laboratory
Department of Livestock and Fisheries
Ministry of Agriculture and Forestry, Vientiane, Lao PDR
(b) (6)

Malaysia
Tom J. Hughes
Conservation Medicine, Ltd.
Suite 4A, Level 4, Main Office Tower
Financial Park Complex, Jalan Merdeka, 87000
Federal Territory of Labuan, Malaysia
(b) (6)

Myanmar
Aung Than Toe
San Pya Clinic

20/256, Insein Road
Yangon 11051, Myanmar
(b) (6)

Thailand
Supaporn Wacharapluesadee
Neuroscience Center for Research and Development
King Chulalongkorn Memorial Hospital
Rama 4 Road
Patumwan, Bangkok, Thailand 10330
(b) (6)

Vietnam
Nguyen Huu Nam
Faculty of Animal and Veterinary Science
Hanoi Agricultural University
Trauquy, Gialâm, Hanoi, Vietnam
(b) (6)

If it will be easier to have a quick chat about this, I am happy to call anytime. Also, if this request should be sent more formally as a letter attachment, we can do that rapidly as well.

I hope you and yours had a lovely Holiday and are surviving the blizzard!

Cheers,

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

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On Aug 1, 2016, at 12:39, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Thank you for your email. To answer your questions:

1. To do any work in countries other than China, you will need to request prior approval from NIH. To do so, submit a formal request, including the names, institutions, and full contact information of any institutions with which you will collaborate for such activities. Be sure to indicate whether animal or human research will be conducted and what funds, if any, will be going into these countries. The approval process for new foreign sites takes at least 3 weeks.

1a . If you are introducing new animals into the project, then there may be additional requirements from the Office of Laboratory Animal Welfare (OLAW). Again, you would need to submit a formal request, providing a scientific justification for the inclusion of new species on the project, and, if appropriate, a new Vertebrate Animal Section. If additional IACUC approvals are required, you will need to provide us with the IACUC approval dates (but **not** a copy of the actual approval).

2. These individuals are not listed in the Notice of Award as key personnel, so, from a grants management perspective, you do not need to get prior approval for this change. That said, if this change or other such personnel changes would have a significant impact on the scope of the project or the science itself, you would need to at least run it by your Program Officer. And if it is determined that personnel changes would cause a scope change, then you would need grants management approval as well.
3. I do not know what you are asking here. It looks like we have approved both the Wuhan University and ECNU for work on this project. Therefore, no additional prior approval is required for changes unless otherwise specified in the NIH Grants Policy Statement (eg, a change of scope).

Please don't hesitate to contact me with any additional questions. I will be available until 2:30 eastern and then again on Wednesday.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

From: Aleksei MacDurian
(b) (6)
Sent: Sunday, July 31, 2016 6:06 AM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Dear Jenny,

Since you were not cc'ed on the original email, I wanted to follow up with you on three things from Dr. Daszak's email to Erik (included below):

1) Do we need to formally request permission to sample species of bats and other high-risk [rodents and carnivore] hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). Under this award our current US and China IACUC approved protocol via Tufts University and Wuhan Institute of Virology permits us to sample these species in these regions.

2) We provided Dr. Noam Ross' CV with our Year 2 Report. Dr. Ross has replaced Dr. Hosseini who is no longer working on this project. Do we need to do anything else for this? I have attached his Biosketch here for reference.

3) Our Human surveillance work and local IRB approval have all been through the Wuhan University School of Public Health (WUSPH) in China (DUNS No. 529049295). We would like now - in Years 3 - 5 of our award to subcontract directly with them rather than with the institution on our current budget: East China Normal University (ECNU) School of Life Sciences. The Wuhan University School of Public Health budget amount would be the same annual amount as currently budgeted for East China Normal University in these same years.

It may be easier to briefly chat about these questions via telephone. If so, you may reach me (b) (6) anytime.

Many thanks!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
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(b) (6) direct)
mobile)
Aleksei MacDurian (Skype)

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EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

On Fri, May 13, 2016 at 5:55 PM, Peter Daszak (b) (6) wrote:

> Dear Erik,
>
> I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as a pdf).
>
> It's been a pretty productive year, and some of the highlights include: collecting samples from 15 bat genera in southern China with 280 (12%) testing positive for coronaviruses; SARS-like coronaviruses being detected in*Rhinolophus* spp. bats in both Yunnan and Guangdong provinces; 7 published papers from work under our award

(including one in *J. Virol.* and one in press at *J. Virol*); 218 quantitative interviews with samples and 47 qualitative coded interviews conducted transcribed and translated.

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to (b) (6) earlier this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance

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EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

1. **Kind or species of animal and number to be used:**

Species taxa	Family, Genus or Species Name	Target numbers
Fruit bats	*e.g.: Cynopterus, Rousettus, Eonycterus spp.*	900 individuals (30 individuals from 30 different species)
Insectivorous bats	*e.g.: Rhinilophidae, Hipposideridae, Emballonuridae, Vespertillionidae, Mollsidae, Miniopteridae spp.*	
Rodents	e.g: Chinese bamboo rat (*Rhizomys sinensis*), Malayan porcupine (*Hystrix brachyura*), bandicoot (*Bandicota indica*)	900 individuals
Small Carnivores	e.g.: Raccoon dog (*Nyctereutes procyonoides*), Asian Palm civet (*Paradoxurus hemaphroditus*), ferret badger (*Melogale moschata*)	500 individuals

2. **Location of the source of the animals, if known:**

Free-ranging bat surveys and bats in wet markets: China, Malaysia, Thailand, Cambodia, Lao PDR, Myanmar, Vietnam, and Indonesia.

Other mammals: We will opportunistically sample the other aforementioned taxa that are also sold in live animal markets, trading locations or bred on farms to supply markets throughout southeast Asia. Species and numbers of animals sampled from markets will be based on animal availability.

3. **A brief description of the sampling (blood draw, swab, etc)**

Bat capture. Free-ranging bats will be captured using either a mist net or harp trap and bats are removed from the net as soon as they become entangled to minimize stress and prevent injury. Bats will be manually restrained during sampling. Bats that are fractious may be anesthetized for restraint purposes in order to maximize safety for the bat and handler. Depending on the species and size of bat, swabs will be taken from the oropharynx, urogenital tract, and rectum. Fresh feces will be collected if available, in which case a rectal swab will not be collected. Blood will be collected from either from the cephalic vein or from the radial artery or vein using a 25-gauge needle. Bats are held for a maximum of six hours and then released following sample collection. We will euthanize 2 individuals per bat species for organ tissue banking.

Wild and captive bred rodent capture. Free-ranging rodents will be captured using box traps. Captive bred rodents (e.g. at rodent farms) will be manually captured and restrained. Traps for free-ranging rodents will be checked a minimum of every 12 hours, including once in the morning. Captive bred and wild rodent sampling procedures (including anesthesia, if necessary), will involve manual restraint, venipuncture, mucosal swabs, fecal, and urine sample collection.

Other small mammals: Anesthesia will be used to restrain small mammals such as civets and ferret badgers. Animals will be monitored continuously while recovering from anesthesia and will only be released once fully recovered from anesthesia. Animals that are sourced from markets and that may potentially be consumed, will be manually restrained without anesthesia, if possible, so that they may be returned to the vendor. Otherwise, the animal will be sampled and then euthanized via exsanguination

(cardiac puncture) while under anesthesia, then disposed of using biohazard protocols in order to prevent subsequent human or animal consumption.

4. **Location from where the animals will be obtained (source):**

Markets and surrounding caves/forest: sites will be identified along value chain routes linking southern China to southeast Asian countries that serve as sources for the Chinese market system. Specific field sites have not yet been determined.

5. **If possible, what will be done with the animals after the project ends (e.g., euthanized)**

All wild animals will be released unharmed after sampling at the capture location. While we do not anticipate any severe adverse events related to the capture or sampling of free ranging wildlife, we will observe all animals caught in traps and nets for injuries. Veterinary care of wildlife in the field is limited. Any animal with an injury that is deemed life-threatening, or significant enough to prevent survival upon release, will be humanely euthanized in accordance with the AVMA guidelines for euthanasia (2013). Any animal that is injured in the course of restraint or sampling such that it is deemed unable to survive if released or if appears to be in severe pain due to injury, will be humanely euthanized. Animals that are caught and moribund (depressed mentation, non-responsive to stimuli, emaciated and weak or exhibiting neurological signs), will be humanely euthanized.

From: Aleksei Chmura
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Greer, Jenny (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER
Date: Friday, February 17, 2017 10:19:33 PM
Attachments: NIH-NIAID_5R01AI110964 Additional Site Q and A.pdf

See attached

Dear Erik,

Please find our responses in the attached PDF. If you need any additional details, please let me know.

Many thanks!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

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On Feb 15, 2017, at 08:52, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,
I know you said nothing will be changing from your currently approved animal studies, but it would be helpful for me in preparing the foreign clearance request if you could write a few concise sentences about the new animal work addressing the following points:

- Kind or species of animal and number to be used
- Location of the source of the animals, if known
- A brief description of the sampling (blood draw, swab, etc)
- Location from where the animals will be obtained (source)
- If possible, what will be done with the animals after the project ends (e.g., euthanized)

Let me know if you have any questions.
Thanks!
Erik

From: Aleksei Chmura (b) (6)
Sent: Monday, February 13, 2017 4:23 PM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Cc: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Smith, Philip (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Super! Thanks, Jenny.

Erik and Philip - please let me know, if you have any questions or require additional details. We look forward to your responses.

Sincerely,

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

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> On Feb 13, 2017, at 16:18, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:
>
> Aleksei,
>
> Thank you for your email. I am copying Erik on this response so he can make sure he has everything needed to initiate a request for each of these foreign sites. I am also copying Philip Smith, the grants management specialist assigned to this grant for this fiscal year. Please don't hesitate to contact either of them with any questions you may have.

Please note that this response does not constitute approval and it will take at least 3 weeks for a final determination to be made.

Thanks again! And have a great afternoon!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

***Effective January 1, 2017**, NIH closeout policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.*

From: Aleksei Chmura (b) (6)
Sent: Friday, February 10, 2017 2:54 PM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Dear Jenny,

I am just following up with item 1 and 1a from your email below. As per Peter's email (also below), we would like to request prior approval for collecting non-human animal samples in 7 countries: Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam.

No new animals will be introduced nor any new field procedures, we have submitted IACUC protocol modification - for geographic locations only - and will provide approval dates as soon as they are available.

No work will be conducted until we have your approval and IACUC approval.

Testing would be conducted locally and if any samples were to be transferred to China these would be only extracted viral DNA - and not the original sample material.

Samples will be collected by either our current China field team personnel working directly with our collaborators in these countries or by respective in-country personnel and require no more than 10% budget modification total (from already budgeted China fieldwork) for any non-China in-country work.

Here is the list of our local in-country contacts and institutions:

Cambodia
Veasna Duong
Institut Pasteur du Cambodge
No. 5 Monivong Boulevard
P.O Box. 983, Phnom Penh, Cambodia
(b) (6)

Indonesia
Joko Pamungkas
Primate Research Center at Bogor Agricultural University
JalanLodayaII/5,Bogor16151, Indonesia
(b) (6)

Lao People's Democratic Republic
Watthana Theppangna
National Animal Health Laboratory
Department of Livestock and Fisheries
Ministry of Agriculture and Forestry, Vientiane, Lao PDR
(b) (6)

Malaysia
Tom J. Hughes
Conservation Medicine, Ltd.
Suite 4A, Level 4, Main Office Tower
Financial Park Complex, Jalan Merdeka, 87000
Federal Territory of Labuan, Malaysia
(b) (6)

Myanmar
Aung Than Toe
San Pya Clinic

20/256, Insein Road
Yangon 11051, Myanmar
(b) (6)

Thailand
Supaporn Wacharapluesadee
Neuroscience Center for Research and Development
King Chulalongkorn Memorial Hospital
Rama 4 Road
Patumwan, Bangkok, Thailand 10330
(b) (6)

Vietnam
Nguyen Huu Nam
Faculty of Animal and Veterinary Science
Hanoi Agricultural University
Trauquy, Gialâm, Hanoi, Vietnam
(b) (6)

If it will be easier to have a quick chat about this, I am happy to call anytime. Also, if this request should be sent more formally as a letter attachment, we can do that rapidly as well.

I hope you and yours had a lovely Holiday and are surviving the blizzard!

Cheers,

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

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Aleksei MacDurian (Skype)

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On Aug 1, 2016, at 12:39, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Thank you for your email. To answer your questions:

1. To do any work in countries other than China, you will need to request prior approval from NIH. To do so, submit a formal request, including the names, institutions, and full contact information of any institutions with which you will collaborate for such activities. Be sure to indicate whether animal or human research will be conducted and what funds, if any, will be going into these countries. The approval process for new foreign sites takes at least 3 weeks.

1a . If you are introducing new animals into the project, then there may be additional requirements from the Office of Laboratory Animal Welfare (OLAW). Again, you would need to submit a formal request, providing a scientific justification for the inclusion of new species on the project, and, if appropriate, a new Vertebrate Animal Section. If additional IACUC approvals are required, you will need to provide us with the IACUC approval dates (but **not** a copy of the actual approval).

2. These individuals are not listed in the Notice of Award as key personnel, so, from a grants management perspective, you do not need to get prior approval for this change. That said, if this change or other such personnel changes would have a significant impact on the scope of the project or the science itself, you would need to at least run it by your Program Officer. And if it is determined that personnel changes would cause a scope change, then you would need grants management approval as well.
3. I do not know what you are asking here. It looks like we have approved both the Wuhan University and ECNU for work on this project. Therefore, no additional prior approval is required for changes unless otherwise specified in the NIH Grants Policy Statement (eg, a change of scope).

Please don't hesitate to contact me with any additional questions. I will be available until 2:30 eastern and then again on Wednesday.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

From: Aleksei MacDurian
(b) (6)
Sent: Sunday, July 31, 2016 6:06 AM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Dear Jenny,

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1) Do we need to formally request permission to sample species of bats and other high-risk [rodents and carnivore] hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). Under this award our current US and China IACUC approved protocol via Tufts University and Wuhan Institute of Virology permits us to sample these species in these regions.

2) We provided Dr. Noam Ross' CV with our Year 2 Report. Dr. Ross has replaced Dr. Hosseini who is no longer working on this project. Do we need to do anything else for this? I have attached his Biosketch here for reference.

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It may be easier to briefly chat about these questions via telephone. If so, you may reach me (b) (6) anytime.

Many thanks!

-Aleksei

Aleksei Chmura
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> Dear Erik,
>
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> It's been a pretty productive year, and some of the highlights include: collecting samples from 15 bat genera in southern China with 280 (12%) testing positive for coronaviruses; SARS-like coronaviruses being detected in*Rhinolophus* spp. bats in both Yunnan and Guangdong provinces; 7 published papers from work under our award

(including one in *J. Virol.* and one in press at *J. Virol*); 218 quantitative interviews with samples and 47 qualitative coded interviews conducted transcribed and translated.

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to (b) (6) earlier this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.

Cheers,

Peter

Peter Daszak
President

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1. **Kind or species of animal and number to be used:**

Species taxa	Family, Genus or Species Name	Target numbers
Fruit bats	*e.g.: Cynopterus, Rousettus, Eonycterus spp.*	900 individuals (30 individuals from 30 different species)
Insectivorous bats	*e.g.: Rhinilophidae, Hipposideridae, Emballonuridae, Vespertillionidae, Mollsidae, Miniopteridae spp.*	
Rodents	e.g: Chinese bamboo rat (*Rhizomys sinensis*), Malayan porcupine (*Hystrix brachyura*), bandicoot (*Bandicota indica*)	900 individuals
Small Carnivores	e.g.: Raccoon dog (*Nyctereutes procyonoides*), Asian Palm civet (*Paradoxurus hemaphroditus*), ferret badger (*Melogale moschata*)	500 individuals

2. **Location of the source of the animals, if known:**

Free-ranging bat surveys and bats in wet markets: China, Malaysia, Thailand, Cambodia, Lao PDR, Myanmar, Vietnam, and Indonesia.

Other mammals: We will opportunistically sample the other aforementioned taxa that are also sold in live animal markets, trading locations or bred on farms to supply markets throughout southeast Asia. Species and numbers of animals sampled from markets will be based on animal availability.

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Bat capture. Free-ranging bats will be captured using either a mist net or harp trap and bats are removed from the net as soon as they become entangled to minimize stress and prevent injury. Bats will be manually restrained during sampling. Bats that are fractious may be anesthetized for restraint purposes in order to maximize safety for the bat and handler. Depending on the species and size of bat, swabs will be taken from the oropharynx, urogenital tract, and rectum. Fresh feces will be collected if available, in which case a rectal swab will not be collected. Blood will be collected from either from the cephalic vein or from the radial artery or vein using a 25-gauge needle. Bats are held for a maximum of six hours and then released following sample collection. We will euthanize 2 individuals per bat species for organ tissue banking.

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Other small mammals: Anesthesia will be used to restrain small mammals such as civets and ferret badgers. Animals will be monitored continuously while recovering from anesthesia and will only be released once fully recovered from anesthesia. Animals that are sourced from markets and that may potentially be consumed, will be manually restrained without anesthesia, if possible, so that they may be returned to the vendor. Otherwise, the animal will be sampled and then euthanized via exsanguination

(cardiac puncture) while under anesthesia, then disposed of using biohazard protocols in order to prevent subsequent human or animal consumption.

4. **Location from where the animals will be obtained (source):**

Markets and surrounding caves/forest: sites will be identified along value chain routes linking southern China to southeast Asian countries that serve as sources for the Chinese market system. Specific field sites have not yet been determined.

5. **If possible, what will be done with the animals after the project ends (e.g., euthanized)**

All wild animals will be released unharmed after sampling at the capture location. While we do not anticipate any severe adverse events related to the capture or sampling of free ranging wildlife, we will observe all animals caught in traps and nets for injuries. Veterinary care of wildlife in the field is limited. Any animal with an injury that is deemed life-threatening, or significant enough to prevent survival upon release, will be humanely euthanized in accordance with the AVMA guidelines for euthanasia (2013). Any animal that is injured in the course of restraint or sampling such that it is deemed unable to survive if released or if appears to be in severe pain due to injury, will be humanely euthanized. Animals that are caught and moribund (depressed mentation, non-responsive to stimuli, emaciated and weak or exhibiting neurological signs), will be humanely euthanized.

From: Aleksei MacDurian
To: Smith, Philip (NIH/NIAID) [E]
Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Wednesday, May 03, 2017 4:10:18 PM

No funds to new sites

Dear Philip,

Sincere apologies for my tardy reply. I was out-of-office the past two days unexpectedly and am just catching up with emails.

There are no planned in-country costs associated with these foreign sites. All testing costs will be at the Wuhan Institute of Virology in China - our current, approved partner under our award.

Many thanks!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

On Fri, Apr 28, 2017 at 5:29 PM, Smith, Philip (NIH/NIAID) [E] (b) (6) wrote:

> Hi Aleksei,
>
> Can you provide the direct and indirect costs for the foreign sites we are adding (Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Thailand, Vietnam)? Once this is received we can issue a revised NOA approving these sites.
>
> Thanks,

Philip Smith

Grants Management Specialist

Grants Management Program, DEA, NIAID, NIH

5601 Fishers Lane, Rm 4E48, MSC 9833 GMP

Rockville, Maryland 20892-9824

☎: (b) (6)

✉: (b) (6)

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

State department additional inquiry for Burma

From: Bernabe, Gayle (NIH/NIAID) [E]
To: Yuan, Liz (NIH/FIC) [E]; Officer, Jackie (NIH/FIC) [E]
Cc: Stemmy, Erik (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]; Handley, Gray (NIH/NIAID) [E]; Meegan, James (NIH/NIAID) [E]; Arcuri, Guy (NIH/NIAID) [E]; Dominique, Joyelle (NIH/NIAID) [E]; Rosa, William (NIH/NIAID) [E]
Subject: FACTS: Project for BURMA on queue for SDC: R01AI110964-03; DASZAK, PETER
Date: Saturday, March 25, 2017 12:34:57 PM
Attachments: Burma InfoShare Post Concurrence EcoHealth Alliance_March 2017.docx

See attached

Dear Liz and Jackie:

Please find attached the "Burma Assistance Activity InfoShare & Post/Mission Concurrence Request" form for grant AI110964-03 (Burma).

Please let us know if additional information is needed.

Thank you and kind regards,
Gayle

Gayle Bernabe, MPH
Regional Program Officer-East/SE Asia and the Pacific
Office of Global Research (OGR)
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services
5601 Fishers Ln Rm 1E MSC 9802
Bethesda, MD 20892-9802 [For courier deliveries: 20852]
Phone: (b) (6)
Fax: (301) 480-2954
Email: (b) (6)

Burma Assistance Activity
InfoShare & Post/Mission Concurrence Request

Submitted by
Name: (b) (6)
Title: Understanding the Risk of Bat Coronavirus Emergence – 5R01AI110964-03
Agency/Office: DHHS/NIH

Date Submitted: 3/24/2017
Post/Mission Concurrence: Choose an item.
Post/Mission Comments: Click here to enter text.

Activity:	The National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH), has a pending award to the EcoHealth Alliance, Inc., New York, grant number 5R01AI110964-03. If approved, this award would involve a foreign collaboration in Myanmar. The aims of this research project are to examine the mechanism through which coronaviruses jump from animal hosts/reservoirs to humans (spillover events). To accomplish this work the U.S. Principal Investigator (PI) and his team will conduct detailed surveillance for coronaviruses at eight sites throughout in Asia (China, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam). Sampling sites will include urban centers, rural areas, and live animal markets. Samples will be collected from animals from each of these sites, and will be analyzed to determine what coronaviruses are present, and whether the viruses are able to infect humans. The investigators plan to collect samples from bats (900 samples total across all sites), rodents (900 samples total across all sites), and small carnivores such as palm civets and ferret badgers (500 samples total across all sites). Animals will be captured and lightly anesthetized if necessary. They will be swabbed (mouth/nose, urogenital tract, and rectum), and a small amount of blood will be collected. If available, feces and urine will also be collected. All wild animals will be released unharmed after sampling. Of animals that are collected from live markets, a maximum of two per species may be humanely euthanized for organ tissue sampling. All animal work will be performed by trained individuals in accordance with the American Veterinary Medical Association guidelines, and the project is overseen by veterinarians. This work has also been reviewed and approved by the investigator's Institutional Animal Care and Use Committee.
USG Strategic Goal:	Resilient Communities
Responsible USG Agency/Technical Office:	DHHS/NIH/National Institute of Allergy and Infectious Diseases (NIAID)
Mechanism:	Grant
Prime Partner:	EcoHealth Alliance, New York; Dr. Peter Daszak (Work will be conducted by in-country collaborators. In year 4 the PI will conduct a single site visit.)
Sub-Recipients:	San Pya Clinic, Yangon; Dr. Aung Than Toe

Burma Assistance Activity
InfoShare & Post/Mission Concurrence Request

Duration and Start/End Dates:	2 year project; new sampling work will begin in new budget period 6/1/2017 and continue through the end of the award 5/31/2019
Funding:	HHS Appropriations – FY2017 **FY** Choose an item. **Account** Choose an item. **Budget** **Notwithstanding Authority (NWA)** Please indicate which NWA is being used.
Immediate Cost:	No funds will be sent directly to Myanmar.
Total Estimated Cost:	No funds will be sent directly to Myanmar.
Funding Approval:	This research grant was reviewed by experts in the scientific field and recommended for funding consideration. The NIAID Advisory Council approved the funding of this grant. Research protocols will be cleared through Myanmar and US Institutional Review Boards.
Assistance to the GOB:	No - Assistance to GOB No assistance is being provided to the Government of Burma. NIH provides funding for research activities only.
Congressional Notification:	Has your program been notified to Congress? When? Not required
Beneficiary(ies):	Burmese people and San Pya Clinic staff
Legal Determination:	*Check this box ☒ to confirm that your agency/office has consulted with the relevant legal advisors regarding this activity and that those officers have confirmed the necessary legal authority to provide this assistance. *Check this box ☐ to confirm activity participants/vendors have been screened for inclusion on the SDN list. https://sdnsearch.ofac.treas.gov/. While the Burma Sanctions Program ended in October 2016, other sanctions programs might include people or entities in Burma. **(NIAID Comment: CDC office has offered to confirm for Principal Investigators.)** *Check this box ☐ to confirm due diligence for gross violators of human rights (GVHR) has been conducted. If not, please indicate why:_____ *Check this box ☒ to confirm that Leahy Vetting has been/will be performed for all assistance to security forces, consistent with Embassy in Rangoon Leahy Vetting Policy. **(NIAID Comment: Vetting will be performed if post can provide information regarding this policy and how to complete Leahy Vetting.)** *If this activity requires travel to the United States, please note that certain Burmese nationals are subject to visa restrictions in the 2008 JADE Act, as detailed in 17 State 1214. **(NIAID Comment: NIAID notes this requirement and has made program officer aware of restrictions.)**
Other considerations:	

Burma Assistance Activity
InfoShare & Post/Mission Concurrence Request

Additional Comments:	There are no restrictions on this work proposed in Myanmar. The funding will only be used to support coronavirus research which will be conducted by collaborators in San Pya Clinic, which is a non-government organization. No funds are presently planned to be sent to Myanmar. This is a new project conducted in Myanmar and does not duplicate any known projects in this area. NIH has legislative authority that allows NIH to award funds directly and indirectly to foreign institutions based on scientific merit. NIH is subject to all USG sanctions and other superseding actions and NIH acknowledges that and appreciates careful review by the Embassy committee and others on the ground in Myanmar.

From: Stemmy, Erik (NIH/NIAID) [E]
To: Bernabe, Gayle (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]
Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK , PETER (Embassy Request Form)
Date: Friday, March 24, 2017 2:50:06 PM
Attachments: Re Out of Office RE Year 2 Report for 5R01AI110964 - 02 PI Name DASZAK PETER.msg
Burma InfoShare Post Concurrence EcoHealth Alliance_March 2017.docx

See attached

Hello Gayle and Philip,
My apologies for the slow response. The PI responded on Monday, but I was out of the office on a site visit until last night. Please see attached and let me know if that is sufficient information. Of particular note, the PI said in the attached message that they don't plan on sending any funds directly in country to Burma; they're just coordinating the transfer of samples from the collection site to the collaborator lab in China. Let me know if you need more info from me.

Many thanks,
Erik

From: Bernabe, Gayle (NIH/NIAID) [E]
Sent: Wednesday, March 22, 2017 1:54 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Smith, Philip (NIH/NIAID) [E] (b) (6)
Cc: Bernabe, Gayle (NIH/NIAID) [E] (b) (6)
Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK , PETER (Embassy Request Form)

Dear Erik and Philip:

I just wanted to follow-up with this project and the Embassy request form needed for clearance.

Your time and input are appreciated.

Thanks and kind regards,
Gayle

From: Bernabe, Gayle (NIH/NIAID) [E]
Sent: Thursday, March 16, 2017 1:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Smith, Philip (NIH/NIAID) [E] (b) (6)
Cc: Bernabe, Gayle (NIH/NIAID) [E] (b) (6)
Subject: FW: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK , PETER (Embassy Request Form)

Dear Erik and Philip:

For any projects involving Burma, the U.S. Embassy/Post has requested NIH to submit the attached form. I tried to fill it out with information from the FACTS record, as well as standard language that

has been used for other projects with Burma. Please review it and update any information specific to the activities to be done in Burma, including the text highlighted in yellow.

Once this form is complete, it will be submitted to FIC.

Thank you for your time.

Kind regards,
Gayle

Gayle Bernabe, MPH
Regional Program Officer-East/SE Asia and the Pacific
Office of Global Research (OGR)
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services
5601 Fishers Ln Rm 1E MSC 9802
Bethesda, MD 20892-9802 [For courier deliveries: 20852]
Phone: (b) (6)
Fax: (301) 480-2954
Email: (b) (6)

From: "Arcuri, Guy (NIH/NIAID) [E]" (b) (6)
Date: Friday, March 10, 2017 at 9:41 AM
To: "Smith, Philip (NIH/NIAID) [E]" (b) (6), NIAID State Dept Clearance (b) (6)
Cc: "Bernabe, Gayle (NIH/NIAID) [E]" (b) (6)
Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK , PETER; OGR Contact: Gayle Bernabe

Your request has been received and will be reviewed for OGR by Gayle Bernabe.

Thank you.

V/R,

Guy Arcuri

From: Smith, Philip (NIH/NIAID) [E]
Sent: Thursday, March 09, 2017 3:14 PM
To: NIAID State Dept Clearance (b) (6)
Subject: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK , PETER

Good Afternoon,

The following request for foreign clearance is ready for review. This request is to add protocols to already approved sites in Brazil:

Grant Number: 5R01AI110964 - 03
P.I.: DASZAK, PETER
Applicant Organization: ECOHEALTH ALLIANCE, INC.
Foreign Country: **BURMA**
GMS: Philip Smith
PO: Stemmy, Erik

Thank you,

Philip Smith
Grants Management Specialist
Grants Management Program, DEA, NIAID, NIH
5601 Fishers Lane, Rm 4E48, MSC 9833 GMP
Rockville, Maryland 20892-9824
☎: (b) (6)
✉: (b) (6)

Effective October 1, 2014, NIH closeout policy has changed (see NOT-OD-14-084). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding.

From: Peter Daszak
Sent: Mon, 20 Mar 2017 18:32:16 +0000
To: Stemmy, Erik (NIH/NIAID) [E];Alison Andre
Cc: Aleksei Chmura;Smith, Philip (NIH/NIAID) [E];Evelyn Luciano
Subject: Re: Out of Office RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER
Importance: High

Hi Erik,

Here are the answers to your questions:

1. Will Dr Daszak (or other EcoHealth staff) plan to spend time directly in country in Myanmar? If so, please provide an approximate % of time.

We are in initial planning of approach with these countries including Myanmar and time spent this year in Myanmar would primarily be by our collaborators and *not* EHA staff. In Yr 4, we will probably need to budget one site visit conducted by Dr. Peter Daszak and Senior Personnel Dr. Olival and/or by our field veterinarian. Please let us know what restrictions there might be for this..

2. How long do you anticipate the sampling will continue? That is, through the remainder of the R01, or a shorter amount of time?
Sampling will be conducted a minimum of four times over then remainder of the R01.

3. Can you confirm the total amount of US$ to be sent to Myanmar for the work?
No funds are presently planned to be sent to Myanmar. We plan to coordinate collaborative transfer of samples from Myanmar to our partner Lab in China.

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, March 16, 2017 2:11 PM
To: Peter Daszak; Alison Andre
Cc: Aleksei Chmura; Smith, Philip (NIH/NIAID) [E]; Evelyn Luciano
Subject: RE: Out of Office RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Thank you Peter!

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825

Phone: (b) (6)
Email: (b) (6)

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

****

From: Peter (b) (6)
Sent: Thursday, March 16, 2017 2:10 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Alison Andre (b) (6)
Cc: Aleksei Chmura (b) (6); Smith, Philip (NIH/NIAID) [E] (b) (6); Evelyn Luciano (b) (6)
Subject: RE: Out of Office RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Hi Erik,

I've just returned from travel and we'll get answers to you on this by Monday COB.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street – 17th Floor
New York, NY 10001

(b) (6) (direct)
+1.212.380.4465 (fax)

www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Thursday, March 16, 2017 1:33 PM
To: Alison Andre
Cc: Peter Daszak; Aleksei Chmura; Smith, Philip (NIH/NIAID) [E]
Subject: FW: Out of Office RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Hello Alison,
I received an out of office message from Aleksei. I am working on new foreign clearances for the grant referenced above, and need some additional information for the site in Myanmar. Would you be able to help address the questions below?

Thank you,
Erik

-Will Dr Daszak (or other EcoHealth staff) plan to spend time directly in country in Myanmar? If so, please provide an approximate % of time.
-How long do you anticipate the sampling will continue? That is, through the remainder of the R01, or a shorter amount of time?
-Can you confirm the total amount of US$ to be sent to Myanmar for the work?

From: Aleksei Chmura (b) (6)
Sent: Thursday, March 16, 2017 1:23 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: Out of Office RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Thank you for your email.

I will be out of the office and traveling until 20 March 2017. During this time, I may not have regular access to emails and voice messages. If you should need immediate assistance, please contact Alison Andre at (b) (6). Otherwise, I will respond to your message as soon as possible.

Sincerely,

--
Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

Burma Assistance Activity
InfoShare & Post/Mission Concurrence Request

Submitted by
Name: (b) (6)
Title: Understanding the Risk of Bat Coronavirus Emergence – 5R01AI110964-03
Agency/Office: DHHS/NIH

Date Submitted: 3/16/2017
Post/Mission Concurrence: Choose an item.
Post/Mission Comments: Click here to enter text.

Activity:	The National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH), has a pending award to the EcoHealth Alliance, Inc., New York, grant number 5R01AI110964-03. If approved, this award would involve a foreign collaboration in Myanmar. The aims of this research project are to examine the mechanism through which coronaviruses jump from animal hosts/reservoirs to humans (spillover events). To accomplish this work the U.S. Principal Investigator (PI) and his team will conduct detailed surveillance for coronaviruses at eight sites throughout in Asia (China, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam). Sampling sites will include urban centers, rural areas, and live animal markets. Samples will be collected from animals from each of these sites, and will be analyzed to determine what coronaviruses are present, and whether the viruses are able to infect humans. The investigators plan to collect samples from bats (900 samples total across all sites), rodents (900 samples total across all sites), and small carnivores such as palm civets and ferret badgers (500 samples total across all sites). Animals will be captured and lightly anesthetized if necessary. They will be swabbed (mouth/nose, urogenital tract, and rectum), and a small amount of blood will be collected. If available, feces and urine will also be collected. All wild animals will be released unharmed after sampling. Of animals that are collected from live markets, a maximum of two per species may be humanely euthanized for organ tissue sampling. All animal work will be performed by trained individuals in accordance with the American Veterinary Medical Association guidelines, and the project is overseen by veterinarians. This work has also been reviewed and approved by the investigator's Institutional Animal Care and Use Committee.
USG Strategic Goal:	Resilient Communities
Responsible USG Agency/Technical Office:	DHHS/NIH/National Institute of Allergy and Infectious Diseases (NIAID)
Mechanism:	Grant
Prime Partner:	EcoHealth Alliance, New York; Dr. Peter Daszak (Work will be conducted by in-country collaborators. In year 4 the PI will conduct a single site visit)
Sub-Recipients:	San Pya Clinic, Yangon; Dr. Aung Than Toe

Burma Assistance Activity
InfoShare & Post/Mission Concurrence Request

Duration and Start/End Dates:	2 year project; new sampling work will begin in new budget period 6/1/2017 and continue through the end of the award 5/31/2019
Funding:	HHS Appropriations – FY2017 **FY** Choose an item. **Account** Choose an item. **Budget** **Notwithstanding Authority (NWA)** Please indicate which NWA is being used.
Immediate Cost:	$3,000 for San Pya Clinic
Total Estimated Cost:	Total cost for San Pya Clinic ($3,000 over X years)
Funding Approval:	This research grant was reviewed by experts in the scientific field and recommended for funding consideration. The NIAID Advisory Council approved the funding of this grant. Research protocols will be cleared through Myanmar and US Institutional Review Boards.
Assistance to the GOB:	No - Assistance to GOB No assistance is being provided to the Government of Burma. NIH provides funding for research activities only.
Congressional Notification:	Has your program been notified to Congress? When? Not required
Beneficiary(ies):	Burmese people and San Pya Clinic staff
Legal Determination:	*Check this box ☒ to confirm that your agency/office has consulted with the relevant legal advisors regarding this activity and that those officers have confirmed the necessary legal authority to provide this assistance. *Check this box ☐ to confirm activity participants/vendors have been screened for inclusion on the SDN list. https://sdnsearch.ofac.treas.gov/. While the Burma Sanctions Program ended in October 2016, other sanctions programs might include people or entities in Burma. **(NIAID Comment: CDC office has offered to confirm for Principal Investigators.)** *Check this box ☐ to confirm due diligence for gross violators of human rights (GVHR) has been conducted. If not, please indicate why:_____ *Check this box ☒ to confirm that Leahy Vetting has been/will be performed for all assistance to security forces, consistent with Embassy in Rangoon Leahy Vetting Policy. **(NIAID Comment: Vetting will be performed if post can provide information regarding this policy and how to complete Leahy Vetting.)** *If this activity requires travel to the United States, please note that certain Burmese nationals are subject to visa restrictions in the 2008 JADE Act, as detailed in 17 State 1214. **(NIAID Comment: NIAID notes this requirement and has made program officer aware of restrictions.)**
Other considerations:	

Commented [SE([1]: Per PI, no funds will be sent directly to the country. They will coordinate transfer of samples to the partner laboratory in China

Burma Assistance Activity
InfoShare & Post/Mission Concurrence Request

Additional Comments:	There are no restrictions on this work proposed in Myanmar. The funding will only be used to support coronavirus research which will be conducted by collaborators in San Pya Clinic, which is a non-government organization. This is a new project conducted in Myanmar and does not duplicate any known projects in this area. NIH has legislative authority that allows NIH to award funds directly and indirectly to foreign institutions based on scientific merit. NIH is subject to all USG sanctions and other superseding actions and NIH acknowledges that and appreciates careful review by the Embassy committee and others on the ground in Myanmar.

From: Greer, Jenny (NIH/NIAID) [E]
To: Smith, Philip (NIH/NIAID) [E]
Subject: FW: FACTS: State Department Clearance Request Approved
Date: Friday, March 17, 2017 9:16:24 AM

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

***Effective January 1, 2017**, NIH closeout policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.*

From: era-notify@mail.nih.gov [mailto:era-notify@mail.nih.gov]
Sent: Friday, March 17, 2017 5:14 AM
To: NIAID FCTS <NIAIDFCTS@niaid.nih.gov>; Stemmy, Erik (NIH/NIAID) [E] (b) (6) Bernabe, Gayle (NIH/NIAID) [E] (b) (6) Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: FACTS: State Department Clearance Request Approved

*** This is an automated notification - Please do not reply to this message. ***

Project Number: R01AI110964-03
PI Name: PETER DASZAK
Project Title: Understanding the Risk of Bat Coronavirus Emergence

Country: THAILAND
SDCR Initiated By: Gayle Bernabe
SDCR Status: Approved
Action Comment: We note that the PIs include USAID Regional Development Mission for Asia partners currently undertaking similar work in the same countries through the Emerging Pandemic Threats PREDICT 2 project. The distinction between that project and this one is not immediately clear.

If you have any questions, please contact the eRA Help Desk at

http://grants.nih.gov/support/index.html OR call 1-866-504-9552 (tty: 301-451-5939) OR helpdesk@od.nih.gov.

Greer, Jenny (NIH/NIAID) [E]

From: Aleksei Chmura (b) (6)
Sent: Thursday, October 06, 2016 12:26 PM
To: Greer, Jenny (NIH/NIAID) [E]
Cc: Hongying Li
Subject: Fwd: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Follow Up Flag: Follow up
Flag Status: Completed

Categories: Foreign

Dear Jenny,

Apologies for the delay, here are the details for the new institution that will be an even switch-out for East China Normal University (so no modification to budget or project aims):

CONTACT/PI: Dr. Shiyue Li
TITLE: Professor Committee Director and Professor of Epidemiology and Health Statistics
INSTITUTION: Wuhan University School of Public Health
EMAIL: (b) (6)
TELEPHONE: (b) (6)
INSTITUTION NAME: Wuhan University School of Public Health
DUNS NUMBER: 529049295

No Animal Research Conducted.

Human Research Conducted as per IRB approval.

Please let me know, if you require further information.

Many thanks!

-Aleksei

On Aug 1, 2016, at 18:18, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

> Aleksei,
>
> 1. Sounds good.
> 2. Erik will have to confirm, but from my perspective, we're fine.

3. If this is a new institution, please provide a contact person with all their contact information, the name of the institution, an indication of whether animal or human research will be conducted here and how much money, if any will go to the institution. You can include this information with the request referenced in 1.

Jenny

Jenny Greer

Grants Management Specialist

DHHS/NIH/NIAID/DEA/GMP

5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

Phone: (b) (6)

Email: (b) (6)

From: Aleksei MacDurian (b) (6)
Sent: Monday, August 01, 2016 12:51 PM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Thanks, Jenny!

Quick replies:

1) We will put together a formal request for the additional countries. These will be only for non-human animal sampling.

1a) No new animal species will be introduced to the project.

2) You are correct and as there is no significant change in scope of the project - just (sorry to sound so cavalier!) a change in individual not work performed. Peter already notified Erik about this change in personnel, so are we ok here?

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Cheers,

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

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Aleksei MacDurian (Skype)

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Please don't hesitate to contact me with any additional questions. I will be available until 2:30 eastern and then again on Wednesday.

All the best,

Jenny

Jenny Greer

Grants Management Specialist

DHHS/NIH/NIAID/DEA/GMP

5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

Phone: (b) (6)

Email: (b) (6)

From: Aleksei MacDurian (b) (6)
Sent: Sunday, July 31, 2016 6:06 AM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Dear Jenny,

Since you were not cc'ed on the original email, I wanted to follow up with you on three things from Dr. Daszak's email to Erik (included below):

1) Do we need to formally request permission to sample species of bats and other high-risk [rodents and carnivore] hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). Under this award our current US and China IACUC approved protocol via Tufts University and Wuhan Institute of Virology permits us to sample these species in these regions.

2) We provided Dr. Noam Ross' CV with our Year 2 Report. Dr. Ross has replaced Dr. Hosseini who is no longer working on this project. Do we need to do anything else for this? I have attached his Biosketch here for reference.

3) Our Human surveillance work and local IRB approval have all been through the Wuhan University School of Public Health (WUSPH) in China (DUNS No. 529049295). We would like now - in Years 3 - 5 of our award to subcontract directly with them rather than with the institution on our current budget: East China Normal University (ECNU) School of Life Sciences. The Wuhan University School of Public Health budget amount would be the same annual amount as currently budgeted for East China Normal University in these same years.

It may be easier to briefly chat about these questions via telephone. If so, you may reach me at (b) (6) anytime.

Many thanks!

-Aleksei

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On Fri, May 13, 2016 at 5:55 PM, Peter Daszak (b) (6) wrote:

> Dear Erik,
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> I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as a pdf).
>
> It's been a pretty productive year, and some of the highlights include: collecting samples from 15 bat genera in southern China with 280 (12%) testing positive for coronaviruses; SARS-like coronaviruses being detected in *Rhinolophus* spp. bats in both Yunnan and Guangdong provinces; 7 published papers from work under our award (including one in *J. Virol.* and one in press at *J. Virol*); 218 quantitative interviews with samples and 47 qualitative coded interviews conducted transcribed and translated.

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Camb odia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to (b) (6) this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

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Greer, Jenny (NIH/NIAID) [E]

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thursday, September 01, 2016 8:48 AM
To: Aleksei Chmura
Cc: Greer, Jenny (NIH/NIAID) [E]
Subject: RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Hi Aleksei and Jenny,
Very sorry to have missed this bit from the original email last month. I don't have any problem with the change, and don't need anything else for Dr Ross from my side. Please just be sure to include a brief summary of the change in your next progress report. I believe we are just missing the details of new foreign site (apologies if I've missed it), so we can update the foreign clearance.

Erik

From: Aleksei Chmura (b) (6)
Sent: Monday, August 29, 2016 12:51 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Dear Erik,

I am just following up from Peter's email and to confirm that you approve item 2, below. In particular, do you require any additional documentation or details about Dr. Noam Ross, who is replacing Dr. Parviez Hossini under our award? I have attached his recent NIH formatted CV for reference. This personnel change-out does not alter our project aims nor our budget.

Many thanks!

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On Mon, Aug 1, 2016 at 6:18 PM, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

> Aleksei,

Greer, Jenny (NIH/NIAID) [E]

From: Aleksei Chmura (b) (6)
Sent: Thursday, October 06, 2016 12:26 PM
To: Greer, Jenny (NIH/NIAID) [E]
Cc: Hongying Li
Subject: Fwd: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Follow Up Flag: Follow up
Flag Status: Completed

request for new foreign entity

Categories: Foreign

Dear Jenny,

Apologies for the delay, here are the details for the new institution that will be an even switch-out for East China Normal University (so no modification to budget or project aims):

CONTACT/PI: Dr. Shiyue Li
TITLE: Professor Committee Director and Professor of Epidemiology and Health Statistics
INSTITUTION: Wuhan University School of Public Health
EMAIL: (b) (6)
TELEPHONE: (b) (6)
INSTITUTION NAME: Wuhan University School of Public Health
DUNS NUMBER: 529049295

No Animal Research Conducted.

Human Research Conducted as per IRB approval.

Please let me know, if you require further information.

Many thanks!

-Aleksei

On Aug 1, 2016, at 18:18, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

> Aleksei,
>
> 1. Sounds good.
> 2. Erik will have to confirm, but from my perspective, we're fine.

3. If this is a new institution, please provide a contact person with all their contact information, the name of the institution, an indication of whether animal or human research will be conducted here and how much money, if any will go to the institution. You can include this information with the request referenced in 1.

Jenny

Jenny Greer

Grants Management Specialist

DHHS/NIH/NIAID/DEA/GMP

5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

Phone: (b) (6)

Email: (b) (6)

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Sent: Monday, August 01, 2016 12:51 PM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Thanks, Jenny!

Quick replies:

1) We will put together a formal request for the additional countries. These will be only for non-human animal sampling.

1a) No new animal species will be introduced to the project.

2) You are correct and as there is no significant change in scope of the project - just (sorry to sound so cavalier!) a change in individual not work performed. Peter already notified Erik about this change in personnel, so are we ok here?

3) We do work with Wuhan Institute of Virology on this award, but not with Wuhan University School of Public Health. These two Institutions are distinct - though both located fairly close to each other in Wuhan! - one is Chinese Academy of Science and the other is University. There will not be a change in scope of work. It is just that we could subcontract directly to Wuhan University for the human surveillance work in China.

Cheers,

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Please don't hesitate to contact me with any additional questions. I will be available until 2:30 eastern and then again on Wednesday.

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Peter

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President

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From: Greer, Jenny (NIH/NIAID) [E]
To: (b) (6) ; (b) (6)
Cc: Stemmy, Erik (NIH/NIAID) [E]; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Thursday, July 07, 2016 10:00:00 AM
Attachments: 110964 Daszak GoF Determination Letter 7-7-2016.pdf

---

Aleksei and Peter,

Please find attached a determination regarding your grant.

As always, don't hesitate to contact us with any questions.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 7, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is not subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

From: Aleksei Chmura
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Dr. Peter Daszak; Greer, Jenny (NIH/NIAID) [E]
Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Tuesday, June 28, 2016 11:58:13 PM
Attachments: Response to GoF letter, 5R01AI110964 - 03 DASZAK, PETER.pdf

Dear Erik,

Prof. Zhengli Shi has confirmed that the Wuhan Institute of Virology Institutional Biosafety Committee would be immediately notified as per Peter's comments below. Please find the updated letter attached.

If you require further details, let us know anytime.

Sincerely,

-Aleksei

Aleksei Chmura
Authorized Organizational Representative &
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

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Aleksei MacDurian (Skype)

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On Jun 28, 2016, at 11:22, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

Thanks Peter! Please have Aleksei send us an updated letter once you have one.

Erik

Sent with Good (www.good.com)

-----Original Message-----
From: Peter Daszak (b) (6)
Sent: Tuesday, June 28, 2016 08:02 AM Eastern Standard Time

To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Sorry for not responding more quickly Erik – I've been at meetings for the last couple of weeks. You are correct to identify a mistake in our letter. UNC has no oversight of the chimera work, all of which will be conducted at the Wuhan Institute of Virology. This was a clerical error because we used some language that I asked Ralph Baric to give me because I wanted to make sure we followed an approach that has some precedence.

We will clarify tonight with Prof. Zhengli Shi exactly who will be notified if we see enhanced replication, and then amend and re-send the letter to you so it is clear. I will also confirm with Zhengli the make-up of the Wuhan Institute of Virology's Institutional Biosafety Committee. However, my understanding is that I will be notified straight away, as PI, and that I can then notify you at NIAID.

Apologies for the error!

Cheers,

Peter

Peter Daszak
President

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From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Monday, June 27, 2016 3:49 PM
To: Peter Daszak
Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Peter,

Just wanted to follow up with you to see if you had a chance to look in to the IBC question I sent earlier this month. Please let us know.

Thanks,
Erik

Sent with Good (www.good.com)

-----Original Message-----
From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Friday, June 17, 2016 03:38 PM Eastern Standard Time
To: Dr. Peter Daszak
Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Peter,
Thanks very much for providing the additional information. I did have a couple of follow up questions for you. Can you clarify where the work with the chimeric viruses will actually be performed? Your original application described the BSL3 facilities at the Wuhan Institute of Virology, but your response letter indicated that you would notify the UNC IBC if you observed enhanced replication with any of the proposed chimeras. Therefore it's not clear where the studies are being performed. Please also clarify whether EcoHealth Alliance has its own IBC, and how the UNC IBC would be involved in the oversight of this work.

Many thanks,
Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
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Email: (b) (6)

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From: Greer, Jenny (NIH/NIAID) [E]
Sent: Thursday, June 09, 2016 5:56 PM
To: Aleksei Chmura (b) (6)
Cc: Dr. Peter Daszak (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Thank you for your quick response!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

From: Aleksei Chmura (b) (6)
Sent: Thursday, June 09, 2016 5:43 PM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Cc: Dr. Peter Daszak (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Kirker, Mary (NIH/NIAID) [E] (b) (6); Glowinski, Irene (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Jenny,

I concur with the detailed response that Dr. Daszak just sent to you in response to the Gain of Function questions in your email from 28th May. Please let me know

anytime, if you require any further information.

Many thanks!

Aleksei Chmura
Authorized Organizational Representative &
Senior Coordinator of Operations

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On Jun 9, 2016, at 17:37, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Peter,

Thank you for providing this response. We will review it shortly. In the meantime, I look forward to receiving concurrence from your authorized business official.

Thanks again!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

From: Peter Daszak (b) (6)
Sent: Thursday, June 09, 2016 5:23 PM
To: Greer, Jenny (NIH/NIAID) [E] (b) (6); Aleksei Chmura (b) (6)
Cc: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Kirker, Mary (NIH/NIAID) [E] (b) (6); Glowinski, Irene (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Importance: High

Dear Jenny and Erik,

Please find our response letter to your email below, attached. I really appreciate you giving us the chance to clarify these details and look forward to your decision on our proposed work. As stated clearly in the letter, we will not (of course) move forward with any of the proposed work in Specific Aim #3 until we hear back from you with directions.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
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www.ecohealthalliance.org

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From: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Sent: Saturday, May 28, 2016 5:15 PM
To: Aleksei Chmura

Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Mr. Chmura,

Please find attached an important message about this grant. Your immediate response will be much appreciated.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

"Effective October 1, 2014, NIH closeout policy has changed (see NOT-OD-14-084). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding."

EcoHealth Alliance

Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01AI110964-03). We have provided the details you requested, below, including alternative strategies if we remove work that could be deemed gain of function. We look forward to your response and will modify our workplan accordingly. In the meantime, please rest assured that none of the proposed work for Specific Aim #3 that you have requested information about will begin.

Determination as to whether the above research does or does not include GoF work subject to the funding pause. Please provide a detailed explanation for this determination, including, but not limited to, descriptions of the MERS and MERS-like chimeric CoVs that you propose to create, and detailed descriptions of the experiments you plan to conduct. Your determination should also include whether each chimeric virus is reasonably anticipated to exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type MERS-CoV.

Firstly, we would like to reiterate that this work is *proposed* for year 3, and none has been conducted to date. Furthermore, we will not proceed with any of this unless we are given the go-ahead by NIAID. The goal of our proposed work to construct MERS and MERS-like chimeric CoVs is to understand the potential origins of MERS-CoV in bats by studying bat MERS-like CoVs in detail. The chimeric viruses will be used to ascertain receptor usage and infectivity of bat MERS-related CoVs *in vitro* and in a mouse model. To achieve this purpose, our aim is to firstly construct a MERS-CoV infectious clone based on the genomic sequence of EMC2012 (GenBank no. NC_019843) and then chimeric CoVs with the replacement of the spike envelope genes from bat derived MERS-like CoVs. We have very recently discovered a small number (9 different strains) of bat MERS-like CoVs in 99 samples from bats in Guangxi, Guangdong, and Szechuan provinces. Phylogenetically, these bat viruses are not very close to MERS-CoV (only 63-66% homology to the S-protein of MERS-CoV).

We aim to test the chimeric viruses for receptor usage of DPP4 (the MERS-CoV receptor) in cells and then in DPP4 transgenic mice, to see if these bat viruses have any capacity to use the same receptor. That said, given the phylogenetic distance from MERS-CoV, we believe it is *highly unlikely* that these bat spike proteins attach to DPP4, and if so, that they would have any pathogenic potential. Finally, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or other DPP4 receptor over wildtype parental backbone MERS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.
NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in

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mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.

These two chimeric bat-like CoVs were constructed on September 24, 2015. They use the backbone of a group 2b SARS-like bat CoV WIV1 and the spike proteins of two newly discovered bat SL-CoVs (Rs7327 and RsSHC014). The construction of these chimeric viruses aims to understand the receptor usage and infectivity of bat SL-CoVs that may be progenitors of SARS-CoV. We have not yet tested the pathogenicity of these viruses in animals.

We believe that this work would not be considered GoF because the pause specifically targeted experiments that altered the pathogenicity or transmissibility of SARS-CoV, MERS-CoV and any influenza virus. Our molecular clone is WIV1, which is a group 2b SARS-like bat coronavirus that has never been demonstrated to infect humans or cause human disease. It is about 10% different from SARS-CoV. Thus, we feel that introducing other group 2b SARS-like bat coronavirus spike glycoproteins into WIV1 is not subject to the pause. Moreover, we are introducing progressively more distant S glycoproteins into WIV1 (The RBD of Rs7327 differs from WIV1 in several amino acid residues while RsSHC014 is even more distantly related phylogenetically), so it seems progressively less likely that any of these viruses would be more pathogenic or transmissible than the SARS-CoV. This is further supported by the fact that Prof. Ralph Baric's group (Menacherya *et al*., 2015, Nature Medicine, 21 (12):1508-1512; Menacherya *et al*., 2016, PNAS, 113 (11): 3048-3053) took WIV1 spike and inserted it onto a SARS-CoV backbone and showed reduced pathogenicity in mice with human ACE-2 relative to SARS-CoV (mortality rates were much lower, therefore this is *loss-of-function*). This strongly suggests that the chimeric bat spike/bat backbone viruses should not have enhanced pathogenicity in animals.

Finally, as proposed above for the MERS-like viruses, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or civet receptor over wildtype parental backbone SARS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

If it is determined that the above research DOES include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:

- For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or
- Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If these proposed activities within Specific Aim #3 are considered gain of function, we would propose changing them as follows:

1) Instead of the proposed work on MERS-like chimeric CoVs, we would
    a. model the 3-D structure of bat MERS-like CoV spike to assess its potential to bond to DPP4; and
    b. build pseudoviruses with MERS-like CoV spike to conduct experiments for DPP4 binding.

2) Instead of the proposed work on SARS-like chimeric bat CoVs, we would build pseudoviruses with the spike proteins from these viruses and assess receptor binding *in vitro*.

We look forward to your response to our letter and will not conduct any of this proposed work until we hear back from you.

Yours sincerely,

Dr. Peter Daszak

PI
President and Chief Scientist
EcoHealth Alliance

Tel: (b) (6)
e-mail: (b) (6)

From: Peter Daszak
To: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Cc: Stemmy, Erik (NIH/NIAID) [E]; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Thursday, June 09, 2016 5:23:51 PM
Attachments: Response to GoF letter, 5R01AI110964 - 03 DASZAK, PETER.pdf
Importance: High

Dear Jenny and Erik,

Please find our response letter to your email below, attached. I really appreciate you giving us the chance to clarify these details and look forward to your decision on our proposed work. As stated clearly in the letter, we will not (of course) move forward with any of the proposed work in Specific Aim #3 until we hear back from you with directions.

Cheers,

Peter

Peter Daszak
President

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From: Greer, Jenny (NIH/NIAID) [E] (b) (6)
Sent: Saturday, May 28, 2016 5:15 PM
To: Aleksei Chmura
Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Mr. Chmura,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

May 28, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 West 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-03

Dear Mr. Chmura:

Based upon information in the most recent progress report, NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the U.S. Government funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The following specific aims appear to involve research covered under the pause:

Aim 3: Testing predictions of CoV inter-species transmission

As per the funding pause announcement, new USG funding will not be released for GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. Therefore, the next non-competing segment of the award that starts June 1, 2016 cannot be released until a determination is reached based on the receipt and review of the information requested below. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, or SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.

NIAID requests that you provide the following information within 15 days of the date of this letter:

- **Determination as to whether the above research does or does not include GoF work subject to the funding pause**. Please provide a detailed explanation for this determination, including, but not limited to, descriptions of the MERS and MERS-like chimeric CoVs that you propose to create, and detailed descriptions of the experiments you plan to conduct. Your determination should also include whether each chimeric virus is reasonably anticipated to exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type MERS-CoV.

- **In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.** NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.
- **If it is determined that the above research <u>DOES</u> include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:**
    - For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or
    - Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If you have any questions about this matter please do not hesitate to contact the NIAID Program Officer.

Sincerely,

(b) (6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b) (6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

EcoHealth Alliance

Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01AI110964-03). We have provided the details you requested, below, including alternative strategies if we remove work that could be deemed gain of function. We look forward to your response and will modify our workplan accordingly. In the meantime, please rest assured that none of the proposed work for Specific Aim #3 that you have requested information about will begin.

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    b. build pseudoviruses with MERS-like CoV spike to conduct experiments for DPP4 binding.

2) Instead of the proposed work on SARS-like chimeric bat CoVs, we would build pseudoviruses with the spike proteins from these viruses and assess receptor binding *in vitro*.

We look forward to your response to our letter and will not conduct any of this proposed work until we hear back from you.

Yours sincerely,

Dr. Peter Daszak

PI
President and Chief Scientist
EcoHealth Alliance

Tel: (b) (6)
e-mail: (b) (6)

Please find attached an important message about this grant. Your immediate response will be much appreciated.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)

"Effective October 1, 2014, NIH closeout policy has changed (see NOT-OD-14-084). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding."

From:	Normil, Carine (NIH/NIAID) [C]
To:	Greer, Jenny (NIH/NIAID) [E]
Subject:	FW: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER
Date:	Friday, May 13, 2016 12:57:57 PM
Attachments:	Year 2 NIAID CoV Report as submitted via eRA Commons.pdf
Importance:	High

From: Peter Daszak (b) (6)
Sent: Friday, May 13, 2016 12:55 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Normil, Carine (NIH/NIAID) [C] (b) (6); Pone, Laura (NIH/NIAID) [E] (b) (6); Aleksei Chmura (b) (6)
Subject: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER
Importance: High

Dear Erik,

I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as a pdf).

It's been a pretty productive year, and some of the highlights include: collecting samples from 15 bat genera in southern China with 280 (12%) testing positive for coronaviruses; SARS-like coronaviruses being detected in *Rhinolophus* spp. bats in both Yunnan and Guangdong provinces; 7 published papers from work under our award (including one in *J. Virol.* and one in press at *J. Virol*); 218 quantitative interviews with sa mples and 47 qualitative coded interviews conducted transcribed and translated.

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to (b) (6) this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.

Cheers,

Peter

Peter Daszak
President

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EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

A. COVER PAGE

Project Title: Understanding the Risk of Bat Coronavirus Emergence	
Grant Number: 5R01AI110964-03	**Project/Grant Period:** 06/01/2014 - 05/31/2019
Reporting Period: 06/01/2015 - 05/31/2016	**Requested Budget Period:** 06/01/2016 - 05/31/2017
Report Term Frequency: Annual	**Date Submitted:** 05/13/2016
Program Director/Principal Investigator Information: PETER DASZAK , BS PHD **Phone number:** (b) (6) **Email:** (b) (6)	**Recipient Organization:** ECOHEALTH ALLIANCE, INC. ECOHEALTH ALLIANCE, INC. 460 W 34TH ST 17TH FLOOR NEW YORK, NY 100012320 **DUNS:** 077090066 **EIN:** 1311726494A1 **RECIPIENT ID:**
Change of Contact PD/PI: N/A	
Administrative Official: ALEKSEI CHMURA 460 W 34th St., 17th Floor New York, NY 10001 **Phone number:** (b) (6) **Email:** (b) (6)	**Signing Official:** ALEKSEI CHMURA 460 W 34th St., 17th Floor New York, NY 10001 **Phone number:** (b) (6) **Email:** (b) (6)
Human Subjects: Yes HS Exempt: No Exemption Number: Phase III Clinical Trial:	**Vertebrate Animals:** Yes
hESC: No	**Inventions/Patents:** No

B. ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002, and the recent emergence Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then hundreds of novel bat-CoVs have been discovered (including >260 by our group). These, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating a largescale human-wildlife interface, and high risk of future emergence of novel CoVs.
To understand the risk of zoonotic CoV emergence, we propose to examine 1) the transmission dynamics of bat-CoVs across the human-wildlife interface, and 2) how this process is affected by CoV evolutionary potential, and how it might force CoV evolution. We will assess the nature and frequency of contact among animals and people in two critical human-animal interfaces: live animal markets in China and people who are highly exposed to bats in rural China. In the markets we hypothesize that viral emergence may be accelerated by heightened mixing of host species leading to viral evolution, and high potential for contact with humans. In this study, we propose three specific aims and will screen free ranging and captive bats in China for known and novel coronaviruses; screen people who have high occupational exposure to bats and other wildlife; and examine the genetics and receptor binding properties of novel bat-CoVs we have already identified and those we will discover. We will then use ecological and evolutionary analyses and predictive mathematical models to examine the risk of future bat-CoV spillover to humans. This work will follow 3 specific aims:

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces. We will examine if: 1) wildlife markets in China provide enhanced capacity for bat-CoVs to infect other hosts, either via evolutionary adaptation or recombination; 2) the import of animals from throughout Southeast Asia introduces a higher genetic diversity of mammalian CoVs in market systems compared to within intact ecosystems of China and Southeast Asia; We will interview people about the nature and frequency of contact with bats and other wildlife; collect blood samples from people highly exposed to wildlife; and collect a full range of clinical samples from bats and other mammals in the wild and in wetmarkets; and screen these for CoVs using serological and molecular assays.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk. We propose two competing hypotheses: 1) CoV host-range in bats and other mammals is limited by the
phylogenetic relatedness of bats and evolutionary conservation of CoV receptors; 2) CoV host-range is limited by geographic and ecological opportunity for contact between species so that the wildlife trade disrupts the 'natural' co-phylogeny, facilitates spillover and promotes viral evolution. We will develop CoV phylogenies from sequence data collected previously by our group, and in the proposed study, as well as from Genbank. We will examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes. We will predict host-range in unsampled species using a generalizable model of host and viral ecological and phylogenetic traits to explain patterns of viral sharing between species. We will test for positive selection in market vs. wild-sampled viruses, and use data to parameterize mathematical models that predict CoV evolutionary and transmission dynamics. We will then examine scenarios of how CoVs with different transmissibility would likely emerge in wildlife markets.

Specific Aim 3: Testing predictions of CoV inter-species transmission. We will test our models of host range (i.e. emergence potential) experimentally using reverse genetics, pseudovirus and receptor binding assays, and virus infection experiments in cell culture and humanized mice. With bat-CoVs that we've isolated or sequenced, and using live virus or pseudovirus infection in cells of different origin or expressing different receptor molecules, we will assess potential for each isolated virus and those with receptor binding site sequence, to spill over. We will do this by sequencing the spike (or other receptor binding/fusion) protein genes from all our bat-CoVs, creating mutants to identify how significantly each would need to evolve to use ACE2, CD26/DPP4 (MERS-CoV receptor) or other potential CoV receptors. We will then use receptor-mutant pseudovirus binding assays, in vitro studies in bat, primate, human and other species' cell lines, and with humanized mice where particularly interesting viruses are identified phylogenetically, or isolated. These tests will provide public health-relevant data, and also iteratively improve our predictive model to better target bat species and CoVs during our field studies to obtain bat-CoV strains of the greatest interest for understanding the mechanisms of cross-species transmission.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Year 2 NIAID CoV Report Final.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

File uploaded: Year 2 NIAID CoV Report Professional Development.pdf

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

1) Conference and University lectures: PI Daszak, and Co-investigators Shi, Epstein, Olival, Ge, and Zhang gave >100 invited University and Conference lectures including Forum on Microbial Threats (National Academies of Science), Symposium at École du Val-de-Grâce in Paris, Leadership Roundtable at Concordia University Montreal, 1st annual Global Pandemic Policy Summit at Texas A&M Univ., Intl. Conf. of the Wildlife Disease Association in Australia, Intl. Conf. of Conservation Biol in Montpellier France, Michigan State University, Duke University, WDA, ISID conference, Zoological Society of London Symposium, Future Earth meeting, North American Bat Research Symposium, and others that included specific discussion of the current project and results.

2) Agency and other briefings: PI Daszak and Research Technician Dr. Guangjian Zhu introduced this project to potential collaborators within the following agencies: Forestry Dept of Peoples' Republic of China, FAO, TNC, TRAFFIC, China CDC, and TA Foundation in Beijing China in meetings (2015) and also at presentations at the first Wildlife and Public Health Workshop in China (2016) co-hosted by EcoHealth Alliance, the State Forestry Administration of China, and China CDC.

3) Public outreach: PI Daszak presented this work to members of the NIH, NSF, DoD, IUCN, EPA, and the general public, at an EcoHealth Alliance meeting hosted by the Cosmos Club, Washington D.C. (2015); PI Daszak and Co-investigator Zhu reported on this project at a Wildlife Trade and Public Health Seminar, Beijing (2016); PI Daszak introduced this project in a lecture on Pandemics at a New York Academy of Science Panel (2016); Co-PI Y-Z Zhang presented project and results-to-date to department heads and senior researchers at Infectious Disease Departments of four Yunnan Hospitals (2015)

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces.

- Given the reduced amount of wildlife in the local markets within Southern China, and the continued expansion of the Chinese wildlife trade within SE Asia, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia. EcoHealth Alliance has other activities in these countries which would provide leverage to reduce costs of fieldwork, and samples would be tested in Wuhan, China.

- Following the successful collection of ethnographic interviews and focus groups in Year 2, we will be analyzing the qualitative data collection from Years 1 and 2.

- Finalize and conduct survey collection tool for a network study of wildlife farmers using a questionnaire to characterize and map the wildlife value chain.

- After the success of our pilot studies in Year 2, we will continue targeted (at individuals with high risk of exposure to bats), integrated behavioral and biological survey work in Yunnan and expand to Guangxi and Guangdong provinces.

- We will commence our anonymized, surveillance data collection from acutely ill hospital in-patients who satisfy syndromic eligibility criteria; have complete medical records; non-normative laboratory confirmed diagnostic results; and suspected acute viral infection. Eligibility criteria are: (a) suspected acute viral infection; (b) fever > 38˚C, and (c) presenting symptoms of at least one of the following:
•Encephalitis of unknown origin
•Hemorrhagic fever of unknown origin
•Respiratory disease
oInfluenza-like illness (ILI)
oSevere Acute Respiratory like Illness (SARI)
•Rash
•Diarrhea
Some patients with particular infections such as with HIV, HCV, and HBV, may be excluded from the study on that basis. Hospital surveillance has the advantage of monitoring an acutely ill population. Anonymized, passive hospital surveillance allows for data collection and viral testing from all eligible hospital patients thereby limiting population sample bias and increasing the likelihood of identifying positive cases. The strengths of this approach are enormous: an unbiased patient population; prospectively collected, anonymized patient data; a low resource effort with a high efficiency design; and impactful research potential for both case series and case control studies. We have already secured approval from the Institutional Review Boards of the Wuhan School of Public Health and Hummingbird IRB.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk.
Future steps to optimize the model of role of species diversity in CoV emergence risk will include:

- Test and implement our respondent-driven survey to collect specific data on the diversity, abundance, and turnover of species along the wildlife trade network in south China.

- Model viral mixing across the full range parameters found along the wildlife trade network to identify the trade nodes with highest mixing potential. This will include a network analysis of market facility/site connectivity including wild harvest sites, wildlife farming operations, transit holding facilities, and small and large wildlife markets.

- Phylogeographic study of bat-CoV to better understand the geographic distribution and evolution of bat-CoV genetic diversity in south

China.

- Phylogeographic study of bat host (Rhinolophus) species to assess the connectivity of bat populations and infer their historical movements and demographic history to improve our understanding of CoV transmission among bat populations in southern China. Preliminary sequences data has been generated and will be completed and analyzed.

- Cophylogenetic analyses of bat host and CoV phylogenies to assess frequency of cross-species transmission. Comparison of Alpha- and Beta-CoV cophylogenetic patterns building on Year 2 analyses using published sequences and also including Spike gene and additional sequences obtained in Year 2.

- Test and implement our respondent-driven survey to assess diversity, abundance, and turnover of species along the wildlife trade network.

- Examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes;

- Parameterize mathematical models that predict CoV evolutionary and transmission dynamics
- Continued surveillances of SARS-like CoVs and lineage C betacoronaviruses (MERS-related CoVs) in Southern China;

- Full-length genome sequencing and evolution analysis of SARS-like coronaviruses identified from different bat species and different geographical locations across China;

- Full-length genome sequencing and evolution analysis of Lineage C betacoronaviruses identified from different bat species and different geographical locations across China;

- Full-length genome sequencing and evolution analysis of HKU9-related and HKU10-related bat coronaviruses in China;

Specific Aim 3: Testing predictions of CoV inter-species transmission. The following experiments will be undertaken in Year 2:

- Humanized mice with human ACE2 receptors will be infected with WIV1 and the two rescued chimeric SARS-like coronaviruses to determine the tissue tropism and pathogenicity of bat SL-CoV

- Isolation of novel bat coronaviruses. Live virus or pseudovirus will be used to infect cells of different origin or expressing different receptor molecules. Spillover potential for each isolated virus will be assessed.

- An infectious clone of full-length MERS-CoV will be constructed using reverse genetic method. Using the S sequence of different MERS-related viruses identified from Chinese bats, the chimeric viruses with S gene of bat MERS-related coronaviruses and backbone of the infectious clone of MERS-CoV will be constructed to study the receptor usage and infectivity of bat MERS-related coronavirus.

- Surveillance of infection in human populations by SARS-like CoVs. This work will be performed at locations in Yunnan, Guangxi, and Guangdong provinces, in previously identified areas with human populations of high risk of exposure to bats. PCR and ELISA will be used, respectively, for detection of viral replicase gene and antibodies against the viral nucleocapsid protein.

Year 1 Report: Understanding the Risk of Bat Coronavirus Emergence

Award Number: 1R01AI110964-02

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Section B: Accomplishments

B.1 What are the Major Goals of the Project

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B.1a Have the major goals changed since the initial competing award or previous report? No.

B.2 What was accomplished under these goals?

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces

In year 2, we continued and expanded the qualitative research begun at the end of Year 1. In addition, a community based integrated biological behavioral surveillance system was developed and pilot tested to identify specific animal exposure risk factors associated with biological evidence of exposure to SARS-like CoV (i.e., seropositive status).

QUALITATIVE RESEARCH

Targeted, in-depth ethnographic interviews were conducted with 47 individuals (18 women; 29 men) in rural Southern China where wildlife trade routes have been documented. Yunnan, Guangxi and Guangdong provinces were specifically selected for study because they have large wildlife populations, a diversity of wildlife species and numerous live animal markets. Individuals who were 18 years of age or older and who were able to provide informed consent were eligible to participate. Twenty-three (49%) in-depth interviews were conducted in Yunnan province at nine different sites, 24 (51%) in Guangxi province at six different sites. In addition, one focus group was conducted in Guangxi. The study was approved by the Institutional Review Boards of the Wuhan School of Public Health and Hummingbird IRB.

Recruitment sites in each province included forested areas or preserves, wildlife farms, hunting areas, wildlife restaurants, live animal markets, caves where people dwell or collect guano and residential areas/farms near known bat caves or roosts. Participants were recruited primarily through local contacts developed as part of wildlife conservation and health research conducted by team members over the past decade. Contacts including wildlife conservationists and researchers, local government health outreach workers and wildlife farmers facilitated introductions and provided referrals. To achieve a sample with sufficient representation of categories of interest, participants were recruited using

purposive sampling, which provides minimum quotas in terms of sex, age and wildlife exposure setting (e.g., live animal market, forest preserve).

The five core themes that guided the in-depth discussions are: 1) human-animal contact, 2) unusual illness experience and response, 3) socioeconomics and daily living, 4) biosafety and 5) human environments and movement/travel. An ethnographic interview guide was developed with examples of questions that could be asked for each theme. In addition, field based participant-observation was ongoing throughout the study and involved observing and talking informally with people in their own natural setting. Field notes were maintained of these ongoing observations and discussions.

Table 1: Species Observed in Wetmarkets in Guangdong Province from 2015 - 2016

Genus species	Common Name
Prionailurus bengalensis	Leopard Cat
Nyctereutes procyonoides	Raccoon Dog
Sus scrofa	Wild Boar
Lepus sinensis	Chinese Hare
Arctonyx collaris	Hog Badger
Hystrix brachyura	Porcupine
Marmota sp.	Marmot
Rhizomes sinensis	Bamboo Rat
Erinaceus sp.	Hedgehog
Mustela putorius	Ferrets
Muridae	Rat (species unknown)
Myocastor coypus	Nutria
Vulpes sp.	Fox
Mustela sibirica	Siberian weasel
Paguma larvata	Masked Palm Civet
Felis catus	Domestic Cat
Canis lupus familiaris	Domestic Dog
Cervinae	Sambar Deer
Ovis aries	Sheep
Capra sp.	Domestic Goat
Ratus norvegicus	Common Rat

Interviews were conducted between March and June 2105 by 10 trained interviewers, none of whom had social science training. Interviewers conducted between one and 22 interviews; three interviewers conducted two thirds of all interviewers. Interviews lasted between 20 and 60 minutes, and were tape-recorded and transcribed verbatim before they were translated into English. All participants received cooking oil valued at US$10 in appreciation of their time.

The data are currently being coded and an analytic database is being constructed. Initial insights include observations by a number of participants, especially those who are older, that there has been a decrease in wildlife in the surrounding environment. This decrease is attributed to many factors including infrastructure development. The government has invested resources to build new roads and renovate local infrastructure with the intention of increasing tourism. This has reduced forested area.

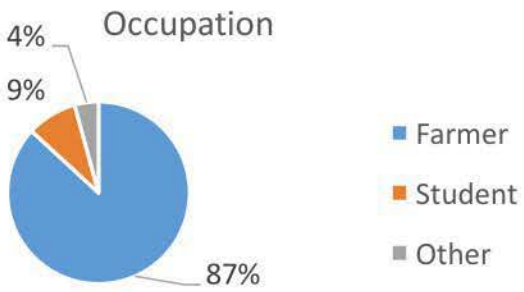
Observations by research staff in live animal markets in Guangzhou found wildlife to be plentiful (see Table 1), although no bats were seen for sale during the observation period. In contrast, wildlife was not found in live animal markets at the sites we visited in either Yunnan or Guangxi. This is a change from previous research visits to the same or similar communities, when bats, rodents and wild boar could be found. Locals in Yunnan and Guangxi attribute the change to conservation law enforcement. The success of conservation enforcement may have moved hunting and trapping underground and made the capture of local wildlife less economically feasible than other income generating activities.

Preliminary analyses are underway. Three specific studies in support of Specific Aim 1 are being developed: the changing wildlife trade in Southern China, the economics of wildlife farming, and zoonotic disease risks resulting from a rapidly changing wildlife trade.

INTEGRATED BIOLOGICAL BEHAVIORAL SURVEILLANCE PILOT STUDY

Currently, mechanisms of zoonotic viral spillover are unknown. In order to evaluate potential risk factors, it is necessary to measure both exposure and outcome data. Therefore, a behavioral risk survey was developed that assessed both animal exposure and experiences of unusual illness both during lifetime and in the past 12 months. In addition, participants were requested to provide serum to test for previous exposure to SARS-like CoV. The integrated surveillance was pilot tested in October 2015 among residents living near bat caves or roosts where SARS-like-CoV has been previously detected in the bat population in Jinning County, Yunnan. Please view the full survey here:

https://www.dropbox.com/s/sv62neywuvl027r/Questionnaire%20Complete.docx?dl=0



Of 218 participants, 139 (64%) were women and 79 (36%) were men, with a mean age of 48 (range: 12-80). Most reported being farmers (87%, and see chart to left); a majority were long term residents (97%). Animal exposures in the past year were extensive, including general (e.g., buying live animals at markets [61%]) and intimate (e.g., being scratched or bitten [9%], slaughter [38%]). In fact, two-thirds of participants reported handling recently killed animal parts and 2 out of 5 reported slaughtering animals. Only 20 (9%) participants reported known exposure to bats.

Standardized syndromic case definitions informed questions concerning unusual illness experience (e.g. severe acute respiratory infections [SARI], influenza-like illness [ILI]). Lifetime, 12 month and unusual illness experience in family for the past 12 months were assessed for all participants. In the past year, SARI was reported by 4 (2%) respondents and for 4 additional family members. Table 2 provides data for all unusual illness experience assessed. None of the participants were found to be seropositive for SARS-like CoV.

Table 2. Unusual Illness Experience

Symptoms	Ever	Past 12 months	Family (12m)
Severe Acute Respiratory Infections (SARI)	15 (6.9%)	4 (1.8%)	4 (1.8%)
Influenza Like Illness (ILI)	54 (24.8%)	16 (7.3%)	26 (11.9%)
Encephalitis	19 (8.7%	4 (1.8%)	3 (1.4%)
Hemorrhagic Fever	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fever with Diarrhea /Vomiting	12 (5.5.%)	2 (0.9%)	3 (1.4%)
Fever with Rash	2 (0.9%)	2 (0.9%)	3 (1.4%)

Although the sample size was small, animal exposures among those who reported unusual illness experiences in the past 12 months were evaluated. Of the four respondents who reported SARI symptoms, 75% reported: raising animals, animals in the home, preparing recently killed animals and buying live animals; 50% reported slaughter. Among the 16 respondents who reported ILI symptoms, 12 (75%) reported handling/preparing recently killed animals, 11 (69%) Handling live animals or having animals in the home, 10 (63%) reported slaughtering/killing animals or buying live animals at wet market, 9 (56%) raised live animals, 7 (44%) reported a pet, and 1 (6%) reported animal feces near food or eating animal touched or damaged food, hunting, or eating raw/undercooked animal products. Finally, among the four respondents who reported encephalitis symptoms, 3 (75%) reported hunting, handling or raising animals, 2 (50%) reported animals in the home, 1 (25%) reported having animals as pets, slaughtering/killing animals, or having bought live animals at wet market.

Respondents were asked about the source of their unusual illnesses. None reported any kind of animal exposure as a potential source of infection and most stated they had no idea how they had become infected. However, when asked about potential behavior changes made at live animal markets in the last 12 months, participants reported a great deal of change. In particular, respondents reported buying live animals less often (38%), only buying farmed wildlife (54%) or buying meat at the supermarket (23%). (See Table 3).

Table 3: Behavior Change at Wet Market in the last 12 months

Behavior	N	(%)
Wear a mask	4	(3.0)
Wear gloves	5	(3.8)
Wash hands	80	(60.6)
Sometimes shop for meat at supermarket	30	(22.7)
Buy live animals less often	50	(37.9)
Buy only farmed wildlife	71	(53.8)
No longer buy wildlife at wet market	39	(29.5)

The results of this pilot study conducted with a largely female farmer population found high levels of unusual illness, as well as high levels of exposure to animals. There was a notable lack of knowledge of animals' ability to transmit infection. Despite this lack of knowledge, there may be a sense of unease about animal exposures, given the fairly dramatic behavior changes reported at live animal markets. The finding of a reduction in wildlife purchase may be due to sensitivity to the legality of wildlife trade, biasing respondents towards not admitting purchasing wildlife. Although, there were no participants seropositive for SARS-like CoV, serological data may add support to the findings from self-reported syndromic surveillance, once serological assays are optimized.

In preparation for full implementation of the integrated biological behavioral surveillance, the survey has been programmed as an application for use on either a mobile device or computer. Electronic data collection will facilitate survey implementation in the field and quality control of the data being collected. Four field team leads were trained on behavioral survey data collection, data collection technologies (the tablet application) and analysis.

Nucleic acid test results of human biological samples

Testing High-Risk Human Populations for Coronavirus Infection

Surveillance of CoV infections in human populations by SARS-like CoVs was significantly expanded in Year 2, including both custom-built ELISA serology (an assay developed by the Wuhan Institute of Virology to test antibodies against the N protein of SL-CoV) and PCR detection of viral RNA.

Serological test for SL-CoV antibodies in human samples from Jinning, Yunnan Province
In order to assess past exposure to bat CoVs, 223 human sera samples were collected in villages in proximity to the bat habitat from which two SL-CoVs with potential for interspecies infection, WIV1 and WIV16, were discovered in our previous research. An ELISA developed by the Wuhan Institute of Virology was used to test antibodies against the N protein of SL-CoV. A number of human specimens generated high OD values and neutralization test to WIV1 and WIV16 was then performed. These findings are encouraging; however, no neutralization antibodies were detected. In Year 3, we will continue to validate and optimize these ELISA assays and other serological tests to obtain data on past CoV exposure.

PCR test for CoV Nucleic Acid in human samples from several Provinces
We tested 405 individual human samples for CoV RNA to identify evidence of active infection in human populations and to obtain sequence data on strain variation. Individual samples (4 each) were pooled prior to nucleic acid extraction then tested using PCR. When a group tested positive, we then conducted the confirmation test in the individual samples. One single sample (14XN611) from someone who had identified as having had a fever and suffered both a cough and headache in the past 7-days was then identified to be positive for HCoV-HKU1. The low number of PCR detections in human specimens is not unexpected, and will be improved in Year 3-5 by better targeting syndromic individuals for specimen collection and continuing to optimize PCR assays. Refined serological assays (above) will provide sufficient data to assess past exposure to specific CoV lineages, and optimizing of PCR detections will allow for more CoV positive human sequences moving forward.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk

Bat CoV PCR detection and sequencing from live-sampled bat populations
We collected 1,714 anal swab samples, 677 fecal samples, 53 blood samples, and 38 serum samples from 15 bat genera in Guangdong, Yunnan, Sichuan, Hubei, Hunan, Guizhou, Guangxi provinces (Table 4).

Table 4 Bat Samples collected for CoV surveillance in 2015

Sample date	Sample location	Anal	Fecal	Blood	Serum
Mar. 2015	Huidong, Guangdong	69	--	--	--
Jun. 2015	Guangdong	495	--	12	--
Apr. 2015	Menglun, Yunnan	51	--	--	--
May 2015	Jinning, Yunnan	--	193	--	--
May. 2015	Mojiang, Yunnan	93	--	--	--
Oct. 2015	Jinning, Yunnan	30	--	--	--

Dec, 2015	Jingna, Yunnan	15	15	13	13
	Miaoxin, Yunnan		42	28	25
Jul, 2015	Zigong, Sichuan	128	--	--	--
Aug, 2015	Hubei		332		
Sep, 2015	Xianning, Hubei		95		
Aug, 2015	Jishou, Hunnan	204			
Aug-Sep, 2015	Tongren, Guizhou	438			
Dec, 2015	Longzhou, Guangxi	191			
	Total	1714	677	53	38

We tested 2,256 samples for CoV RNA and 280 tested positive. The total positive rate is 12.4% (Table 5). Diverse alphacoronaviruses related to Bat CoV 1A, 1B, HKU2, HKU6, HKU7, HKU8 and HKU10 were identified; SARS-like coronaviruses were detected in *Rhinolophus* bats in both Yunnan and Guangdong (Fig 1). Novel lineage B betacoronaviruses more distantly related to SARS-CoV than other SL-CoVs were detected in *Vespertilo superans* in Sichuan. HKU4-related coronaviruses were found in *Tynolycteris pachypus* in Guangdong and Guangxi while HKU5-related coronaviruses were found to be highly prevalent in *Vespertilio superans* in Zigong, Sichuan (41 bats out of 128 tested positive).

Table 5 Test result of bat CoV surveillance in 2015 – 12% positive (280/2,256)

	Yunnan	Guangdong	Hubei	Sichuan	Guangxi	Guizhou	Hunan	Total
Bat species	**No.positive/No.tested**							
Rhinolophus spp.	47/98	12/103				16/225	8/63	83/489
Hipposideros spp.	0/35	0/51	26/152			0/131	0/91	26/460
Ia io						0/3		0/3
Pipistrellus spp.	1/1	0/19				0/2	0/4	1/26
Miniopterus spp.	6/7	34/83				2/6		42/96
Eonycteris spp.	0/3							0/3
Vespertilio superans				41/128				41/128
Myotis spp.		1/38				0/70	0/35	1/143
Taphozous spp.	0/25					0/1		0/26
Tynolycteris pachypus		8/25			27/191			35/216
Scotophilus kuhlii		1/1						1/1
Eptesicus fuscus		0/1						0/1
Tadrida spp.		0/5						0/5
Barbastella							0/1	0/1
Nyclatus velutiaus							0/10	0/10
Fecal samples	28/468		22/180					50/648
Sub-total	82/637	56/326	48/332	41/128	27/191	18/438	8/204	**280/2256**

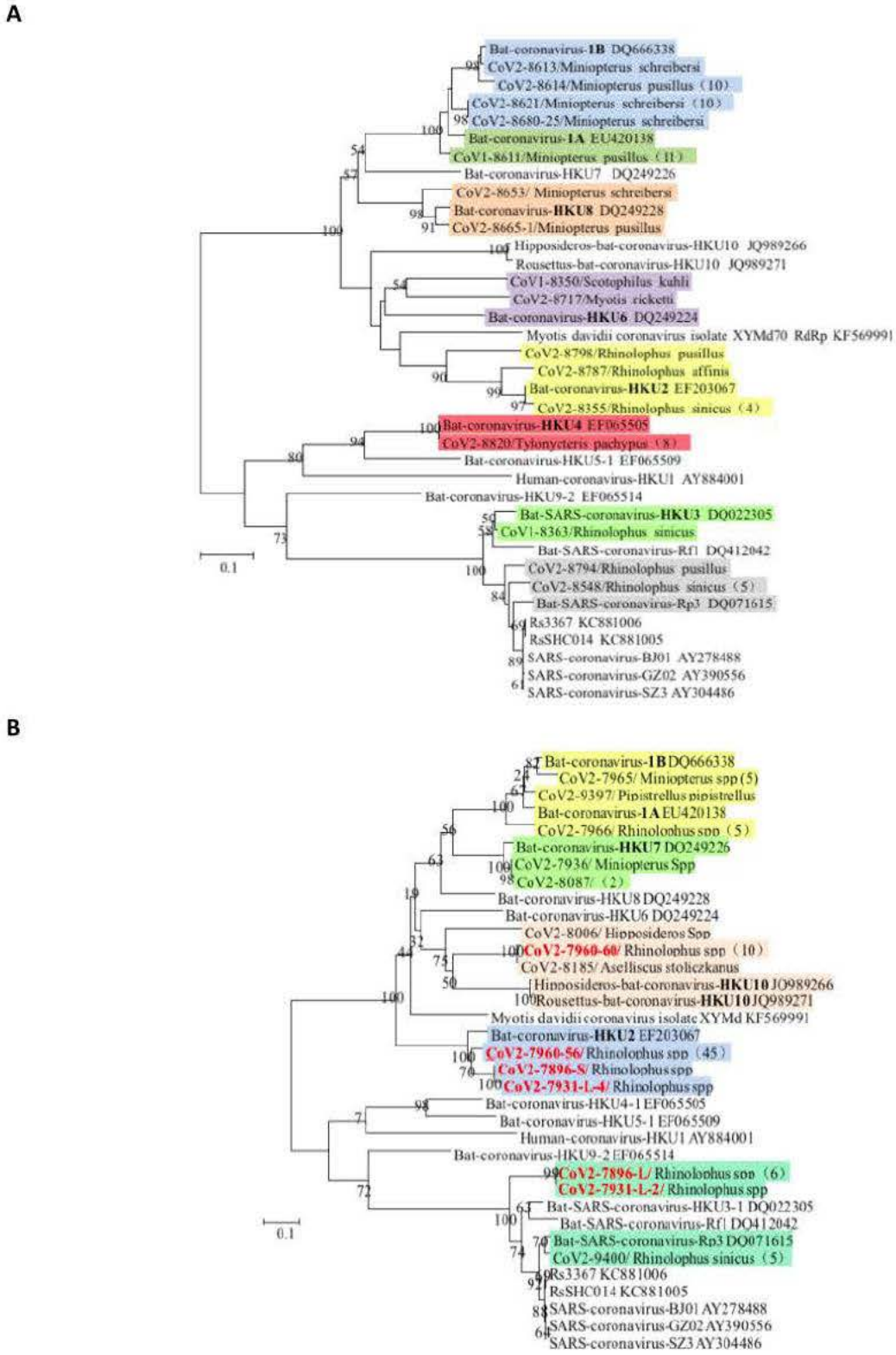


Fig 1 Phylogenetic analysis of partial RdRp gene of CoV (440-nt partial sequence). CoVs identified in 2015 are named by the sample numbers. Sequence amplified from samples co-infected with two CoV strains are indicated in red. (A) CoVs detected in Guangdong. (B) CoVs detected in Yunnan.

Cophylogenetic analysis of CoV host switching

We completed preliminary cophylogenetic analysis of bat host – CoV sequences using data published in the literature and available on Genbank. Two figures from these analyses are highlighted below (Figs 2 and 3) and these methods are currently being extended using partial RdRp CoV and bat mitochondrial DNA sequences from a large number of bat specimens found CoV positive in Year 2 (Table 5, above).

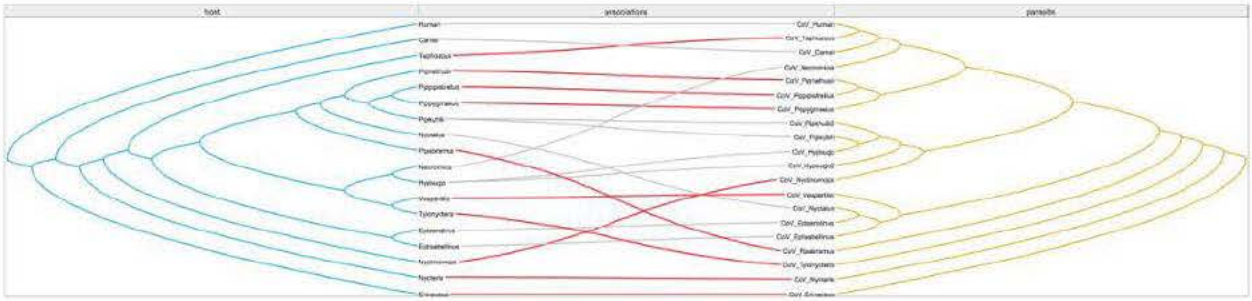


Figure 2: Tanglegram depicting the pattern of infection of bats (and outlier mammalian hosts) by CoVs. The CoV tree was reconstructed from DNA sequences available in GenBank (partial RdRp gene) using Bayesian inference (MrBayes). The topology of host tree was reconstructed using the mammal and bat phylogenies available in Asher & Helgen (2010) and Agnarsson et al. (2011), using methods our group has previously applied to bat parasite cophylogenetic analyses (Lei and Olival 2014). Both ParaFit (ParaFitGlobal = 64957.61, p-value = 0.001) and PACo (m2 = 366.44, p-value = 0.013) provided evidence for significant global congruence between the two topologies, and evidence for coevolution. Lines connecting taxa indicate host-CoV associations. Red lines indicate significant host-CoV associations as indicated by ParaFit ($p \leqslant 0.05$, 999 permutations).

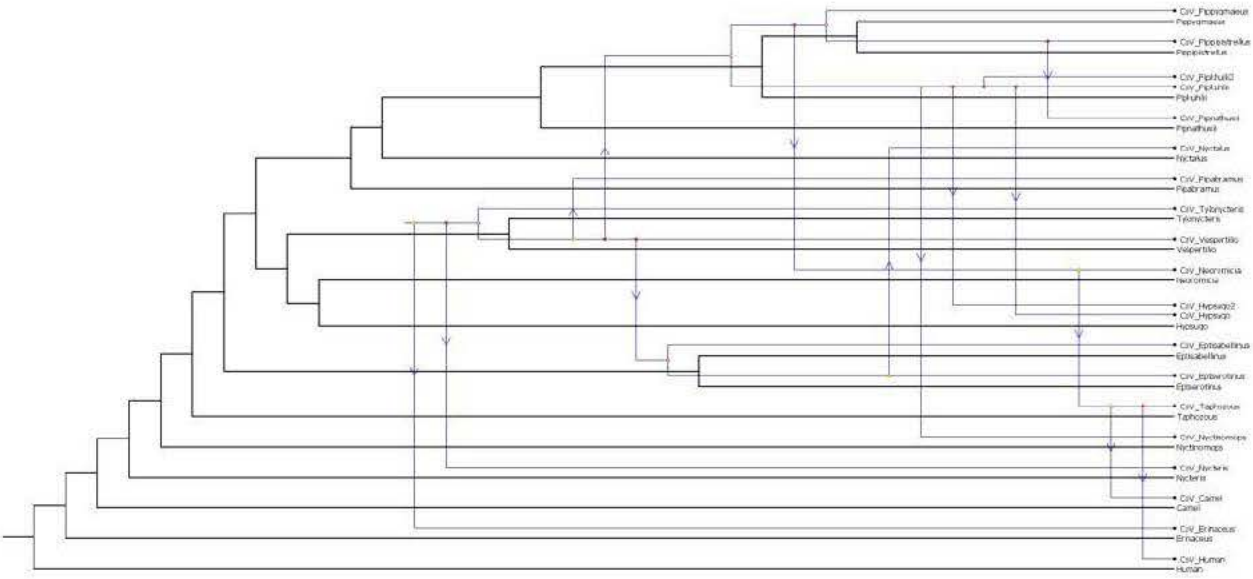


Figure 3: Reconstruction of one of 3 potentially optimal solutions of reconciled host-CoV trees recovered from a Jane analysis. Black and blue lines represent the host and CoV trees, respectively. For each solution, the number of co-speciation events inferred by Jane was always significantly greater than expected by chance. Jane inferred 4 co-speciation events (hollow colored circles), 1 duplication (solid

colored circle), 14 host switches (solid colored circle with arrow), 0 loss and 0 failure to diverge.

Our findings demonstrate co-speciation alone is not sufficient to explain the observed co-phylogenetic pattern and several host switches can be specifically identified. This is the case even if a significant global signal of co-speciation has been detected. This work highlights, the need for these types of detailed cophylgoenetic analyses to best explain the evolutionary history and host-switching of bat-CoVs.

References cited for the above analysis: Agnarsson, I., Zambrana-Torrelio, C.M., Flores-Saldana, N.P. & May-Collado, L.J. (2011) A time-calibrated species-level phylogeny of bats (Chiroptera, Mammalia). *PLOS Currents*, 3:RRN1212. Asher, R.J. & Helgen, K.M. (2010) Nomenclature and placental mammal phylogeny. *BMC Evolutionary Biology*, 10, 1-9. Lei BR, Olival KJ (2014) Contrasting Patterns in Mammal–Bacteria Coevolution: *Bartonella* and *Leptospira* in Bats and Rodents. *PLoS Negl Trop Dis* 8(3): e2738.

Market Characterization Model Parameterization

Our ongoing observational research and mapping of farms and markets suggests that rapid changes in the market and regulatory environment are changing the nature and location of the wildlife market trade. The nexus of the wildlife trade and the potential hotspots of interspecies viral mixing is now in many cases in animal storage facilities and transport between high-volume customers. To define realistic parameters for intermixing wildlife species in areas of high potential mixing, we have developed a preliminary survey and sampling protocol to assess these values as animals move along the value chain – through these storage facilities - using respondent-driven questionnaires to follow and sample along the wildlife trade network and reveal hidden nodes and sites of intermixing of species.

We have expanded our intermixing modeling framework to incorporate the variations along this value chain, where the diversity, abundance, residence time, and contact rates between species change as animals move through the trade network.

Specific Aim 3: Testing predictions of CoV inter-species transmission.

In Year 2, we continued surveillance for novel SARS-like CoVs from bats in Yunnan and Guangdong provinces and obtained full genome sequence for 11 CoV isolates. Full genome analysis of these CoV isolates was completed, including phylogenetic and recombination analyses. Importantly, recombination analysis of the full-length SL-CoV genome sequences from a single bat population revealed that frequent recombination events among different SL-CoV strains occur. Several SL-CoVs that are more genetically similar to SARS-CoV (2003) than any previously discovered were also identified from bat populations in Yunnan province. Full genome analysis suggests that an epicenter of SL-CoV occurs in rhinolophid bats and provides more insight into the evolutionary origin of SARS-CoV.

Full-length genome sequencing of SL-CoVs identified from a single bat colony

To date, including preliminary data submitted for this R01 that we are now analyzing under the current funding, we have conducted 5-years of surveillance of SL-CoV in a single bat colony in Yunnan Province (from 2011 to 2015), leading to the discovery of diverse novel SL-CoVs. Based on genotyping of these SL-CoVs by the region corresponding to the receptor-binding domain (RBD) of SARS-CoVs, 11 isolates were selected and full-length genome sequencing was performed in Year 2.

These SL-CoVs, including four others isolated previously from this colony, Rs3367, RsSHC014, WIV1 and WIV16, are highly diversified in the S gene, but share similar sequence identity to SARS-CoV in ORF1ab (Fig 4). Genomic phylogenetic analysis showed that the SL-CoVs detected in this colony are more closely

related to SARS-CoVs from other geographic regions, especially three isolates, WIV16, Rs4874 and Rs4231 (Fig 5). Notably, among the 15 SL-CoVs, two isolates, Rs4084 from *Rhinolophus sinicus* and Rf4092 from *Rhinolophus ferrumequinum*, are highly similar to SARS-CoV in the ORF8 region (Fig 5). Rf4092 possessed a single ORF8 of the same length (369bp) as that in civet SARS-CoV SZ3, and the sequence showed only 10 nucleotide substitution (Fig 6). The ORF8 sequence of Rs4084 is highly similar to that of Rf4092, however in the region corresponding to the 29-bp deletion acquired in human SARS CoVs (e.g Tor2), a shorter deletion of only 5-bp is present, resulting in two overlapping ORF8s, ORF8a and ORF8b. The position of start codon and stop codon of the two ORFs were consistent with those in human strains (Fig 6).

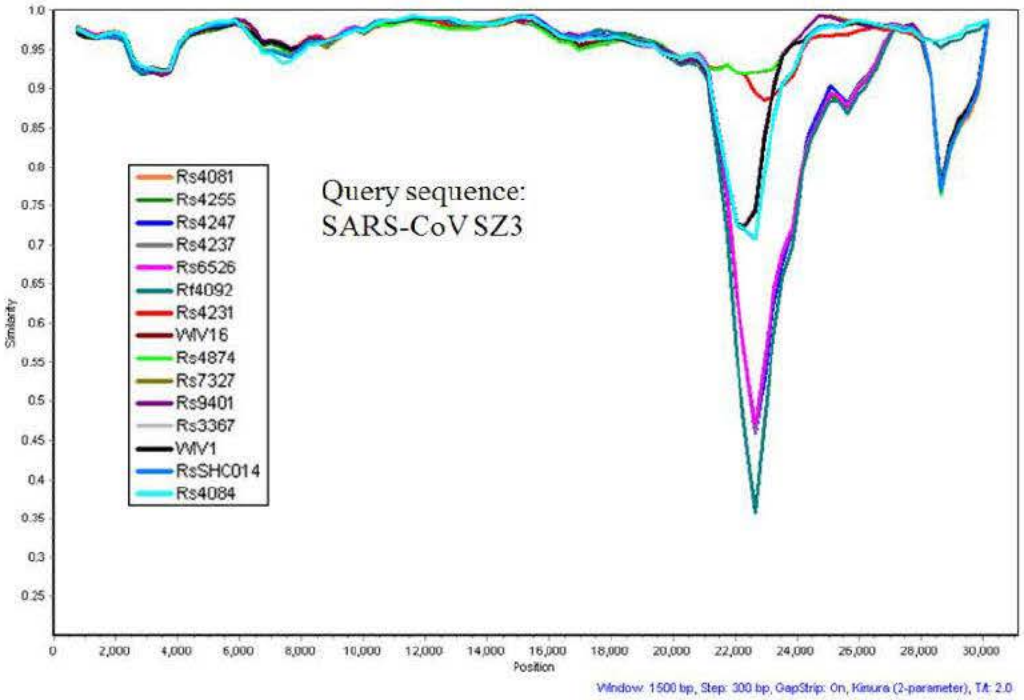


Fig 4. Simplot analysis of the 15 SL-CoVs identified from a single bat colony in Yunnan. SARS-CoV SZ3 is used as query sequence.

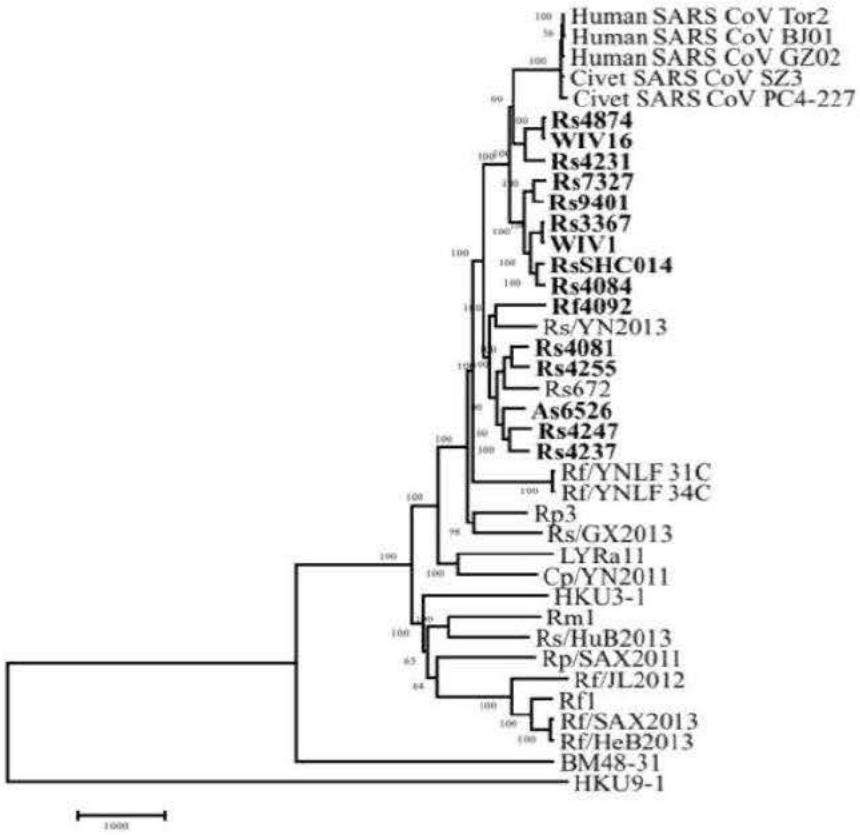
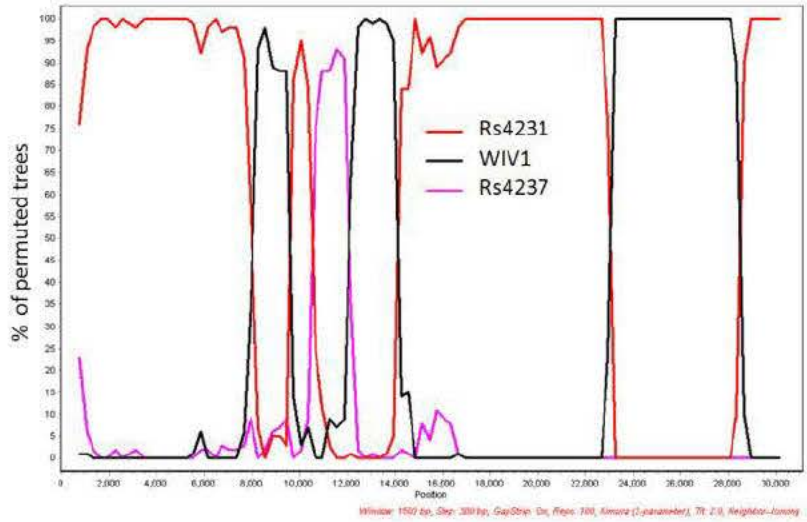


Fig 5. Phylogenetic analysis of full-length genome sequences of SL-CoVs and SARS-CoVs. Isolates identified in the single investigated bat colony in Yunnan in in bold.

Fig 6. Alignment of ORF8 nucleotide sequences of SARS-CoV and bat SL-CoVs. The red box indicates the 29-nt deletion present in SARS-CoV of middle and late phase.

Recombination analysis of the full-length genome sequences reveals frequent recombination events among different SL-CoV strains circulating in this bat population. For example, WIV16 appears to be a recombination product of WIV1 and Rs4231. An important breakpoint is identified between the N-terminal domain (NTD) and RBD region in the S gene (Fig 7A). Consequently, WIV16 is identical to Rs4231 and WIV1 in NTD and RBD of the spike protein, respectively, and is highly homologous to SARS-CoV in both NTD and RBD. This makes it the SL-CoV most closely related to the direct progenitor of SARS-CoV discovered to date. Moreover, evidence is found to support the hypothesis that the direct progenitor of SARS-CoV was generated from recombination of WIV16 with Rf4092 at the site near ORF8. This work, which identifies diverse SL-CoVs highly homologous to SARS-CoV in different regions of the genome, suggests that rhinolophid bats are an evolutionary epicenter of SL-CoV and offers more insights into the evolutionary origin of SARS-CoV.

A.



B.

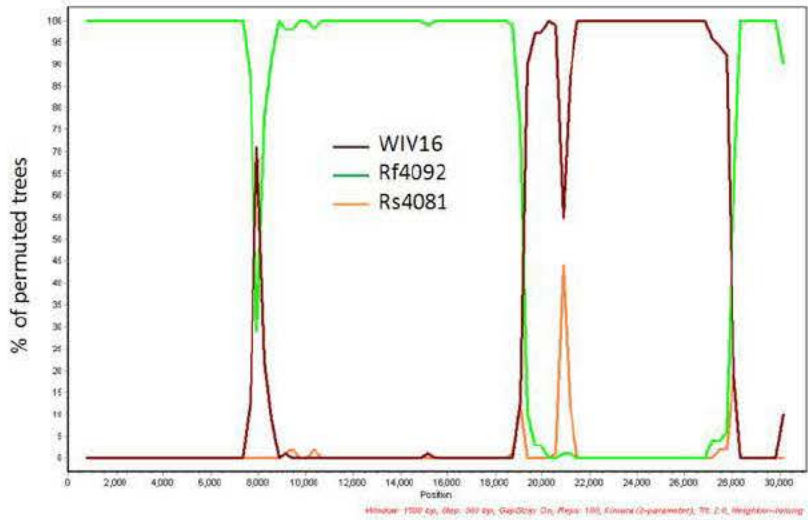


Fig 7 Bootscan analysis of full-length genome sequences of SL-CoVs. (A) WIV16 is used as query sequence. (B) SARS-CoV SZ3 is used as the query sequence. (Kimura model, window size, 1500bp, step size, 300bp)

Additional Year 2 items for Specific Aim 3:

- The infectious clone of WIV1 was successfully constructed using reverse genetic methods;
- Two chimeric bat SARS-like coronavirus strains were constructed by replacing the S gene in the backbone of WIV1;
- Permission to import mice with human ACE2 to China was obtained, so as to conduct the experimental infections proposed in our R01 specific aims.

Specific Goals Not Met.

- Comparative cophylogenetic analyses of bat host and CoV RdRp and Spike gene phylogenies, to assess patterns of evolutionary congruence and frequency of cross-species transmission (This will be conducted in year 3);
- Animal infection experiments of SARS-like coronaviruses were not done, because of the unavailability of mice with human ACE2 in Year 2. We now have secured these mice and will begin this work in year 3.
- Sampling of bat and other mammalian species in markets to screen for CoVs. We will begin this work in year 3.

Section C: Accomplishments: Publications

PUBLISHED

Xing-Yi Ge, Ning Wang, Wei Zhang, Ben Hu, Bei Li, Yun-Zhi Zhang, Ji-Hua Zhou, Chu-Ming Luo, Xing-Lou Yang, Li-Jun Wu, Bo Wang, Yun Zhang, Zong-Xiao Li, and Zheng-Li Shi. Coexistence of multiple coronaviruses in several bat colonies in an abandoned mineshaft. *Virologica Sinica* 31, 31–40 (2016).

Mei-Niang Wang, Wei Zhang, Yu-Tao Gao, Ben Hu, Xing-Yi Ge, Xing-Lou Yang, Yun-Zhi Zhang, Zheng-Li Shi. Longitudinal surveillance of SARS-like coronaviruses in bats by quantitative real-time PCR, *Virologica Sinica* 31(1): 78-80 (2016).

Cristin C. W. Young and Kevin J. Olival. Optimizing Viral Discovery in Bats. *PLoS ONE* 11(2) (2016).

Kevin J. Olival. To Cull, or Not To Cull, Bat is the Question. *Ecohealth* 13, 6–8 (2015).

Xing-Lou Yang, Ben Hu, Bo Wang, Mei-Niang Wang, Qian Zhang, Wei Zhang, Li-Jun Wu, Xing-Yi Ge, Yun-Zhi Zhang, Peter Daszak, Lin-Fa Wang, Zheng-Li Shi. Isolation and characterization of a novel bat coronavirus closely related to the direct progenitor of Severe Acute Respiratory Syndrome Coronavirus, *Journal of Virology* 90(6): 3253-6 (2015).

Ben Hu, Xingyi Ge, Lin-Fa Wang, Zhengli Shi. Bat origin of human coronaviruses. *Virology Journal* 12 (1): 221 (2015)

ACCEPTED, IN PRESS

Lei-Ping Zeng, Yu-Tao Gao, Xying-Yi Ge, Qian Zhang, Cheng Peng, Xinglou Yang, Bin Tan, Jing Chen, Aleksei Chmura, Peter Daszak, and Zheng-Li Shi. Bat SARS-like coronavirus WIV1 encodes an extra accessory protein ORFX involving in modulation of host immune response. *Journal of Virology* (in press, 2016)

B.4 What opportunities for training and professional development has the project provided?

We presented our project to graduate students, laboratory personnel, directors, and doctors from three Hospitals in Yunnan Province: Yunnan Provincial Institute of Endemic Diseases Control & Prevention (YNCDC); Dali Provincial Hospital; and The Third People's Hospital of Kunming. Select doctors at YNCDC (1) and Dali Provincial Hospital (3) were trained in the passive Hospital surveillance project protocols.

We trained graduate students from Dali School of Public Health (1) and the Wuhan University School of Public Health (3) in qualitative behavioral risk data collection methodologies and data collection technologies, survey data collection and analysis. These were also enrolled in and passed the Human Subjects Research Course provided by the Collaborative Institutional Training Initiative (CITI Program) at the University of Miami (http://citiprogram.org). The CITI Program is a leading provider of research education content with web based training materials serving millions of learners at academic institutions, government agencies, and commercial organizations in the U.S. and around the world.

C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

Yes

Publications Reported for this Reporting Period

Public Access Compliance	Citation
Complete	Yang XL, Hu B, Wang B, Wang MN, Zhang Q, Zhang W, Wu LJ, Ge XY, Zhang YZ, Daszak P, Wang LF, Shi ZL. Isolation and Characterization of a Novel Bat Coronavirus Closely Related to the Direct Progenitor of Severe Acute Respiratory Syndrome Coronavirus. J Virol. 2015 Dec 30;90(6):3253-6. PubMed PMID: 26719272; PubMed Central PMCID: PMC4810638.
Complete	Olival KJ. To Cull, or Not To Cull, Bat is the Question. Ecohealth. 2016 Mar;13(1):6-8. PubMed PMID: 26631385; PubMed Central PMCID: PMC4833651.

Non-compliant Publications Previously Reported for this Project

Public Access Compliance	Citation
Non-Compliant	(b) (4)

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period?

No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	SSN	DOB	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
(b) (6)	Y	DASZAK, PETER	(b) (6)	(b) (6)	BS,PHD	PD/PI	(b) (4), (b) (6)					NA
	N	HOSSEINI, PARVIEZ RANA	(b) (6)	(b) (6)	BS,PHD	Co-Investigator						NA
(b) (6)	Y	Ross, Noam Martin		(b) (6)	PhD	Co-Investigator						NA
	N	OLIVAL, KEVIN J	(b) (6)	(b) (6)	PHD	Co-Investigator						NA
	N	KE, CHANGWEN			PHD	Co-Investigator				Center for Disease Control and Prevention of Guangdong Province	CHINA	NA
	N	ZHANG, SHUYI		(b) (6)	PHD	Co-Investigator				East China Normal University	CHINA	NA
	N	ZHANG, YUNZHI		(b) (6)	PHD	Co-Investigator				Yunnan Provincial Institute of Endemic Diseases Control & Prevention	CHINA	NA
	N	ZHU, GUANGJIAN		(b) (6)	PHD	Co-Investigator				East China Normal University	CHINA	NA
	N	GE, XINGYI			PHD	Co-Investigator				Wuhan Institute of Virology	CHINA	NA
	N	EPSTEIN, JONATHAN H	(b) (6)	(b) (6)	MPH,DVM,BA,PHD	Co-Investigator						NA
	N	CHMURA, ALEKSEI A	(b) (6)	(b) (6)	BS	Non-Student Research Assistant						NA
	N	SHI,		(b) (6)	PhD	Co-				Wuhan	CHINA	NA

		ZHENGLI				Investigator				Institute of Virology		

Glossary of acronyms:
S/K - Senior/Key
DOB - Date of Birth
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RE - Reentry Supplement
DI - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

No

D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

Yes

File uploaded: Noam Ross CV 2016.pdf

D.2.c Changes in Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

No

D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

D.2.e Multi-PI (MPI) Leadership Plan

Will there be a change in the MPI Leadership Plan for the next budget period?

NA

Noam Ross

(b) (6)
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EDUCATION

University of California — Davis, CA
Doctoral Candidate in Ecology — Expected Completion Summer 2015

- Dissertation Committee: Alan Hastings (major professor, Ecology), David Rizzo (Plant Pathology), Jim Sanchirico (Natural Resource Economics)
- Dissertation Research: "Managing Emerging Forest Disease Under Uncertainty"

Brown University — Providence, RI
Bachelor of Science in Environmental Science, Magna Cum Laude — May 2006

- Honors Thesis: "Soil Organic Matter in Northern Mongolia: Permafrost and Land-Use interactions"
- Phi Beta Kappa, Sigma Xi, Environmental Science Honors, Rosenberger Prize for Outstanding Service

SCIENTIFIC PUBLICATIONS

- Carl Boettiger*, **Noam Ross***, Alan Hastings (2013) *Early Warning Signals: The Charted And Uncharted Territories.* Theoretical Ecology http://dx.doi.org/10.1007/s12080-013-0192-6
- Fuller, Kate, David Kling, Kaelin Kroetz, **Noam Ross**, and James N. Sanchirico (2013) *Economics and Ecology of Open-Access Fisheries.* In: Shogren, J.F., (ed.) Encyclopedia of Energy, Natural Resource, and Environmental Economics, Vol. 2 Encyclopedia of Energy, Natural Resource, and Environmental Economics p.39-49. Amsterdam: Elsevier. http://dx.doi.org/10.1016/B978-0-12-375067-9.00114-5

In preparation

- (b) (4)
-

**Co-equal authorship*

POSTERS

- **Ross, Noam**. "Optimal Control of Disease in Space: An Approach Using Individual-based Models," June 1-4, 2014. 12th Annual Conference of Ecology and Evolution of Infectious Disease, Fort Collins, Colorado.
- **Ross, Noam**. "Designing Protective Treatments for Forest Disease Using a Spatial Point Process Model," November 20-21, 2014. California Forest Pest Council Annual Meeting, McClellan, CA.
- **Ross, Noam**. "Optimal Control of Forest Disease Under Changing Community and Spatial Structure," November 4-18, 2013. Sustainable Management of Natural Resources Workshop, Mathematical Biosciences Institute, Columbus, OH.

PRESENTATIONS

- **Ross, Noam**, "Fungal Disease Mortality: Modeling for Management of Sudden Oak Death." Dec 1, 2014 Invited talk at EcoHealth Alliance, New York, NY.
- **Ross, Noam**, "Modeling forest disease using a macroparasite framework ," Agust 13, 2014. 99th Annual Ecological Society of America Meeting, Sacramento, CA.
- Ashander, Jamie, Kelly Gravuer, Megan Kelso, Mary E. Mendoza and **Noam Ross** "Managing River-Floodplains Systems: A Historical and Ecological Perspective" September 14, 2002. Presentation at NSF REACH IGERT Floodplains Workshop

AWARDS + FELLOWSHIPS (*Total received $225,429*)

- Don Dahlsten Memorial Grant ($325) — California Forest Pest Council, 2012
  Designing Protective Treatments for Forest Disease Using Spatial Point Process Models
- NSF IGERT Bridge Fellowship ($57,500) — UC Davis, CA, 2012
  Managing Emerging Forest Disease Under Uncertainty
- NSF IGERT Traineeship in Rapid Environmental Change ($115,00) — UC Davis, CA, 2010
  Modifying River-Floodplain Systems: A Historical and Ecological Approach
- UC Davis Graduate Group in Ecology Fellowship ($40,604) — UC Davis, CA, 2010
- NSF Research Experience for Undergraduates Fellowship ($8,000) — Acad. of Natural Sciences, PA, 2005
- Undergraduate Research Fellowship ($4,000) — Brown University, RI, 2003

SERVICE + PROJECTS

- **Workshop Instructor,** Software Capentry and Data Carpentry Foundations — Jan 2015–Present
- **Student Rep,** UC Davis Graduate Group in Ecology Executive Committee — Sep 2013–Present
- **Reviewer:** *Theoretical Ecology* (4 reviews) — Feb 2013–Present
- **Web Developer and Technology Chair,** Ecology Graduate Student Association — June 2013–Present
  Creator + Maintainer of graduate student blog, resources, and news site (egsa.ucdavis.edu)
- **Founder + Organizer,** Davis R Users' Group — Sep 2012–Present
  Created users group that provides tutoring and seminars to graduate students in 10+ departments
- **Contributor,** R packages `knitr, knitcitations, rcrossref, rethinking` — 2012-Present
- **Organizer:** NSF REACH IGERT Workshop on Multiple Goals in Floodplain Restoration — Sep 2012
- **Organizer,** UC Davis Conference on Ecology and the Business Sector — Apr 2011
- **Organizer**, UC Davis Graduate Group in Ecology Symposium — May 2010-2011
- **External Reviewer,** World Resources Institute Corporate Ecosystem Services Review — Jan 2008
- **External Reviewer,** McKinsey-Clinton Global Initiative Forestry Project — Mar 2008
- **Business Stewardship Volunteer,** NY Coastal Marine Resources Center — Feb-Apr 2007

OTHER WORK EXPERIENCE

GreenOrder — New York, NY
Analyst, Senior Analyst: Corporate Environmental Strategy + Governance — Sep 2006–Oct 2009

- Conducted environmental performance analysis for products in energy, transportation, and water sectors
- Created green product metrics system R&D stage-gating system for construction products manufacturer
- Managed engagement with equipment rental company to identify growth opportunities in green building
- Performed market and competitive analyses for a wide array of clients in retail, real estate financial and cleantech sectors; prepared and delivered client presentations; managed projects
- Managed analysts performing environmental product certifications and market research
- Developed firm seminar series and analyst training materials; conducted trainings on topics including auditing, statistical analysis, and environmental performance benchmarking
- Audited certifications for environmental products and facility performance

Wal-Mart — Providence, RI
Contract Researcher/Consultant: Energy Efficient Products Initiative — May-Sep 2006

- Developed forecasting model for sales of energy-efficient lamps at Wal-Mart stores
- Created guidelines for design of lamp recycling program

Brown University Facilities Management Providence, RI
Administrative, Research, + Teaching Assistant: Energy and Design Jan 2003–May 2006

- Developed energy-use and financial projections for university energy usage scenarios
- Performed background research and feasibility analysis for university energy efficiency projects
- Provided tutoring, logistical support and web design for two courses in sustainable design
- Responsible for maintenance of energy efficient, low-impact building

Hovsgol Lake Global Environmental Facility and Brown University Mongolia + Providence, RI
National Science Foundation REU Fellow, Thesis Research June 2005-May 2006
Advisor: Clyde Goulden

- Independent research on climate-land use interactions on permafrost soil carbon storage
  Plant surveys, soil pit excavation, soil physical and chemical analysis, soil microbial process incubations

Marine Biological Laboratory Ecosystems Center Woods Hole, MA
Semester in Environmental Science Student Aug-Dec 2004
Advisor: Charles Hopkinson

- Examined effects of nitrogen pollution on structure of microplankton food webs
- Microcosm experiments, fluorescence microscopy, dissolved nutrient analysis, planktonic growth incubations

Brown Center for Environmental Studies Providence, RI
Undergraduate Research Fellow Jun-Aug 2003
Advisor: Steven Hamburg

- Conducted research in biogeochemistry at Hubbard Brook Experimental Forest and surrounding region; oversaw soil pit excavation by undergraduate and graduate field crew
- Plant surveys, forest floor measurements, litter collection, soil pit excavation, soil physical and chemical analysis, GIS analysis in ESRI ArcMap

PUBLICATIONS IN POPULAR PRESS

- "Extinction Debt,"(Initial author) Wikipedia. Wikimedia Foundation, Inc., February 23, 2011 http://en.wikipedia.org/wiki/Extinction_debt
- "If Everyone Moves to the City, What Gets Left Behind?" *Good.is,* January 17, 2011. http://www.good.is/post/if-everyone-moves-to-the-city-what-is-left-behind/
- "Why the Ethanol Debate Isn't Helping Anyone," *GreenBiz.com*, Jun 3, 2009. http://www.greenbiz.com/blog/2009/06/03/why-ethanol-debate-isnt-helping-anyone
- "Four Lean, Green Strategies for an Uncertain Economy," (with Andrew Shapiro) *Harvard Business Review's Leading Green*, Oct 29, 2008. http://blogs.hbr.org/2008/10/4-lean-green-strategies-for-an/
- "What a Silent Spring Means for Business Risk," *GreenBiz.com*, Mar 6, 2007. http://www.greenbiz.com/blog/2007/03/05/what-silent-spring-means-business-risk

E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Dollar Amount	Country
211699	CHINA

F. CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

Yes

Is the research exempt from Federal regulations?

No

Does this project involve a clinical trial?

No

G.4.b Inclusion Enrollment Data

Report Attached: Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001

G.4.c ClinicalTrials.gov

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?

No

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Are there personnel on this project who are newly involved in the design or conduct of human subjects research?

No

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Does this project involve vertebrate animals?

Yes

G.8 PROJECT/PERFORMANCE SITES

Organization Name:	DUNS	Congressional	Address

		District	
Primary: EcoHealth Alliance, Inc.	077090066	NY-010	460 West 34th Street 17th Floor New York NY 100012317
Wuhan Institute of Virology	529027474		Xiao Hong Shan, No. 44 Wuchang District Wuhan
East China Normal University	420945495		3663 Zhongshan Beilu Shanghai
ECOHEALTH ALLIANCE	077090066		ECOHEALTH ALLIANCE, INC. 460 W 34TH ST NEW YORK NY 100012320
EcoHealth Alliance, Inc.	077090066	NY-010	460 West 34th Street 17th Floor New York NY 100012317
Wuhan Institute of Virology	529027474		Xiao Hong Shan, No. 44 Wuchang District Wuhan
East China Normal University	420945495		3663 Zhongshan Beilu Shanghai

G.9 FOREIGN COMPONENT

Organization Name: Wuhan Institute of Virology
Country: CHINA
Description of Foreign Component:
Principal Laboratory for all Research in China as per section G8 (above) and detailed in our Specific Aims

Organization Name: East China Normal University
Country: CHINA
Description of Foreign Component:
Principal Coordinating Team for all project field work as per section G8 (above) and detailed in our Specific Aims

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

No

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period?

No

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?

No

Inclusion Enrollment Report

Inclusion Data Record (IDR) #: 166195

Using an Existing Dataset or Resource: No

Delayed Onset Study ?: No

Clinical Trial: No

Enrollment Location: Foreign

NIH Defined Phase III Clinical Trial: No

Study Title: Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001

Planned Enrollment

Planned Enrollment Total: 2,460

NOTE: Planned enrollment data exists in the previous format; the PD/PI did not enter the planned enrollment information in the modified format and was not required to do so. Only the total can be provided.

Cumulative Enrollment

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native	0	0	0	0	0	0	0	0	0	**0**
Asian	157	108	0	0	0	0	0	0	0	**265**
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	**0**
Black or African American	0	0	0	0	0	0	0	0	0	**0**
White	0	0	0	0	0	0	0	0	0	**0**
More than One Race	0	0	0	0	0	0	0	0	0	**0**
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	**0**
Total	**157**	**108**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**265**

Greer, Jenny (NIH/NIAID) [E]

From: Normil, Carine (NIH/NIAID) [C]
Sent: Friday, May 13, 2016 10:25 AM
To: Greer, Jenny (NIH/NIAID) [E]
Subject: FW: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Friday, May 13, 2016 9:11 AM
To: Normil, Carine (NIH/NIAID) [C] (b) (6)
Cc: DMID GrantOps <DMIDGrantOps@niaid.nih.gov>
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Carine,
The PI submitted their progress report last night and I reviewed it this morning. They have proposed work for the next year of the award that may be subject to the gain-of-function funding pause. This means that we will need to review the work in our DMID GoF committee and determine whether the proposed work is subject to the pause. This process can take several weeks, especially if we need to request additional information from the PI. I am planning to bring this up at our DMID GoF committee meeting this afternoon, and will keep you updated.

Let me know if you have any questions.
Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: (b) (6)
Email: (b) (6)

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.
****

From: Normil, Carine (NIH/NIAID) [C]
Sent: Monday, May 09, 2016 5:27 PM
To: (b) (6)
Cc: Stemmy, Erik (NIH/NIAID) [E] (b) (6); (b) (6)

Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Importance: High

Dear Dr. Daszak,

This is the second communication from NIAID requesting that you file the progress report for the above-referenced grant that was due no later than April 15, 2016. Please submit the delinquent report by May 12, 2016.

If you experience any difficulties meeting the submission deadline, please contact me immediately. Otherwise, please be advised that continued late submission of your non-competing grant progress report and any subsequently requested documentation will result in a reduction of time and/or funds for this grant.

Thank you,
Carine

Carine Normil
Grants Management Specialist (Contractor)
Grants Management Program, DEA, NIAID, NIH, HHS
5601 fishers Lane, Rm 4G46, Bethesda , Maryland 20892
Phone: (b) (6)
Fax: (301)-493-0597
Email: (b) (6)
NIH National Institute of Allergy and Infectious Diseases

Greer, Jenny (NIH/NIAID) [E]

From: Normil, Carine (NIH/NIAID) [C]
Sent: Friday, May 13, 2016 10:21 AM
To: Greer, Jenny (NIH/NIAID) [E]
Subject: FW: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Importance: High

From: Aleksei MacDurian (b) (6)
Sent: Friday, May 13, 2016 9:58 AM
To: Normil, Carine (NIH/NIAID) [C] (b) (6)
Cc: Dr. Peter Daszak (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Pone, Laura (NIH/NIAID) [E] (b) (6)
Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Importance: High

Dear Carine,

Dr. Daszak submitted his report yesterday.

We received a warning that one of the publications (b) (4) listed from the past year is non-compliant. We have been in touch with NCBI about removing the non-compliant reference as we are not able to remove it via Dr. Daszak's account. As of this week, Dr. Daszak's My NCBI bibliography is correct, but it appears that the eRA Commons form has not yet populated or updated?

Please let me know any time (b) (6) if there are any questions or additional details necessary.

Many thanks!

Aleksei Chmura
Senior Coordinator of Operations
Authorized Organizational Representative

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

On May 10, 2016, at 05:26, Normil, Carine (NIH/NIAID) [C] (b) (6) wrote:

Dear Dr. Daszak,

This is the second communication from NIAID requesting that you file the progress report for the above-referenced grant that was due no later than April 15, 2016. Please submit the delinquent report by May 12, 2016.

If you experience any difficulties meeting the submission deadline, please contact me immediately. Otherwise, please be advised that continued late submission of your non-competing grant progress report and any subsequently requested documentation will result in a reduction of time and/or funds for this grant.

Thank you,
Carine

Carine Normil

Grants Management Specialist (Contractor)

Grants Management Program, DEA, NIAID, NIH, HHS
5601 fishers Lane, Rm 4G46, Bethesda , Maryland 20892

Phone: (b) (6)

Fax: (301)-493-0597
Email: (b) (6)

From:	OERWebmaster (NIH/OD)
To:	Stemmy, Erik (NIH/NIAID) [E]; Pone, Laura (NIH/NIAID) [E]; Schafer, Susan (NIH/NIAID) [E]; Sindall, Elisa (NIH/NIAID) [E]; O"Brien, Janet (NIH/NIAID) [E]; OEP-HS
Subject:	1R01 AI110964-01 (PI: Daszak)
Date:	Tuesday, June 09, 2015 3:14:06 PM

STATUS Resolved

Do NOT click 'reply' to this e-mail message. The mailbox is not staffed.

- Click here - to REPLY/EDIT submission/ATTACH documents.
  (Include a message in the **"Add a Communication"** field.)

- Click here to VIEW submission

COMMUNICATION
Adetayo, Kemi (NIH/OD) [C] (6/9/2015 3:14:00 PM):

Subject: 1R01 AI110964-01: Daszak Concurrence for change of HS code from 44 to 54
After careful examination of the information provided and detailed assessment of the application in regards to the SRG concerns about the potential risk to human subjects not fully addressed and raises concerns about the potential economic risk to subjects that may be involved in illegal wildlife trading should be described and addressed, we concur that the human subjects issues have been appropriately addressed. Our Human Subjects Protection Officer has changed the human subjects code **44** for grant **1R01 AI110964-01: Daszak** to Code **54** in IMPAC II as per: http://nih-extramural-intranet.od.nih.gov/nih/committees/hsp/hsp_memo_20020828.html to allow you to issue an award or a revised award.

From our understanding the PI will be conducting most subject enrollment in high-risk areas. For this reason, the Program Officer may wish to discuss with the PI a plan for providing participants information regarding coronavirus prevention and risk reduction.

If you wish to make an award in the absence of institutional assurances from OHRP and/or prior to receipt of certification of IRB review and approval, you will need to make a conditional award and include terms on the NGA. Sample terms may be found at: http://nih-extramural-intranet.od.nih.gov/nih/policies/hs/restrictive_terms.htm

Sincerely, OEP-HS
OEP-HS introduces our new e-Learning series on the Protection of Human Subjects for NIH Extramural Staff; click https://nih-extramural-intranet.od.nih.gov/d/node/1880 for training.

From:	Aleksei Chmura
To:	Pone, Laura (NIH/NIAID) [E]
Cc:	Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject:	Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER
Date:	Monday, June 08, 2015 4:36:13 PM

Dear Laura,

Apologies for our delay in response. Our PIs were out-of-office last week and I wanted to confirm the details in the response. Here, below, are answers to the questions.

The PI mentioned recruiting participants at bat caves, wet markets etc., would the PI please discuss the method of recruitment on how participants would be approached to be involved in the study?

Our study will include adults living or working in the study sites selected as priority surveillance sites with high risk for viral spillover, evolution, amplification, and spread (i.e., 'hotspots'). Study sites are prioritized by identifying areas considered high-risk for contact with wildlife known to be associated with zoonotic viral diversity and with ecological and epidemiological conditions associated with disease emergence. Locations of the one-on-one interviews and focus groups will be in targeted 'hotspot' areas and determined ahead of time based upon our previous research and substantiated by observational research conducted by our research team. Sites will be selected to ensure inclusion of individuals that have contact with live, wild, and farmed animals through either direct contact (raising, hunting, selling, trading, or purchasing) or indirect contact (animals living in or entering dwellings, buildings, caves, or gardens/crops).

In order to participate in one-on-one interviews for the qualitative study, an individual must have direct or indirect contact with live animals, which includes raising, hunting, selling, trading, and/or purchasing live animals. Indirect contact includes living in or entering dwellings, buildings or gardens/crops e.g., bat roosts along roofs, rats or other animals invading stored food or crops. Our research team will use existing, local contacts for introductions to qualifying individuals who may be eligible and interested in participating. Efforts will be made to include a large variety of people with exposure to wildlife especially and initially targeting people who have more power or influence (e.g. farm owners, market leaders, restaurant owners, work-group leaders) as well as those with less (e.g. market vendors and cleaners, rat catchers, individual shoppers).

Our team will recruit adults living at the site or working or visiting the site by asking individuals if they would like to participate. Our study is completely voluntary. Our team will be thoroughly trained on communicating the research objectives and will be able to address any questions that potential subjects may have. As part of the informed consent process, both written and oral descriptions of the study will be provided in Chinese and via an interpreter if participants are not fluent in Mandarin and speak a local dialect. Contact details of our trained field-team coordinator will be provided to all subjects. All personnel on our research team will be available on site to answer questions from the study subjects.

In our previous set of questions we asked about maintaining the privacy of subjects, specifically we would like the PI to discuss how will he ensure and maintain privacy of participants during the one-on-one interviews, e.g., what is the location of the interviews?

One-on-one interviews for our qualitative survey locations will be identified prior to the interviews and will be performed in quiet and private areas where there are no other individuals present within a 10-foot distance. Specific sites for interviews will depend on the type of targeted "hotspot" area and may be in farming or rural areas, inside wildlife restaurants, behind animal storage sheds, in private rooms of dwellings, or in offices of business owners, hotel meeting rooms, etc. If necessary, a barrier will be created so that no other individuals may view the participant while interviews are conducted in order to maintain confidentiality. Research procedures will not include accessing personal health information.

To ensure compliance with informed consent procedures, all potential one-on-one interviewees will be given a consent form prior to being asked to participate. The participant will review the consent form with our research staff and will be given time to ask questions. When reviewing the consent form with participants, our research staff will explain details of the study including why each participant was selected, potential risks to participation, how participation is beneficial, that participation is completely voluntary, and that s/he may withdraw participation at any time. It will be explained that the researchers will not share responses. A small token or gift equivalent to no more than $10 USD will be provided to each participant upon completion of the one-on-one interview.

Measures will be taken to assure the respect, dignity, and freedom of each participant. Each participant's identity will remain anonymous. All responses recorded from participants (of either one-on-one or focus group interviews) will not have names or any identifying details included with recoded responses. Results will be transcribed and/or translated into English and reports will be in aggregate form only. No individual names will ever be reported or published. For the purposes of achieving the aims of our study, data derived from interviews will be analyzed in aggregate by region within a province, without revealing any names of individuals and names/locations of specific markets. This will serve to minimize the legal and economic risks to specific markets or vendors that may provide information about potentially unlawful actions. Dr. Daszak the PI has entered into a confidentiality agreement with NIH to further protect study subjects from the release of any personally identifying information.

There is mentioned of focus group interviews, would the PI please explain which groups of participants are included and the location of the focus groups?

Focus group interview locations for the qualitative study will be identified prior to the focus group sessions and will be performed in quiet and private areas where there are no other individuals present. Specific sites for interviews depend on the type of targeted "hotspot" area and may be in farming or rural areas, inside wildlife restaurants, in private rooms of dwellings, or in offices of business owners, hotel meeting rooms, etc. If necessary, a barrier will be created so that no individuals other than those in the focus group may view or otherwise interfere with the focus group in order to maintain confidentiality. Research procedures in the current study will not include accessing personal health information.

To ensure compliance with informed consent procedures, all potential focus group participants will be given a consent form prior to being asked to participate. The participant will review the consent form with our research staff and will be given time to ask questions. When reviewing the consent form with participants, our research staff will explain details of the study including why each participant was selected, potential risks to participation, how participation is beneficial, that participation is completely voluntary, and that s/he may withdraw participation at any time. It will be explained that the researchers will not share responses. A small token or gift equivalent to no more than $10 USD will be provided to each participant upon completion of the focus group interview.

For both focus group and one-on-one participants, our research team will use existing, local contacts for introductions to individuals who are eligible and interested in being interviewed. Efforts will be made to include a large variety of people with exposure to wildlife especially targeting people who have more power or influence (e.g. farm owners, market leaders) as well as those with less (e.g. market cleaners, rat catchers, individual vendors or shoppers).

Our team will recruit adults living at the site or working or visiting the site by asking individuals if they would like to participate. The study is completely voluntary. Our team will be thoroughly trained on communicating the research objectives and will be able to address any questions that potential subjects may have. As part of the informed consent process, both written and oral descriptions of the study will be provided in Chinese and via an interpreter if a local dialect is required. Contact details of our trained field-team coordinator will be provided to all subjects and all personnel on our research team will be available on site to answer questions from the study subjects.

Lastly, in addition to following up with participants who test positive for coronavirus in 6 months, what is the PI's plan for linking positive participants to treatment?

The test we will use is not a diagnostic test for SARS-like Coronaviruses. We will be identifying SARS-like Coronavirus from genetic fragments using consensus PCR. We will also be conducting serological assays, which represent exposure, but not active virus. There is no treatment for Coronavirus unless there is acute illness in which case treatment would be supportive care. If a participant tests antibody positive for SARS-like Coronaviruses, this would be a measure of past exposure and no treatment would be necessary. If SARS-like Coronavirus RNA is found, we will inform the participant that SARS-like Coronavirus was identified and that she or he should seek medical attention if respiratory symptoms occur and inform doctor of possible SARS-like Coronavirus infection.

******

Please note that our study has an initial qualitative component with the one-on-one interviews and focus groups as detailed above and a separate survey component with questionnaires and biological specimen collection. No clinical specimens will be collected in the initial qualitative component. For clarity, here are details on participant and site selection for our survey component:

A site-specific approach to 'hotspot' identification has been widely used in infectious disease research. Specific well-defined sites are referred to as 'clusters.' Cluster sampling is a standardized sampling methodology that is used when it is either impossible or impractical to compile an exhaustive list of the elements that make up the target population. Usually, as is the case in our study, the population elements are already grouped into subpopulations, e.g., wildlife market vendors, hunters, people who live in caves that have bats. To conduct a cluster sample, clusters (i.e., hotspot settings) are identified and selected for inclusion. If the cluster is small enough, the entire cluster of respondents may be approached to be included in the final sample. This is considered to be a one-stage cluster sample. However, if the cluster is large, then a two-stage cluster sample must be obtained; that is, only a subset of respondents from the cluster will be included in the final sample.

In order to obtain a subset of respondents from large clusters, systematic random sampling will be used. The procedure involved in systematic random sampling is easy, can be done manually and is a commonly used method in two-stage cluster sampling. A random starting point is selected to begin the study. From that point the study staff will move X units (e.g., market stalls, dwellings, houses near a cave) and select that unit for study participation. For example, in a large wildlife market, the first vendor would be selected for study participation. Upon completion of the study requirements, study staff would move 3 stalls down and select a stall on the right for study participation. Upon completion the staff would move another 3 stalls down and select a stall on the right for participation and so on. Only one person per unit (e.g., household, market stall) will be interviewed.

In order to improve recruitment within target communities, introductory visits will be made to each of the selected study site. These visits will be advertised through word of mouth or letter to town leaders depending on the size of the community/site. The letter will inform the community that a research team will be coming on a particular day(s) to discuss health related to animal contact. The letter would not be for advertising recruitment purposes. It would only be used to inform the community of the research visit(s).

During these visits, discussions and meetings will be held to educate, sensitize, and inform people about infections animals may carry, which may then be transferred to humans and cause disease and potential pathways for disease spread/emergence. When appropriate and following approval from local representatives, the research team will post flyers to inform the community of when the team will be coming back to speak to them about enrollment. This "town hall" meeting is completely voluntary, and those interested would likely attend. Although local representatives may be present to introduce the study team members, he/she will not be involved in the recruitment of the participants for the study. Once initial group meetings have been completed, and the type of research to be performed introduced, individual sessions with trained counselors, nurses, and phlebotomists (as appropriate) will be set up for interested persons. Every effort will be made to minimize any form of coercion in this protocol. Local representatives will not play a role in the recruitment of participants. During the consent process, local representatives will not be present when the consent is discussed with the participant. If research visits or enrollment will be held at a workplace, subjects shall be clearly informed during the recruitment process that their

participation in the study will not impact their employment. Translators will be provided, if participants are not fluent in Mandarin.

To ensure compliance with informed consent procedures, all potential participants will be given a consent form prior to being asked to participate. The participant will review the consent form with our research staff and will be given time to ask questions. When reviewing the consent form with participants, our research staff will explain details of the study including why each participant was selected, potential risks to participation, how participation is beneficial, that participation is completely voluntary, and that s/he may withdraw participation at any time. It will be explained that the researchers will not share responses. A small token or gift equivalent to no more than $10 USD will be provided to each participant following his/her time spent in the study.

Measures will be taken to assure the respect, dignity, and freedom of each participant. Each participant's identity will remain anonymous. Each participant will be assigned a coded identification number that will link his or her responses to their clinical specimens, but any identifying information will be kept separate from these data and held in a secure, locked cabinet by the local investigator on-site. Researchers and investigators handling the data will not have access to participant names. The participants' identifiable data and contact information will be kept until the end of the study and then destroyed. Results will be translated into English and reports will be in aggregate form only; no individual names will ever be reported or published. For the purposes of achieving the aims of our study, data derived from questionnaires will be analyzed in aggregate by region within a province, without revealing the names of individuals and names/locations of specific markets. This will serve to minimize the legal and economic risks to specific markets or vendors that may provide information about potentially unlawful actions. Dr. Daszak the PI has entered into a confidentiality agreement with NIH to further protect study subjects from the release of any personally identifying information.

Please let me know, if you have further questions.

Many thanks most,

Sincerely,

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

On Jun 1, 2015, at 08:38, Pone, Laura (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,

Thank you for providing additional information. However, there are still some concerns related to the protections of human subjects proposed in this project that we ask that the PI address. Would the PI please address the following by **close of business Tuesday, June 2nd**:

- The PI mentioned recruiting participants at bat caves, wet markets etc., would the PI please discuss the method of recruitment on how participants would be approached to be involved in the study?
- In our previous set of questions we asked about maintaining the privacy of subjects, specifically we would like the PI to discuss how will he ensure and maintain privacy of participants during the one-on-one interviews, e.g., what is the location of the interviews?
- There is mentioned of focus group interviews, would the PI please explain which groups of participants are included and the location of the focus groups?
- Lastly, in addition to following up with participants who test positive for coronavirus in 6 months, what is the PI's plan for linking positive participants to treatment?

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
5601 Fishers Lane, Room 4E29, MSC 9824
Bethesda, MD 20892-9824
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

From: Aleksei Chmura
To: Pone, Laura (NIH/NIAID) [E]
Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak
Subject: Fwd: (HD-43100) Unable to delete an My NCBI entry
Date: Tuesday, May 26, 2015 1:46:57 PM
Attachments: bib.pdf
ATT00001.htm

Dear Laura,

We have heard back from NCBI - see email response, below.

Please contact the My NCBI Helpdesk (PublicAccess@nih.gov) to confirm removal of the paper in review: [redacted] (b) (4)
In Review).

We sent the revised NCBI Award Compliance Report previously on 5th May; it is attached here for reference. Let me know, if you require any further details.

Many thanks!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

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EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

From: tkt-helpdesk@ncbi.nlm.nih.gov <tkt-helpdesk@ncbi.nlm.nih.gov>
Sent: Wednesday, May 13, 2015 11:04 AM
To: Peter Daszak
Subject: (HD-43100) Unable to delete an My NCBI entry

Dear Colleague,

The silver lock on the grant association is preventing you from removing the grant

from the citation, or the citation from your Bibliography. You will need to have the lock removed before you can do either of those things.

The silver padlock indicates that the paper has been reported to NIH on a progress report. To remove the lock, you have to effectively revise the progress report that listed the paper. Please contact your NIH program officer to let them know you wish to revise the report and have the paper removed. They can explain what documentation they will need from your institution to make the revision. Your program officer can then contact our help desk (PublicAccess@nih.gov) to confirm that NIH can remove the papers.

Please let me know if you have any questions.

Thank you!
David Brodsky

Summary: Unable to delete an My NCBI entry

Description:
Dear Help Desk, I uploaded the following reference to My NCBI (b) (4) Forthcoming;), but it is currently IN REVIEW and not yet accepted for publication. This was an error on my part and I would like to delete this entry. It is associated with an award (R01 AI110964), but I am unable to disassociate this via the "add or delete award" link. Also, when I select the journal article and click on the "delete" button under Display Settings, I receive a notice that the action cannot be undone and when I click "delete" the item remains in My Bibliography. I appreciate your help with this. Sincerely, - Peter Daszak (b) (6)

Please do not change the subject line when replying to this message.

Regards,
NCBI Help Desk

Publications Reported for this Reporting Period

NIH Public Access Compliance	Citation
PMC Journal In Process	(b) (4)
Not applicable	

From:	Aleksei Chmura
To:	Pone, Laura (NIH/NIAID) [E]
Cc:	Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject:	Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER
Date:	Wednesday, May 20, 2015 3:58:46 PM
Attachments:	R01AI110964 IRB Approval Letter.pdf ATT00001.htm

Dear Laura,

Attached is our IRB approval notice, which includes both our IRB protocol and our informed consent forms. The text (pages 4-5 in the PDF) details how we plan to recruit participants and ensure their privacy (consent forms in English and Chinese on pages 7-13 of the PDF).

We do not have formal plans to provide participants with information about minimizing risks of exposure to Coronavirus infection, but test-retest studies have shown that participants in surveys similar to ours do increase their knowledge about the survey topics. All participants will be allowed to ask questions and discuss any related topics.

Please call or email me anytime, if further information is required. We are still waiting on the FWA number from Wuhan University and I will keep you updated early next week with any progress.

Many thanks!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

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hummingbirdIRB

November 17, 2014

Peter Daszak Ph.D.
EcoHealth Alliance
460 West 34th St., 17th Floor
New York, NY 10001-2320

Protocol Title:	Understanding the Risk of Bat Coronavirus Emergence
Hummingbird IRB #:	2014-23
Grant Number:	1R01AI110964-01
Sponsor:	EcoHealth Alliance
Approval Period:	November 14, 2014 – November 13, 2015

Dear Dr. Daszak:

At the convened board meeting of November 14, 2014, Hummingbird IRB approved the above referenced study for one year.

The following document was approved:

Protocol Date: May 27, 2014

We wish to acknowledge the approval from Wuhan University's IRB which approved the portion of the study for which there was human subject intervention. Hummingbird IRB's approval extends only to the data analysis which will take place for anonymized data transferred to Dr. Daszak.

Any changes made to the protocol must be submitted to the Hummingbird IRB. Approval from Hummingbird IRB must be secured prior to initiation of the revision(s). You will receive a reminder to renew approval of the study approximately 3 months prior to the end of the approval period.

Attached, you will find a summary of investigator commitments with which the Board requires each investigator to adhere to during the approval period.

Sincerely,

(b) (6)

Isaac M. Colbert, Ph.D.
Chairman, Hummingbird IRB

Attachment
cc: Maureen Miller, EcoHealth Alliance
Hummingbird IRB File

Investigator Commitments

All Hummingbird IRB (HIRB) approved investigators are required to fulfill these commitments.

In granting approval to the investigator for the conduct of an investigational study, Hummingbird IRB requires the investigator to understand and agree to these commitments:

1. The investigator will conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol when necessary to protect the safety, rights, or welfare of subjects.

2. The investigator will personally conduct or supervise the described investigation(s).

3. The investigator will delegate tasks to only trained, experienced and appropriately credentialed individuals who are familiar with the protocol and understand the tasks required to conduct the study and protect human subjects during screening and while enrolled.

4. The investigator is obligated to inform Hummingbird IRB of any financial conflicts of interest which may exist through submitting appropriate forms on an annual basis. Should a conflict arise during the course of the study, this conflict will be promptly reported to the IRB.

5. The investigator will inform any patients involved in a study involving drugs, devices or biologics, or any persons used as controls, that the drugs, devices or biologics are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

6. The investigator will report to the sponsor and Hummingbird IRB (when applicable) adverse and unanticipated problems that occur in the course of the investigation(s). If after the study has concluded, new information is made available that is relevant to ongoing health or safety, the investigator will inform subjects of these results.

7. When applicable, the investigator will read and understand the information in the investigator's brochure, device manual and other scientific background that describes the potential risks and side effects of the drug, procedure or device.

8. The investigator will ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the commitments outlined in this document.

9. The investigator will maintain adequate and accurate records and make those records available for inspection.

10. The investigator will promptly report Hummingbird IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, the investigator will not make any changes in the research without Hummingbird IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
11. The investigator will have in place at his or her site, a process by which the HIRB approved consent form is compared to the executed contract to ensure that consistency exists between documents in terms of procedures, study visits, payment to subjects and compensation for injury as well as other conditions effecting human subjects. The investigator and sponsor will resolve any difference and notify HIRB of any changes impacting the consent.

12. The investigator will provide referrals to any subject for whom a condition or potentially adverse information is uncovered during the study. This may include, for example, learning of suicidality or a previously unknown disease. This does not pertain to results of genetic testing unless sharing this information is part of the protocol.

PROTOCOL: Understanding the Risk of Bat Coronavirus Emergence

Protocol #: R01AI110964

Version Date and Number: 6/5/13 updated 10/21/14 Version #1

The behavioral component of this multidisciplinary study has been designed directly in concert with the novel work of zoonotic viral detection and the identification and characterization of spillover and further transmission risk from wildlife. The approach is iterative and begins with rapid and focused qualitative research conducted in natural settings at biological and ecological surveillance sites. The research includes observation and mapping of public spaces, as well as focus groups and ethnographic interviews conducted with two groups of individuals: those involved with the wildlife value chain (from hunter through market to consumer) and those highly exposed exposure to wildlife, particularly bats (eg, cave dwellers). The focus is on the type and frequency of animal contact, as well as the range of wildlife observed. Participants will also be asked about observed environmental/ecological changes and impact; travel with animals, animal responsibilities and how these are divided by age and gender, and animal taboo; daily life, seasonal changes, times of shortage and other socioeconomic factors; and finally the frequency, types, causes and understanding of illness. This information provides a framework to gain rapid understanding of human-animal interactions and the actions/meanings surrounding these interactions, as well as for the exploration of unanticipated knowledge, such as the presence and rationale for taboos on certain human-animal interactions. These data will directly inform the development of detailed behavioral surveys. Alignment of the behavioral studies will coincide with animal biological surveillance to maximize the understanding of risk and reconcile information gathered on transmission risk with the actual presence of potentially zoonotic pathogens.

Consistent with the original proposal, we will recruit volunteers for the qualitative research by word of mouth or by referral from key informants or other participants from the two target groups (ie, wildlife value chain participants and those highly exposed to wildlife, particularly bats) in Guangdong, Guangxi, Yunnan, and Fujian provinces in cooperation with local Bureaus of Public Health and CDCs. To recruit participants, we will identify local individuals influential with the target population, introduce the study in public community fora and identify volunteers through these mechanisms. We will identify three sites in each province for a total of 12 sites representing the range of settings where the target population may be found (eg, bat caves, wet markets; formal and informal wildlife trade posts; animal transport/travel routes and mechanisms including transport storage and exchange centers, and wildlife value chain supporting industries such as guesthouses, restaurants, medicinal/magical/material animal parts and animal by-product preparers, vendors and purchasers). It is anticipated that eight focus groups (two per province) of approximately 8-10 individuals each (ie, a total of 48-80) and 144 ethnographic interviews (12 per site) will be conducted. Therefore, a total of 192 to 224 individuals will participate in qualitative research. With participant permission, qualitative interviews and focus groups will be recorded.

For the behavioral survey, in each of the four provinces in southern China we will aim to include 10 markets and survey 20 vendors per market; an additional 420 individuals will be selected based on the results of qualitative data analysis. In each province, 620 people will be surveyed for a total of 2480 individuals. A sampling frame and recruitment materials for this quantitative research will be developed in Year 2. Participants in the survey will be asked to provide blood (no more than 550ml), sputum, and stool samples. We will screen sera for antibodies to SARS-CoV, other alpha & beta coronaviruses including MERS-CoV,

and novel bat-CoVs. We will screen stool from CoV seropositive participants for CoV nucleic acid. We will also develop specific bat-CoV serological assays and share these with our Chinese collaborators.

In recognition of the time and expertise offered by study participants, each person will be offered a small token of practical, emotional or social significance. The token will not cost a lot of money, nor will it be money.

Only adults 18 years or older will be invited to participate. At least one of the focus groups and an estimated 35-40% of the interviews and surveys will be conducted with women. Subjects will be enrolled in this study without regard to ethnicity. The primary enrollment criteria are related to occupational exposure to wildlife and residence near wildlife.

We currently have no plans to pursue the substudy in Shanghai mentioned in the text. There are also no current plans for follow up of any study participants. In addition, if SARS virus is identified in any human sample, it will be immediately reported to public health authorities because we will have identified an outbreak.

The original sources of this information are on p112 section C1b and p120 Human subjects in the grant proposal.

On May 18, 2015, at 13:49, Pone, Laura (NIH/NIAID) [E] [redacted] (b) (6) wrote:

Hi Aleksei,

Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.quested the following additional information. Please provide a response no later than **Wednesday, May 20th.**

-

- Please have the PI discuss the recruitment of participants.
- Please have the PI discuss how privacy is ensured, particularly with face-to-face interviews.
- Will participants be provided any information regarding minimizing their risks of Coronovirus infection?

NIH Instructions for Grant Applications may be found at:
http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerB.pdf, Part II onwards for requirements on the Protection of Human Subjects
Please also visit our public website for information on "Research Involving Human Subjects":
http://grants.nih.gov/grants/policy/hs/index.htm

Thank you,

Laura

From:	Aleksei Chmura
To:	Pone, Laura (NIH/NIAID) [E]
Cc:	Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject:	Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER
Date:	Thursday, May 14, 2015 4:11:59 PM
Attachments:	Wuhan IRB_fin.pdf ATT00001.htm

Dear Laura,

That is very good to hear!

Here is another update: attached is our IRB approval from Wuhan University.

In summary, we have IRB approval from US and China and are waiting on the FWA number for Wuhan University. I will let you know about the FWA as soon as possible.

Thanks again!

-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

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WUHAN UNIVERSITY

299 Bayi Rd., Wuhan 430072, Hubei, P.R. China

Wuhan University Ethics Approval Board

Research Study US NIAID R01AI110964: Understanding the Risk of Bat Coronavirus Emergence

This multidisciplinary study will include human subjects research. The human subjects research is both qualitative and quantitative. The focus is on the type and frequency of animal contact, as well as the range of wildlife observed. The research provides a framework to gain rapid understanding of human-animal interactions. Alignment of the human subjects research will coincide with animal biological surveillance to maximize the understanding of transmission risk with the potentially zoonotic pathogens identified in animal populations.

Volunteers will be recruited by word of mouth or by referral from key informants or other participants from the two target groups (ie, wildlife value chain participants and those highly exposed to wildlife, particularly bats) in Guangdong, Guangxi, Yunnan, and Fujian provinces in cooperation with local Bureaus of Public Health and CDCs. We will identify three sites in each province for a total of 12 sites representing the range of settings where the target population may be found (eg, bat caves, wet markets; formal and informal wildlife trade posts; animal transport/travel routes and mechanisms including transport storage and exchange centers, and wildlife value chain supporting industries such as guesthouses, restaurants, medicinal/magical/material animal parts and animal by-product preparers, vendors and purchasers). It is anticipated that eight focus groups (two per province) of approximately 8-10 individuals each (ie, a total of 48-80) and 144 ethnographic interviews (12 per site) will be conducted. Therefore, a total of 192 to 224 individuals will participate in qualitative research. With participant permission, qualitative interviews and focus groups will be recorded.

For the behavioral survey, a sampling frame and recruitment materials for this quantitative research will be developed in Year 2. It is anticipated that approximately 2500 individuals will be interviewed and asked to provide blood (no more than 550ml), sputum, and stool samples. We will screen sera for antibodies to SARS-CoV, other alpha & beta coronaviruses including MERS-CoV, and novel bat-CoVs.

Only adults 18 years or older will be invited to participate. At least one of the focus groups and an estimated 35-40% of the interviews and surveys will be conducted with women. Subjects will be enrolled in this study without regard to ethnicity. The primary enrollment criteria are related to occupational exposure to wildlife and residence near wildlife. All participants will sign an informed consent approved by the Wuhan Ethics Approval Board. In recognition of the time and expertise offered by study participants, each person will be offered a small token of practical, emotional or social significance. The token will not

WUHAN UNIVERSITY

299 Bayi Rd., Wuhan 430072, Hubei, P.R. China

cost a lot of money, nor will it be money.

All data, including notes, recordings, questionnaires, and computer files will be will be coded to strictly preserve confidentiality. Paper files will be scanned electronically and then shredded. Biological samples will be coded to maintain anonymity of sample results. Identifying information such as consent forms and test results will be kept under lock and key in a file cabinet. All electronic data will be encrypted. Data access will be limited to investigators conducting analyses; data will have protections with data access codes required. Data collection is cross sectional and master list data will not be required for the analysis of data. Data will be presented in the aggregate. Original data will be stored for five years after the completion of the study. At that time, electronic files will be permanently deleted.

(b) (6)

Chuanhua Yu, Ph.D
Director of Medical Ethics Committee
School of Public Health
Wuhan University
115 Donghu Rd.
Wuhan, Hubei 430071
Tel: (b) (6)
Fax: (+8627)68758648
Email: (b) (6)

Nov. 11, 2014

On May 14, 2015, at 16:00, Pone, Laura (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,

Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.was responded to and have submitted that for review. Please let me know once Wuhan has the FWA.

Thank you!

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
5601 Fishers Lane, Room 4E29, MSC 9824
Bethesda, MD 20892-9824
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

please consider the environment before printing this e-mail.

From: Aleksei Chmura (b) (6)
Sent: Wednesday, May 13, 2015 4:36 PM
To: Pone, Laura (NIH/NIAID) [E]
Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject: Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER
Importance: High

Dear Laura,

Apologies for any delays or confusion on my part, but I am not certain what summary statement concerns you are requesting. We provided details about protection of human subjects via our Just in Time Report in May of last year and sent our US IRB approval for our human research protocol under our award last month (attached here for reference). We expect to have an FWA for Wuhan University before the end of the month, but I will update you on our progress in the next week.

Can we have a quick chat about the summary statement concerns anytime that is good for you. Once we are clear on what is required, we will provide the requested details immediately.

Is the deleted reference with updated My NCBI report for Dr. Daszak ok as well? I have not yet had a response from the NCBI support re. removing and/or disassociating the reference.

Please call me anytime day/night at (b) (6)

Many thanks!

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) direct)
mobile)
Aleksei MacDurian (Skype)

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EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

From: Williams, Barbara (NIH/OD) [C]
To: (b) (6)
Cc: (b) (6) (b) (6) Pone, Laura (NIH/NIAID) [E]; OLAW Division of Assurances (NIH/OD)
Subject: Animal Welfare Interinstitutional Assurance #A7941-02 - EcoHealth Alliance & Tufts University Cummings School of Veterinary Medicine - 1R01AI110964-01
Date: Tuesday, May 20, 2014 9:40:52 AM
Attachments: Animal Welfare Assurance #A7941-02.pdf

Dear Dr. Chmura,

Attached is a copy of the signed, approved Animal Welfare Interinstitutional Assurance between EcoHealth Alliance and Tufts University Cummings School of Veterinary Medicine, needed for animal research to be conducted under grant 1R01A110964-01. The Assurance number is A7941-02 and became effective on 5/19/2014. I am also mailing this information to you.
Thank you for your assistance.

Barbara Williams
Program Analyst
Office of Laboratory Animal Welfare, NIH
Phone: (b) (6)
Email: (b) (6)

Division of Assurances
E-fax : 301-480-3117
Email: OLAWdocs@mail.nih.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC EALTH SERVICE

NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3117

May 19, 2014

Project #: 1 R01 AI 110964-01
Project Title: Understanding the Risk of Bat Coronavirus Emergence
Investigator: Dr. Peter Daszak
Animal Facility: Tufts University Cummings School of Veterinary Medicine

Dr. Aleksel Chmura
Program Coordinator
EcoHealth Alliance
460 West 34th Street, 17th Floor
New York, New York 10001

Dear Dr. Chmura:

The Division of Assurances, Office of Laboratory Animal Welfare (OLAW) has reviewed and approved the new Interinstitutional Assurance which was submitted by your institution in compliance with the Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals (Policy) revised August 2002.

The Assurance, with identification number **A7941-02** became effective on 5/19/2014. The Assurance is good for the current period of support. Under your approved Assurance with Tufts University Cummings School of Veterinary Medicine, their Institutional Animal Care and Use Committee (IACUC) is authorized to conduct subsequent reviews of this project.

The Assurance is a key document in defining the relationship of your Institution to the PHS and the cooperating institution's IACUC, since they set forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals.

A copy of the approved Assurance is enclosed. If I can be of any further assistance, please feel free to contact me by phone or email.

Sincerely,

(b) (6)

Doreen H. Bartlett
Senior Assurance Officer
Division of Assurances
Office of Laboratory Animal Welfare

Enclosure

cc:
Dr. Diane Souvaine
Dr. Barry Goldin
Ms. Laura Pone, NIAID

Interinstitutional Assurance

The Interinstitutional Assurance is used by U.S. institutions that receive Public Health Service (PHS) funds through a grant or contract award when the institution has neither its own animal care and use program, facilities to house animals, nor an Institutional Animal Care and Use Committee (IACUC) and will conduct the animal activity at an Assured institution (named as a performance site).

I. Awardee Institution

Name of Awardee Institution: EcoHealth Alliance

Address: *(street address, city, state, zip code)*
460 West 34TH STREET, 17TH FL.
NEW YORK, NY 10001, USA

Project Title: *(from grant application/contract proposal)*
UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE

Grant/Contract Number: R01 AI 110964

Principal Investigator: DR. PETER DASZAK

A. Applicability

This Interinstitutional Assurance between the awardee institution and the Assured institution is applicable to research, research training, and biological testing involving live vertebrate animals supported by the PHS and conducted at the Assured institution.

B. Awardee and Assured Institutional Responsibilities

i. The institutions agree to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

ii. The institutions agree to be guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and comply with the PHS Policy on Humane Care and Use of Laboratory Animals (Policy).

iii. The institutions acknowledge and accept responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, the institutions will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

iv. The awardee institution acknowledges and accepts the authority of the IACUC of the Assured institution where the animal activity will be performed and agrees to abide by all conditions and determinations as set forth by that IACUC.

Name of Assured Institution: Tufts University Cummings School of Veterinary Medicine

Address: *(street address, city, state, zip code)*
IACUC/Office of the Vice Provost for Research
136 Harrison Ave.
Boston, MA, 02111

II. Institutional Endorsement

By signing this document, the authorized official at the awardee institution and the Institutional Official and IACUC Chairperson at the Assured institution (performance site) provide their assurances that the project identified in Part I will be conducted in compliance with the PHS Policy and the Assurance of the Assured institution.

A. Endorsement of Awardee Institution

Name of Awardee Institution: EcoHealth Alliance
Authorized Official: Aleksei Chmura
Signature: (b) (6) Date:08 May 2014
Title: Authorized Organizational Representative
Address: *(street address, city, state, zip code)*
460 WEST 34TH ST., 17TH FL.
NEW YORK, NY 10001, USA

Phone:+ (b) (6) | Fax:+1.212.380.4465
E-mail: (b) (6)

B. Endorsement of Assured Institution

Name of Assured Institution: Tufts University Cummings School of Veterinary Medicine
Institutional Official: Dr. Diane L. Souvaine
Signature: (b) (6) | Date: May 14, 2014
Title: Vice Provost for Research
Address: *(street address, city, state, zip code)*
136 Harrison Avenue
Boston, MA 02111

Phone: (b) (6) | Fax:617-636-8354
E-mail: (b) (6)

IACUC Chairperson: Dr. Barry Goldin
Signature: (b) (6) Date: May 2014
Title: Professor, Department of Public Health and Community Medicine
Address: *(street address, city, state, zip code)*
136 Harrison Avenue, Boston, MA 02111
Phone: (b) (6) | Fax: 617-636-8354
E-mail: (b) (6)
Date of IACUC Approval: *(within 3 years, pending not acceptable)* 05/08/2014

III. PHS Approval *(to be completed by OLAW)*

Signature of OLAW Officia (b) (6) Date: 5/19/2014

Doreen H. Bartlett - Senior Assurance Officer
Office of Laboratory Animal Welfare
National Institutes of Health
Bethesda, MD 20892-7982
(b) (6)
Phone: (b) (6)
FAX: 301-451-5672

Grant/Contract #:1R01AI110964-01
Animal Welfare Assurance #: A7941-02
Effective Date: 5/19/2014
Expiration Date: *(duration of project, up to 5 years)*

VERTEBRATE ANIMALS:

1. Detailed description of animal use.

All work with vertebrate animals will be conducted in China.

Capture and sampling techniques for all wild animals described in this study have been approved by Tufts University IACUC. Experimental work using humanized mice will be conducted at the Center for Animal Experiment Biosafety 3 lab of Wuhan University at the School of Medicine in Wuhan, China. The Center is AAALAC accredited and has both an Institutional Biosafety Committee and an Institutional Animal Care and Use Committee and all animal work to be done at Wuhan has been approved by the Wuhan IRB (IACUC) #WIVA05201402. Animals will be housed in a BSL-3 facility and will be under the care of a full-time veterinarian. Conditions for animal use are described below.

Note: The majority of wild animals captured and sampled will be done using non-destructive, techniques. In a small number of instances (~ 2 bats per species), where intestine and lung tissue is required to establish cell lines, animals will be humanely euthanized and a necropsy performed according to accepted protocols (see euthanasia section)

Bat capture. Free-ranging bats will be captured using either a mist net or harp trap. The net system is manned by two people during the entire capture period, and bats are removed from the net as soon as they become entangled to minimize stress and prevent injury. In the Co-PI's (Dr. Epstein) experience, a maximum of 20-30 bats can be safely held and processed by a team of three people per trapping period. Duration of trapping will depend on the capture rate. Bats are placed into a pillowcase or small cloth bag and hung from a branch or post until samples are collected. Bats are held for a maximum of six hours.

Wild rodent capture. Free-ranging rodents will be captured through pit traps and box traps; captive rodents, including resident free-ranging wild rats/rodents in markets, will be manually captured or captured through traps. Traps will be checked a minimum of once daily in the morning. If adverse weather (extreme heat, rain) is expected or researchers are working in areas where predation is common, traps will be checked more frequently, and closed during the adverse weather. Handling of rodents will involve morphometric measurements. Captive and wild rodent sampling procedures (including anesthesia if necessary), will involve manual restraint, venipuncture, mucosal swabs, fecal, urine, and external parasite collection. Following capture, small animals will be restrained with a fine mesh bag to minimize entanglement, taking precautions to ensure the animals are not traumatized by the hoop of the net or through net removal. Larger rodents will be restrained for sampling in specialized squeeze-cages, allowing adjustments appropriate to the size of the animal. Squeeze-cages consist of a wooden frame with a plasticized wire bottom and a Plexiglas shield used to press the animal, while ensuring visible communication between the field veterinarian and the animal. Once squeezed, a rod is inserted to keep the plastic shield in place. The box is then inverted, allowing sampling to be conducted through the open wire bottom and abdomen of the animal when the animal is safely immobilized. Anesthesia for small rodents will be conducted using plastic tubes, with the animals transferred directly from the traps to the tubes containing a cotton swab soaked in ether, isoflurane, or methoxyflurane for anesthetic induction. For larger rodents, chemical restraint and anesthesia (ketamine alone, or ketamine combined with xylazine) will be applied either through the squeeze cages by syringe if applicable.

Laboratory mice. Lab mice will be sourced commercially by the Wuhan Center for Animal Experiment at Wuhan University.

Sample Collection. Bats will be manually restrained during sampling.

Bats: Depending on the species and size of bat, swabs will be taken from the oropharynx, urogenital tract, and rectum. Fresh feces will be collected if available, in which case a rectal swab will not be collected. Blood will be collected from fruit bats either from the cephalic vein or from the radial artery or vein using a 25 gauge needle and 1cc syringe. Blood will be collected from bats weighing less than 100g according to published techniques (*126*).

Rodents: Rodents will be anesthetized prior to sampling. Once anesthetized a small blood sample will be collected using the submandibular vein or tail vein. Femoral or jugular venipuncture may be used for larger rodents (e.g. rats). In all rodents, blood volumes of no more than 1% of body weight will be withdrawn. (example 0.2 ml blood from a 20 gram rodent).

Civets and other small mammals: Anesthesia will be used to restrain small free ranging mammals according to published protocols. Animals will be monitored continuously while recovering from anesthesia. Animals that are sampled in the marketplace, and that may potentially be consumed, will not be anesthetized. Manual restraint will be used and blood will be drawn from the femoral artery or saphenous vein.

Laboratory Mice. Humanized mice will be bred at the University of Wuhan. Mice will be inoculated with a specific dose (e.g. $1x10_6$ TCID50) of virus through different routes (intranasally and intraperitoneally). Mouse body temperature will be monitored with implanted temperature sensing microchips (LifeChip Bio-thermo, Destron Fearing), and mice will be weighed daily. Animals will be observed daily for clinical signs of illness. Moribund mice will be euthanized, according to AVMA recommendations. Live animals will be euthanized at three weeks post-inoculation and organs harvested. We will collect sera on days 10, 15 and 21 to test for neutralizing antibodies against bat CoVs. We will collect nasal washes, oral swabs, and rectal swabs, and urine every two days. These are minimally invasive procedures, and will be performed by experienced lab technicians under the supervision of a full-time veterinarian.

2. Justify use of animals, choice of species, numbers to be used. Species and number used in study:
The purpose of this study is to conduct multi-regional surveillance in large populations of animals to detect coronaviruses that may pose a risk to the health of both humans and animals. The experimental work is designed to understand the ability of bat coronaviruses to bind to human receptors. Because we don't have prevalence estimates for novel strains of coronaviruses, we assume a conservative estimate of 10% prevalence. SARS-like coronaviruses have been found in between 10% and 38% of bats studied (*4, 25*). A 10% in wild populations of bats would require a sample of 30 individuals per species in order to ensure detection of an infected individual with 95% confidence.

Wild bats: We will sample 30 individuals from 30 different species in each province in China (2 per species euthanized for organ tissue); representing but not limited to the following families: *Rhinolophidae, Hipposideridae, Vespertillionidae, Mollossidae,* and *Pteropodidae*, all of which are present in Southern China and potentially in the wildlife markets.
Bats in wet markets: We will opportunistically sample a wide variety of insectivorous and frugivorous bats according to what is present in markets. In addition to bats, we will sample civets, raccoon dogs, rats, bandicoots, bamboo rats, and other rodents present in the markets that may act as intermediate hosts. Numbers of animals sampled from markets will be limited to animal availability. In every situation, sampling of wildlife will be conducted in the most humane

manner while minimizing the impacts on individual animals and their wild populations. In cases where feces are collected for testing, non-invasive techniques will be used. In all instances, the fewest number of animals will be sampled that will provide valid information and statistical inference for the pathogen and disease of interest and every effort will be made to minimize stress and discomfort for the animal.
A small number of bats (maximum 2 per species) representing each of the species in this study may be euthanized in order to collect lung and intestinal tissue required for characterizing coronavirus receptors. Voucher specimens may also be collected at the discretion of the team leader for the accurate identification of species using molecular methodology.

Humanized mice for experimental infection for Specific Aim 3: In order to understand whether bat coronaviruses that utilize receptors found in people have the potential to infect people, we will use Swiss albino mice (standard breed at Wuhan University) that have been genetically modified to have human receptors. We'll infect them with cultured bat coronaviruses and determine which organs become infected and whether these mice are capable of shedding infectious virus. Humanized mice will be genetically modified to carry human ACE2 or DPP4 gene will be used to evaluate pathogenesis of CoVs. We cannot anticipate exactly how many viruses we will find that are candidates for experimental models, however we estimate that we will use four adult mice (2 male, 2 female) per virus and that we will identify approximately 20 viruses that will be used for mouse infection experiments. This will require a total of 80 mice over the study period.

3. Provide information on veterinary care. For wild caught animals, **t**here is no specific veterinary care that is appropriate, nor will clinical veterinary facilities be available. Animals that are injured during the capture or sampling process will be assessed by an experienced team leader, and if the animal is determined to be unlikely to survive if released, it shall be euthanized humanely (see euthanasia section). Animals will be released within hours of capture. In the markets, animals will be sampled using manual restraint or anesthesia. Animals will be returned to vendors after sampling, or, if wild caught in the markets (e.g. rodents), they will be released in the area outside the marketplace.

Laboratory mice will be housed in the BSL-3 small animal facility Center for Animal Experiment at Wuhan Institute of Virology. Two senior Wuhan Institute of Virology veterinarians (Drs. An XueFang and Zhang Fan) will oversee the experiments. Experimental animals will be regularly monitored by experienced staff and a supervising veterinarian. The supervising veterinarian will have responsibility for the care and well-being of all mice used in the experimental studies. The animal facility operates 24 hours a day and has full-time veterinarians on staff. All animals will be provided with food and water ad libitum and will otherwise receive standard care. The Veterinarian in charge will notify the on-site Co-PI (Dr. Zhengli Shi) and the Principal Investigator (Dr. Daszak) by telephone and email if there are any issues regarding animal health and welfare.

4. Procedures for ensuring animal comfort, lack of distress, pain, or injury:
Wild-caught animals: Animals will not be held longer than 6 hours. Co-PIs, Drs. Epstein and Olival have extensive experience in capture, anesthesia, and sampling wildlife, including bats. In our experience, bats and rodents tolerate the described procedure well. Mist nets will be attended continuously during capture periods, and bats will be extracted from the net as soon as they become entangled. This will minimize stress and injury from entanglement. Bats will be placed individually in cotton bags and hung from tree branches while awaiting processing and during recovery. The bags are sufficiently porous as to allow for ventilation and are designed for bat capture. The enclosed environment seems to calm the bats, as they do not struggle once

inside, but they hang quietly. Animals will be monitored by a veterinarian or experienced field team member during all stages of capture, processing, and release. Animals will be kept in a cool place while in the pillowcases. Rodent traps will be set overnight and all traps will be checked in the morning while it still cool outside. Rodents will be kept in a cool, shaded environment during sampling and will be released within 10 hours of capture. The procedures used in this experiment (blood draw, nasal, oral, and rectal swabs) are minimally invasive, however, mice that show signs of morbidity post-infection will be examined and euthanized according to AVMA standards (see below).

Market animals: Bats, rodents, and small mammals sampled in markets, sourced from vendors, will be manually restrained and sampled on-site, to minimize stress and discomfort. Because these animals are designated for human consumption, we will not use anesthetic agents if the animal is to be returned to the vendor following sampling. Manual restraint and sampling will be conducted by experienced members of the field team. Any animal that shows signs of distress (respiratory distress, pale mucous membranes) will be immediately released into a holding cage to recover. If the veterinarian or senior scientist in charge of sampling deems an individual animal to be fractious, or at risk for excessive stress and discomfort, anesthetic agents may be used for the safety of both animal and handler. Injectable tiletamine zolazepam (Telozol HCl) given intramuscularly, or isoflurane gas using a portable vaporizer may be used. Any animal that has been anesthetized for sampling will not be returned to the food chain due to possibility of human consumption of anesthetic drug. These animals will be purchased from the vendor and not returned to the market. Following sampling the animal will be euthanized according to AVMA standards and disposed of according to safe biohazard practices.

Experimental animals (mice): All experimental work will be conducted at Wuhan Institute of Virology under the supervision of senior veterinarians Drs. An XueFang and Zhang Fan. Animals will be observed daily for clinical signs of illness. All mice will be provided comfortable housing with regular access to water and food throughout the experiment. The experiments under this study do not include surgical procedures or use of experimental pharmacological agents. Mice will be anesthetized prior to sampling using isoflurane gas, which will reduce stress and discomfort. During experimental infections, mice will be monitored for signs of pain and discomfort. Moribund mice (e.g. mice showing depression, inappetance, respiratory distress, or severe fever) will be euthanized, according to AVMA recommendations.

5. Euthanasia: In the event of injury to an animal that results in pain and suffering, and reasonable veterinary care is unavailable, the animal will be euthanized by a veterinarian or trained field team member using ketamine injected intramuscularly 37.5mg/kg and sodium pentobarbital injected intravenously at a dose of 1.0ml per 5kg injected intravenously. This protocol is in accordance with the AVMA euthanasia report (2013). Any animal that is euthanized using a chemical agent will be disposed such that it will not be permitted to enter the food supply either through markets or hunting.

From: Aleksei Chmura
To: Pone, Laura (NIH/NIAID) [E]
Cc: Jon Epstein; Peter Daszak; Parkison Valerie
Subject: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section
Date: Friday, May 16, 2014 12:16:02 PM
Attachments: response to VAS NIAID CoV_updated.docx

Dear Laura,

Tufts has requested we provide you with an update to our Vertebrate Animal Section in accordance with the IACUC. Please see our updated form attached to this email. I have also cc'ed Valerie Parkison the IACUC/IBC Regulatory Director at Tufts on this email.

Many thanks!

Aleksei Chmura
Program Coordinator
EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
(b) (6) (China)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

Just In Time Report

Report submitted on : 01/24/2014 08:25 PM

IRB Confirmation:

Human Subjects Assurance Number:

Human Subjects Education: No Human Subjects Education was provided

IACUC Confirmation:

CURRENT OTHER SUPPORT

DASZAK, PETER

ACTIVE

DEB-0955897 (Daszak) 07/01/10 – 06/30/15 (b) (4), (b) (6)
NSF $497,121
EcoHealthNet: Ecology, Environmental Science and Health Research Network
Funding for student exchange and workshops to fuse veterinary science, ecology and human medical sciences.
Role: PI

5R01GM100471 (Perrings) 09/15/11 – 06/30/15 (b) (4), (b) (6)
NIGMS $289,953
Modeling Anthropogenic Effects in the Spread of Infectious Disease
A collaborative international proposal using interdisciplinary approaches to address the links between globalization and emerging infectious disease risks.
Role: Co-Investigator

1R56TW009502 (Daszak) 09/17/12 – 04/30/14 (b) (4), (b) (6)
NIH Fogarty International Center $300,000
Comparative Spillover Dynamics of Avian Influenza in Endemic Countries
Our research will advance the understanding of the long-term dynamics of H5N1 by relaxing the assumption of homogeneous mixing implicit in classical epidemiological models through fine-scale measurements of realistic contact networks in Bangladesh, China, and Egypt.
Role: PI

Emerging Pandemic Threats (Morse) 10/01/09 – 09/30/14 (b) (4), (b) (6)
USAID $18,000,000
PREDICT
Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.
Role: PI on Subcontract from UC Davis

2R01TW005869 09/01/08 – 06/30/14 (b) (4), (b) (6)
NIH Fogarty International Center $2,498,829
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh
To conduct mathematical modeling and fieldwork to understand the dynamics of Nipah virus in Bangladesh
Role: PI

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: PI

OVERLAP: none

CURRENT OTHER SUPPORT

SHI, ZHENG LI

ACTIVE

2011CB504700 (Shi) 01/01/2011-12/31/2015 (b) (4), (b) (6)
National Basic Research Program, China $150,000
Mechanism of interspecies transmission of zoonotic viruses
Study of the means of transmission of zoonotic viruses.
Role: PI

81290341 (Shi) 01/01/2013-12/31/2017 (b) (4), (b) (6)
NSF China $100,000
Genetic diversity, identification, and pathogenesis of bat viruses
Molecular characterization of viruses of bats in China.
Role: PI

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

ZHANG, SHU-YI

ACTIVE

Emerging Pandemic Threats (Morse) 10/01/09 – 09/30/14 (b) (4), (b) (6)
USAID $18,000,000
PREDICT
Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.
Role: PI on Subcontract from EcoHealth Alliance

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

From: Stemmy, Erik (NIH/NIAID) [E]
To: Pone, Laura (NIH/NIAID) [E]
Subject: RE: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section
Date: Friday, May 16, 2014 2:41:18 PM

Hi Laura,
Yes, the updates to the animal section look fine to me.

Thanks,
Erik

Please note my updated contact information below:

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: (b) (6)
Email: (b) (6)

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

-----Original Message-----
From: Pone, Laura (NIH/NIAID) [E]
Sent: Friday, May 16, 2014 2:39 PM
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: FW: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section

Hi Dr. Stemmy,

Please let me know if you approve this revised VAS.

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

please consider the environment before printing this e-mail.

-----Original Message-----
From: Pone, Laura (NIH/NIAID) [E]
Sent: Friday, May 16, 2014 2:38 PM
To: Williams, Barbara (NIH/OD) [C]
Cc: OLAW Division of Assurances (NIH/OD); Stemmy, Erik (NIH/NIAID) [E]
Subject: FW: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section

Hi Barbara,

Please see the attached revised VAS to accompany the IIA submitted for grant AI110964.

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)
please consider the environment before printing this e-mail.

-----Original Message-----
From: Aleksei Chmura (b) (6)
Sent: Friday, May 16, 2014 12:16 PM
To: Pone, Laura (NIH/NIAID) [E]
Cc: Jon Epstein; Peter Daszak; Parkison Valerie
Subject: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section

Dear Laura,

Tufts has requested we provide you with an update to our Vertebrate Animal Section in accordance with the IACUC. Please see our updated form attached to this email. I have also cc'ed Valerie Parkison the IACUC/IBC Regulatory Director at Tufts on this email.

Many thanks!

Aleksei Chmura
Program Coordinator

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
(b) (6) (China)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

From: Williams, Barbara (NIH/OD) [C]
To: (b) (6)
Cc: (b) (6); (b) (6) Pone, Laura (NIH/NIAID) [E]; OLAW Division of Assurances (NIH/OD)
Subject: Animal Welfare Interinstitutional Assurance #A7941-01 - EcoHealth Alliance & Wuahn Institute of Virology - 1R01AI110964-01
Date: Thursday, May 08, 2014 9:43:31 AM
Attachments: Animal Welfare Interinstitutional Assurance #A7941-01.pdf

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Dear Dr. Chmura,

Attached is a copy of the signed, approved Animal Welfare Interinstitutional Assurance needed between EcoHealth Alliance and the Wuhan Institute of Virology, for animal research to be conducted under grant 1R01AI110964-01. The Assurance number is A7941-01 and became effective on 5/7/2014. I am also mailing this information to you.

Barbara Williams
Program Analyst
Office of Laboratory Animal Welfare, NIH
Phone: (b) (6)
Email: (b) (6)

Division of Assurances
E-fax : 301-480-3117
Email: OLAWdocs@mail.nih.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 451-5672

May 7, 2014

Project: 1 R01 AI 110964-01
Project Title: Understanding the Risk of Bat Coronavirus Emergence
Principal Investigator: Dr. Peter Daszak
Animal Facility: Wuhan Institute of Virology

Dr. Aleksei Chmura
Authorized Organizational Representative
EcoHealth Alliance
460 West 34th Street, 17th Floor
New York, New York 10001

Dear Dr. Chmura:

The Division of Assurances, Office of Laboratory Animal Welfare (OLAW), has reviewed and approved the new Interinstitutional Assurance which was submitted by your institution in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) revised August 2002.

The Assurance, with identification **#A7941-01,** became effective on 05/07/2014. The Assurance is good for the current period of support. Under your approved Assurance with the Wuhan Institute of Virology, their Institutional Animal Care and Use Committee (IACUC) is authorized to conduct subsequent reviews of this project.

The Assurance is a key document in defining the relationship of your Institution to the PHS and the cooperating institution's IACUC, since they set forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals.

A copy of the approved Assurance is enclosed. If I can be of any further assistance, please feel free to contact me by phone or email.

Sincerely,

(b) (6)

Eileen Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare

Enclosure

cc:
Dr. Xinwen Chen
Dr. Wuxiang Guan
Ms. Laura Pone, NIAID

Interinstitutional Assurance

The Interinstitutional Assurance is used by U.S. institutions that receive Public Health Service (PHS) funds through a grant or contract award when the institution has neither its own animal care and use program, facilities to house animals, nor an Institutional Animal Care and Use Committee (IACUC) and will conduct the animal activity at an Assured institution (named as a performance site).

I. Awardee Institution

Name of Awardee Institution: EcoHealth Alliance
Address: *(street address, city, state, zip code)* 460 West 34TH STREET, 17TH FL. NEW YORK, NY 10001, USA
Project Title: *(from grant application/contract proposal)* UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE
Grant/Contract Number: R01 AI 110964
Principal Investigator: DR. PETER DASZAK

A. Applicability

This Interinstitutional Assurance between the awardee institution and the Assured institution is applicable to research, research training, and biological testing involving live vertebrate animals supported by the PHS and conducted at the Assured institution.

B. Awardee and Assured Institutional Responsibilities

i. The institutions agree to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

ii. The institutions agree to be guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and comply with the PHS Policy on Humane Care and Use of Laboratory Animals (Policy).

iii. The institutions acknowledge and accept responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, the institutions will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

iv. The awardee institution acknowledges and accepts the authority of the IACUC of the Assured institution where the animal activity will be performed and agrees to abide by all conditions and determinations as set forth by that IACUC.

Name of Assured Institution: WUHAN INSTITUTE OF VIROLOGY, CHINESE ACADEMY OF SCIENCES
Address: *(street address, city, state, zip code)* XIAO HONG SHAN NO. 44 WUHAN, 430071, CHINA

II. Institutional Endorsement

By signing this document, the authorized official at the awardee institution and the Institutional Official and IACUC Chairperson at the Assured institution (performance site) provide their assurances that the project identified in Part I will be conducted in compliance with the PHS Policy and the Assurance of the Assured institution.

A. Endorsement of Awardee Institution

Name of Awardee Institution: EcoHealth Alliance	
Authorized Official: Aleksei Chmura	
Signature: (b) (6)	Date:20 March 2014
Title: Authorized Organizational Representative	
Address: *(street address, city, state, zip code)* 460 WEST 34TH ST., 17TH FL. NEW YORK, NY 10001, USA	
Phone: (b) (6)	Fax:+1.212.380.4465
E-mail: (b) (6)	

B. Endorsement of Assured Institution

Name of Assured Institution: WUHAN INSTITUTE OF VIROLOGY, CHINESE ACADEMY OF SCIENCES	
Institutional Official: Xinwen Chen	
Signature (b) (6)	Date: 30 April 2014
Title: Director of Wuhan Institute of Virology, Chinese Academy of Sciences	
Address: *(street address, city, state, zip code)* Xiao Hong Shan No.44 Wuhan, 430071, China	
Phone: (b) (6)	Fax: 86-27-87199106
E-mail: (b) (6)	
IACUC Chairperson: Wuxiang Guan	
Signature: (b) (6)	Date: 30 April 2014
Title: Chairman of Institutional Animal Care and Use Committee, Wuhan Institute of Virology, Chinese Academy of Science	
Address: *(street address, city, state, zip code)* Xiao Hong Shan No.44 Wuhan, 430071, China	
Phone: (b) (6)	Fax: 86-27-87197258
E-mail: (b) (6)	
Date of IACUC Approval: *(within 3 years, pending not acceptable)* 3/25/2014	

III. PHS Approval *(to be completed by OLAW)*

Signature of OLAW Official: (b) (6)	Date: 5/7/2014
Eileen M. Morgan **Director, Division of Assurances** **Office of Laboratory Animal Welfare (OLAW)** **National Institutes of Health** **RKL1, Suite 360 – MSC 7982** **6705 Rockledge Drive** **Bethesda, MD 20892-7982**	
Grant/Contract #:1R01AI110964-01	Animal Welfare Assurance #: A3941-01
Effective Date: 5/7/2014	Expiration Date: *(duration of project, up to 5 years)*

From: Aleksei Chmura
To: Pone, Laura (NIH/NIAID) [E]
Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]; Jon Epstein
Subject: Re: URGENT - RE: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER
Date: Friday, March 21, 2014 9:50:56 AM
Importance: High

Dear Laura,

The techniques are the same across the board. There is no animal work being conducted at Guangdong CDC, East China Normal University, or Guangdong CDC. Members of the field team will be composed of personnel from EcoHealth Alliance Headquarters, Guangdong Entomological Institution, and Yunnan CDC. All animal work will occur in the field - excepting the experimental laboratory work done at the Wuhan Institute of Virology in China.

We have submitted two separate IACUC protocols: one at the Wuhan Institute of Virology which will cover the experimental work and the other via Tufts University for our fieldwork. We are waiting on committee review dates. These should be sent to us very soon and we will update you immediately.

If you have any further questions, please let me know anytime.

Sincerely,

-Aleksei

Aleksei Chmura
Program Coordinator & AOR
EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
+86 137-3736-7249 (China)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

From: Pone, Laura (NIH/NIAID) [E]
Sent: Monday, March 10, 2014 11:01 AM
To: (b) (6); Stemmy, Erik (NIH/NIAID) [E];
(b) (6)
Subject: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Good Morning Aleksei,

Please provide a revised VAS including each of the sites listed below.

- Guangdong Entomological Institute (ECNU)
  Zhongshanbei Rd
  Room 1707
  Building 622 3663
  Shanghai Putuo
  CHINA

- East China Normal University
  3663 Zhongshan
  Beilu Shanghai
  CHINA

- Center for Disease Control and Prevention of Guangdong
  176 Xigang Xilu
  Guangzhou
  CHINA

- Yunnan Institute of Endemic Diseases Control and Prevention
  33 Wenhua Rd
  Dali
  CHINA

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

From: Williams, Barbara (NIH/OD) [C]
To: (b) (6)
Cc: (b) (6) (b) (6); Pone, Laura (NIH/NIAID) [E]; OLAW Division of Assurances (NIH/OD)
Subject: Animal Welfare Assurance #A5967-01 Wuhan Institute of Virology
Date: Wednesday, March 19, 2014 12:16:15 PM
Attachments: Animal Welfare Assurance #A5967-01 Wuhan Institute of Virology.pdf

Dear Dr. Chen,

Attached is a letter from Eileen Morgan, Director, Division of Assurances, OLAW, with the signed, approved Animal Welfare Assurance for the Wuhan Institute of Virology. The Assurance number is A5967-01 and is effective until 3/31/2019.

Thank you.

Barbara Williams
Program Analyst
Office of Laboratory Animal Welfare, NIH
Phone: (b) (6)
Email: (b) (6)

Division of Assurances
E-fax : 301-480-3117
Email: OLAWdocs@mail.nih.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982

http://grants.nih.gov/grants/olaw/olaw.

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
6705 Rockledge Drive-Suite 360
Bethesda, Maryland 20817
Telephone: 301-496-7163
FAX: 301-402-7065

March 18, 2014

Animal Welfare Assurance #A5967-01
Institution: Wuhan Institute of Virology, CAS

Dr. Xinwen Chen
Director of Wuhan Institute of Virology
Chinese Academy of Sciences
Xiao Hong shan No. 44
Wuhan, Hubei
China 430071

Dear Dr. Chen:

The Animal Welfare Assurance for foreign institutions that you recently submitted to the Office of Laboratory Animal Welfare (OLAW) has been reviewed and accepted. A copy of the signed Assurance is enclosed.

Your Assurance bears the identification number A5967-01 and became effective on March 18, 2014. The approval period is for five years, covers all Public Health Service (PHS) supported activities involving live vertebrate animals, and will expire on March 31, 2019.

Please include the Assurance number when corresponding with OLAW or with any funding component of the PHS.

Sincerely,

(b) (6)

Eileen Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare

Enclosure

cc:
Dr. Zhengli Shi
Dr. Xuefang An
Ms. Laura Pone, NIAID

Animal Welfare Assurance for Humane Care and Use of Laboratory Animals by Foreign Institutions

Name of Institution: Wuhan Institute of Virology, Chinese Academy of Sciences
Address (*street, city, state, country, postal code*):
Xiao Hong Shan No.44, Wuhan, Hubei, China, 430071

Wuhan Institute of Virology, Chinese Academy of Sciences[*Name of Institution*] hereinafter referred to as Institution, hereby states that, in reference to the Public Health Service Policy on Humane Care and Use of Laboratory Animals, it will comply with laws, regulations, and policies regarding humane care and use of laboratory animals of the jurisdiction in which the research will be conducted.

I. Applicability

This Assurance is applicable to all research, research training, and biological testing activities involving live, vertebrate animals supported by the Public Health Service and conducted at this Institution, or at another Institution as a consequence of the sub-granting or subcontracting of a PHS-supported activity by this Institution. [*List all entities, such as hospitals, separate institutes or centers that will be covered by this Assurance*] ***(Must complete this section)***
Wuhan Institute of Virology, Chinese Academy of Sciences

II. Institutional Commitment

This Institution is guided by the *International Guiding Principles for Biomedical Research Involving Animals* developed by the Council for International Organizations of Medical Sciences (CIOMS). This Institution will comply with all applicable provisions of the following laws, regulations, and policies governing the care and use of laboratory animals. [*List titles of all governing laws, regulations, and policies for your jurisdiction in English*] ***(Must complete this section)***
Regulations for the Administration of Affairs Concerning Experimental Animals. Approved by the State Council of the People's Republic of China on October 31, 1988 and promulgated by Decree No. 2 of the State Science and Technology Commission, the People's Republic of China.

Regulations on Experimental Animals in Hubei Province, enacted on the 16th Conference of the 10th Standing Committee of the Provincial People's Congress, Hubei, 29th, July, 2005.

Guide for the Care and Use of Laboratory Animals 8th Edition. The National Academies Press, Washington, D.C.

This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Animal Welfare Assurance. As partial fulfillment of this responsibility this Institution shall make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with all applicable laws, regulations, and policies pertaining to animal care and use.

Check one: ***(Must complete this section)***
[ ] This Institution is accredited by AAALAC International.
[×] This Institution is not accredited by AAALAC International.

Check one: ***(Must complete this section)***
[ ] This Institution is accredited by Canadian Council on Animal Care.
[×] This Institution is not accredited by Canadian Council on Animal Care.

III. This institution agrees to notify OLAW when contact information changes. This information can be emailed to OLAWDOA@mail.nih.gov or sent by fax to: +1 (301) 915-9465. Include Foreign Animal Welfare Assurance number in all correspondence.

IV. Institutional Endorsement and PHS Approval of Statement

A. Authorized Institutional Official ***(Must complete this section)***

Name: Xinwen Chen

Title: Director of Wuhan Institute of Virology, Chinese Academy of Sciences

Address (*street, city, state, country, postal code*):
Wuhan Institute of Virology, Chinese Academy of Sciences, Xiao Hong Shan No.44, Wuhan, Hubei, China, 430071

Phone: (b) (6) | Fax: 86-27-87199106

Email Address: (b) (6)

(b) (6)
Signature:

Date: 13/03/2014

B. PHS Approving Official *(to be completed by OLAW)*

Eileen M. Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL1, Suite 360 – MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

(b) (6)
Signature:

Date: 3/18/2014

Animal Welfare Assurance #: A3760-01

Effective Date: 3/18/2014 | Expiration Date: 3/31/2019

V. Two additional Institutional Contacts (***Must complete this section***)
Examples include: Chair, Animal or Review Committee, Institutional Representative, Regulatory Official, Veterinarian or Grants Official.

Contact #1	
Name: Zhengli Shi	
Title: Senior Scientist; Director of the Center for Emerging Infectious Diseases, Wuhan Institute of Virology, Chinese Academy of Sciences	
Address (*street, city, state, country, postal code*): Wuhan Institute of Virology, Chinese Academy of Sciences, Xiao Hong Shan No.44, Wuhan, Hubei, China, 430071	
Phone: (b) (6)	Fax: 86-27-87197240
Email Address: (b) (6)	

Contact #2	
Name: Xuefang An	
Title: Director of the Center of Experimental Animals, Wuhan Institute of Virology, Chinese Academy of Sciences	
Address (*street, city, state, country, postal code*): Wuhan Institute of Virology, Chinese Academy of Sciences, Xiao Hong Shan No.44, Wuhan, Hubei, China, 430071	
Phone: (b) (6)	Fax: 86-27-87198353
Email Address (b) (6)	

Note: Please notify OLAW at OLAWDCA@mail.nih.gov when contact information changes.

VI. The *Guide for the Care and Use of Laboratory Animals*

The *Guide for the Care and Use of Laboratory Animals*, 8th Edition pre-publication copy (2010), is available in English as a PDF – click here to download (893 KB).

From: Aleksei Chmura
To: Pone, Laura (NIH/NIAID) [E]
Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak
Subject: Re: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER
Date: Wednesday, February 26, 2014 12:35:14 PM
Importance: High

Dear Laura,

As per our proposed Timeline and Management Plan (Section D, page 119), our human sampling work would not commence until the 6th Quarter ~1.5 years after the commencement of the project, so definitely in Year 2.

Please call or email me, if you have further questions.

Many thanks!

Aleksei Chmura
Program Coordinator
EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
+86 137-3736-7249 (China)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

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EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

On 26 Feb 2014, at 11:31:19, Pone, Laura (NIH/NIAID) [E] (b) (6) wrote:

> Hi Aleksei,
>
> Dr. Stemmy mentioned that the human subject work begins in year 2. I could not find any correspondence from you stating that, so please let me know when the work is schedule to begin.
>
> Thank you,
> ***Laura Pone***
> ***Phone:*** (b) (6)
> ***e-Fax: 301-493-0597***
> ***Email:*** (b) (6)
> please consider the environment before printing this e-mail.

From: Aleksei Chmura (b) (6)
Sent: Monday, February 24, 2014 9:55 PM
To: Pone, Laura (NIH/NIAID) [E]
Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak
Subject: Re: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Dear Laura,

We are in process of obtaining AWAs and FWAs for each site that does not already have these, but this process may take a month or more. Would this hold up an award or could an award be made with a block on human or animal work (until we have FWAs and/or AWAs)?

Many thanks most,

Sincerely,

Aleksei Chmura
Program Coordinator and AOR
EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
(b) (6) (China)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

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EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

On 24 Feb 2014, at 08:47:26, Pone, Laura (NIH/NIAID) [E]
(b) (6) wrote:

Dear Aleksei,

It has come to my attention that animal and human subject work will be done at Guangdong Entomological Institute, Wuhan Institute of Virology, East China Normal

University, Center for Disease Control and Prevention of Guangdong, and Yunnan Institute of Endemic Diseases Control and Prevention. Please begin the process for obtaining AWA's and FWA's for each site that does not already have them.

- Confirmation of FWA for human subject work. If no FWA exists please establish one. http://ohrp.cit.nih.gov/efile/FwaStart.aspx
- Confirmation of AWA for animal subject work. If no AWA exists please establish one. http://grants.nih.gov/grants/olaw/obtain_assurance.htm

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)


please consider the environment before printing this e-mail.

From: Stemmy, Erik (NIH/NIAID) [E]
To: Pone, Laura (NIH/NIAID) [E]
Subject: RE: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER
Date: Wednesday, February 26, 2014 11:44:43 AM
Attachments: RE Just-in-Time Request for Grant Number 1R01AI110964 - 01 PI Name DASZAK PETER.msg

Hi Laura,
Attached is my most recent email from the PI stating the HS work won't begin until year 2. Also, I believe the pop tracking code should be 00.

Erik

From: Pone, Laura (NIH/NIAID) [E]
Sent: Wednesday, February 26, 2014 11:21 AM
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Hi Erik,

Can you please send me the correspondence from the grantee confirming that HS work does not begin until year 2?

Thank you!

Laura Pone
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

please consider the environment before printing this e-mail.

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Friday, February 21, 2014 3:00 PM
To: Pone, Laura (NIH/NIAID) [E]
Subject: RE: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Yes the work will involve both human and animal subjects at all the sites, however the human work won't begin until year 2. The human subjects code has been switched to 48, so they've approved the possibility of making a restricted award. The IACUC review is still pending and will be covered by the domestic institution's assurance number. The PI said the review is pending and he'll let us know when he has a date.

Erik

From: Pone, Laura (NIH/NIAID) [E]
Sent: Friday, February 21, 2014 2:57 PM
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Hi Erik,

Please confirm whether the work being done at each foreign site involves animal subjects and/or human subjects. If so, we will need to wait for each foreign site to establish an FWA and an AWA.

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

please consider the environment before printing this e-mail.

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thursday, February 20, 2014 12:18 PM
To: Pone, Laura (NIH/NIAID) [E]
Subject: RE: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Hi Laura,
I heard back from the PI regarding the animal and human work at the foreign sites. He said that the contacts at the site are necessary in order to access the sites, however all the work will be conducted by the staff of the domestic institution, under their IRB and IACUC. One exception will be the lab work at the Wuhan Institute of Virology, and the IACUC for that site is pending as noted in the JIT documents.

I'm working now on updated the project description based on Gayle's request the other day. Let me know if you need more info.

Erik

From: Pone, Laura (NIH/NIAID) [E]
Sent: Tuesday, February 18, 2014 6:23 PM
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Hi Erik,

I noticed that you marked yes to human subject and yes to animal work for all five foreign site in China. Can you please verify that this is correct? I checked our database and only one of the four has an FWA and an AWA so they will all need to obtain them before we can issue an award (if human and animal work is being done at each site).

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

please consider the environment before printing this e-mail.

From: Peter Daszak
Sent: Wed, 19 Feb 2014 21:00:16 +0000
To: Stemmy, Erik (NIH/NIAID) [E];Aleksei Chmura
Subject: RE: Just-in-Time Request for Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Dear Erik (cc'd to our SOR, Aleksei Chmura),

Thanks for the questions: We do have a collection of banked samples collected from bats in China over the past four years under prior R01 and USAID funding and part of our work will involve further testing and analysis of these. However, these samples were not collected strategically from markets and sites where humans have a high risk of contact with bats. In the specific aims of the current proposal, we aim to generate predictions about how likely inter-species transmission of CoVs is, and whether this is heightened in markets, as well as about how likely it is for people with high risk of contact with bats to be infected. Therefore, at each site we will also collect samples from wild bats, bats within markets, and from other species within markets that may be susceptible to inter-species transmission of CoVs (e.g. insectivorous mammals, rodents, carnivores). This means that animal and human subjects work will be carried out in each of the four Provinces (Yunnan, Guangdong, Fujian and Guangxi, and at each site. Our IACUC and IRB applications in the USA provide information on these details.

In China, all work will be carried out by our staff under our IACUC and IRB (pending). Local contacts within university labs and provincial CDCs are necessary to ensure that access to sites and sampling is smooth and trouble-free, but they will not directly take the samples or interview people in most cases. We are working to clarify their FWA and IRB details and will make sure these are all in order as soon as possible so that where they do plan to take samples or interview people, they will have the correct assurances. The human work will begin in year 2, so that gives us enough time to make sure all these assurances are in order. The lab work at the Wuhan Institute of Virology will involve animals, and we are working on their IACUC right now (as per the just in time docs)

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street – 17th Floor
New York, NY 10001

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+1.212.380.4465 (fax)

www.ecohealthalliance.org

EcoHealth Alliance builds innovative science-based solutions and partnerships that increase our global capacity to achieve two interrelated goals: protecting global health by preventing pandemics; and safeguarding ecosystems by promoting conservation.

From: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, February 19, 2014 1:16 PM
To: Aleksei Chmura
Cc: Peter Daszak
Subject: RE: Just-in-Time Request for Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

HI Aleksei,
Thanks very much for the additional information. I have a few other questions for you regarding the work in China. I know that you have multiple sites in China that will be conducting work on the animal and human samples, and that based on your application a large number of samples were previously collected.

Reading your application it's not immediately clear to me what work and sample collection will be performed at each site in China. Could you please clarify for me what animal and human subjects work will be conducted at each site, and whether it will involve collection of new samples or analysis of previously collected? Also, foreign collaborators that are collecting new animal samples or conducting human subjects work will need to have their own FWA and animal assurance numbers.

You can just email me this information directly. There's no need to update your JIT documents with it.

Thanks very much!
Erik

From: Aleksei Chmura (b) (6)
Sent: Wednesday, February 12, 2014 9:59 AM
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Peter Daszak; Pone, Laura (NIH/NIAID) [E]
Subject: Re: Just-in-Time Request for Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Dear Erik,

We have uploaded a response to the questions about human subjects and I just cc'ed you on my response to Laura's earlier email.

Many thanks!

-Aleksei

Aleksei Chmura
Program Coordinator & AOR
EcoHealth Alliance

460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
(b) (6) (China)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

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On 11 Feb 2014, at 10:09:25, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

Hi Peter and Aleksei,
One other question about your application. There were a couple of human subjects concerns noted by the study section. I know your IRB approval is still pending, but were you able to address the other human subjects questions? Unless I missed it I didn't see anything in the JIT documents you uploaded.

Thanks,
Erik

Erik J. Stemmy, Ph.D.
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/HHS
6610 Rockledge Drive, Room 3210
Bethesda, MD 20892-7630
Phone: (b) (6)
Fax: 301-496-8030
Email: (b) (6)

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

From: Pone, Laura (NIH/NIAID) [E]
Sent: Monday, February 10, 2014 3:56 PM
To: (b) (6); Stemmy, Erik (NIH/NIAID) [E]; (b) (6)

(b) (6)

Subject: Just-in-Time Request for Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

<image001.png>
Dear Mr. Chmura,

For applications well received by study section during peer review, we attempt to obtain documentation that must be submitted to the National Institute of Allergy and Infectious Diseases should an application subsequently be identified for funding. Since your application is among those favorably received, we request that you submit the information listed below:
Please submit this information by close of business **Thursday, February 13th.**

- Human Subjects Assurance documentation. **Include grant specific IRB approval date**. Grant specific IRB approvals must include either the project title or grant number.
- Documentation of the Required Education in the Protection of Human Subject Research Participants for all personnel involved.
- IACUC verification statement/letter with approval date.
- Response to Summary Statement Concern Regarding:
  - Protection of Human Subjects
  - Overlap
- Copy of EcoHealth Alliance's most recent F&A rate agreement.

Timely submission of the above information will enable us to expedite the issuance of an award should an application be identified for funding. Please submit this information by 02/13/14.

JIT information should be submitted using the Just-In-Time feature of the eRA Commons found in the Commons Status section. Submit **all** information at one time. For information on the Commons, go to the Commons Web site: https://commons.era.nih.gov/commons/index.jsp. If not submitting through the Commons ***or*** for information unable to be submitted through the Commons, please email the requested information signed by an authorized institutional business official. **Emailed documents not endorsed by an Institution Business Official will not be accepted as valid.**

Please feel free to contact me with any questions or concerns.

Thanks and have a nice day!

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

From:	OERWebmaster (NIH/OD)
To:	Stemmy, Erik (NIH/NIAID) [E]; Pone, Laura (NIH/NIAID) [E]; Schafer, Susan (NIH/NIAID) [E]; Sindall, Elisa (NIH/NIAID) [E]; O"Brien, Janet (NIH/NIAID) [E]; OEP-HS
Subject:	1R01 AI110964-01 (PI: Daszak)
Date:	Tuesday, February 11, 2014 12:27:40 PM

STATUS Contacted IC
Your submission cannot be further processed until you have responded to our request or provided the relevant information.

Do NOT click 'reply' to this e-mail message. The mailbox is not staffed.

- Click here - to REPLY/EDIT submission/ATTACH documents.
  (Include a message in the **"Add a Communication"** field.)

- Click here to VIEW submission

COMMUNICATION
Adetayo, Kemi (NIH/OD) [C] (2/11/2014 12:27:27 PM):

Our Human Subjects Protection Officer has changed the human subjects code to "48" so that you may make a restricted award with unresolved human subjects protection concerns as per http://nih-extramural-intranet.od.nih.gov/nih/policies/hs/restrictive_terms.htm#term_f.

Restrictive language must be placed on the Notice of Grant Award barring all human subjects activities.
See: http://nih-extramural-intranet.od.nih.gov/nih/policies/hs/restrictive_terms.htm#term_a
Please submit the PI's response to SRG concerns or the relevant Protections of Human Subjects information in HSPAS (see instructions for NIH applications): http://grants.nih.gov/grants/funding/phs398/phs398.html, part II). You can open this case in HSPAS using the links provided above. Check "Edit", "Attach documents" and then click "Okay". Include a brief message in "Add a Communication" then click "Save" to submit the new information. In the meantime, your case will be kept in our inactive folder with the status of "Contacted IC". **After OEP-HS has received and assessed that there is adequate information to resolves concerns, the human subjects code will be changed to reflect resolution of concerns (HS code 54), and the restriction can be removed by the IC.**

Sincerely, OEP-HS

Just In Time Report

Report submitted on : 01/24/2014 08:25 PM

IRB Confirmation:

Human Subjects Assurance Number:

Human Subjects Education: No Human Subjects Education was provided

IACUC Confirmation:

CURRENT OTHER SUPPORT

DASZAK, PETER

ACTIVE

DEB-0955897 (Daszak) 07/01/10 – 06/30/15 (b) (4), (b) (6)
NSF $497,121
EcoHealthNet: Ecology, Environmental Science and Health Research Network
Funding for student exchange and workshops to fuse veterinary science, ecology and human medical sciences.
Role: PI

5R01GM100471 (Perrings) 09/15/11 – 06/30/15 (b) (4), (b) (6)
NIGMS $289,953
Modeling Anthropogenic Effects in the Spread of Infectious Disease
A collaborative international proposal using interdisciplinary approaches to address the links between globalization and emerging infectious disease risks.
Role: Co-Investigator

1R56TW009502 (Daszak) 09/17/12 – 04/30/14 (b) (4), (b) (6)
NIH Fogarty International Center $300,000
Comparative Spillover Dynamics of Avian Influenza in Endemic Countries
Our research will advance the understanding of the long-term dynamics of H5N1 by relaxing the assumption of homogeneous mixing implicit in classical epidemiological models through fine-scale measurements of realistic contact networks in Bangladesh, China, and Egypt.
Role: PI

Emerging Pandemic Threats (Morse) 10/01/09 – 09/30/14 (b) (4), (b) (6)
USAID $18,000,000
PREDICT
Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.
Role: PI on Subcontract from UC Davis

2R01TW005869 09/01/08 – 06/30/14 (b) (4), (b) (6)
NIH Fogarty International Center $2,498,829
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh
To conduct mathematical modeling and fieldwork to understand the dynamics of Nipah virus in Bangladesh
Role: PI

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: PI

OVERLAP: none

CURRENT OTHER SUPPORT

SHI, ZHENG LI

ACTIVE

2011CB504700 (Shi) 01/01/2011-12/31/2015 (b) (4), (b) (6)
National Basic Research Program, China $150,000
Mechanism of interspecies transmission of zoonotic viruses
Study of the means of transmission of zoonotic viruses.
Role: PI

81290341 (Shi) 01/01/2013-12/31/2017 (b) (4), (b) (6)
NSF China $100,000
Genetic diversity, identification, and pathogenesis of bat viruses
Molecular characterization of viruses of bats in China.
Role: PI

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

CURRENT OTHER SUPPORT

ZHANG, SHU-YI

ACTIVE

Emerging Pandemic Threats (Morse) 10/01/09 – 09/30/14 (b) (4), (b) (6)
USAID $18,000,000
PREDICT
Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.
Role: PI on Subcontract from EcoHealth Alliance

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

CURRENT OTHER SUPPORT

KE, CHANG WEN

ACTIVE

2012ZX10004213-004 (Ke) 07/01/2012 – 06/30/2015 (b) (4), (b) (6)
Ministry of Science and Technology, PRC $372,451
National Major Projects of Major Infectious Disease Control and Prevention
Investigation of Disease Outbreaks in Guangdong Province
Role: PI

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

CURRENT OTHER SUPPORT

EPSTEIN, JONATHAN H.

ACTIVE

DEB-0955897 (Daszak) 07/01/10 – 06/30/15 (b) (4), (b) (6)
NSF $497,121
EcoHealthNet: Ecology, Environmental Science and Health Research Network
Funding for student exchange and workshops to fuse veterinary science, ecology and human medical sciences.
Role: Senior Scientist

Emerging Pandemic Threats (Morse) 10/01/09 – 09/30/14 (b) (4), (b) (6)
USAID $18,000,000
PREDICT
Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.
Role: Senior Scientist

2R01TW005869 09/01/08 – 06/30/14 (b) (4), (b) (6)
NIH Fogarty International Center $2,498,829
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh
To conduct mathematical modeling and fieldwork to understand the dynamics of Nipah virus in Bangladesh
Role: Senior Scientist

4500036150 (Epstein) 07/01/14-06/30/19 (b) (4), (b) (6)
NIH $ 275,000
Risk of Zoonotic Transmission of Herpes B Virus from Wild Macaques in Bangladesh
Investigate causes of encephalitis for non-Nipah non-Japanese encephalitis in Bangladesh and determine the shedding prevalence of B Virus in macaques.
Role: PI

F12AP01117 (Epstein) 09/13/12 - 09/13/14 (b) (4), (b) (6)
USFW $35,000
Development of a Great Ape Health Unit in Sabah, Malaysia.
Develop a Great Ape Health unit to evaluate the health of rescued and translocated gibbons and orangutans in Sabah, Malaysia.
Role: PI

See JIT for effort clarification

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

OLIVAL, KEVIN J.

ACTIVE

Award GVSU 04152012 (Russell) 06/18/12 – 06/17/13 (b) (4), (b) (6)
USFWS/USGS $12,000
Genetic Approaches to Defining Taxonomic and conservation Units for the Hawaiian Hoary Bat
Using molecular tools to date the origins and divergence of the endangered Hawaiian Hoary bat.
Role: Co-PI

4500036150 (Epstein) 07/01/12-06/30/14 (b) (4), (b) (6)
USFWS $197,950
Characterization of Climatic Parameters within Bat Hibernacula, their Influence on Environmental Loads of *Geomyces destructans*, and Implications for the Migration of White-Nose Syndrome in Bats.
Role: Co-PI

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

1 R21 AI113205-01 (Olival) 04/01/2014 – 03/31/2016 (b) (4), (b) (6)
NIAID $396,453
Understanding the Origin and Emergence of MERS-CoV
To investigate the ecology and animal origin of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in the Kingdom of Saudi Arabia (KSA). A combination of field sampling and laboratory work to characterize KSA bat CoV diversity, seasonality of viral shedding, and identify ecological risk factors for transmission among bats, humans and livestock

OVERLAP: none

CURRENT OTHER SUPPORT

HOSSEINI, PARVIEZ R.

ACTIVE

EF-1015791 (Mitchell) 07/01/10 – 6/30/15 (b) (4), (b) (6)
NSF $745,295
The community ecology of viral pathogens
Causes and consequences of coinfection in hosts and vectors. To conduct mathematical modeling and fieldwork to understand implications in a wild grass, aphid-vectored disease system.
Role: Co-PI

Emerging Pandemic Threats (Morse) 10/01/09 – 09/30/14 (b) (4), (b) (6)
USAID $18,000,000
PREDICT
Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.
Role: Hotspots Modeler

1R56TW009502 (Daszak) 09/17/12 – 04/30/14 (b) (4), (b) (6)
NIH Fogarty International Center $300,000
Comparative Spillover Dynamics of Avian Influenza in Endemic Countries
Our research will advance the understanding of the long-term dynamics of H5N1 by relaxing the assumption of homogeneous mixing implicit in classical epidemiological models through fine-scale measurements of realistic contact networks in Bangladesh, China, and Egypt.
Role: Senior Scientist

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

CURRENT OTHER SUPPORT

GE, XING YI

ACTIVE: none

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

CURRENT OTHER SUPPORT

ZHU, GUANG JIAN

ACTIVE: none

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

CURRENT OTHER SUPPORT

ZHANG, YUN ZHI

ACTIVE:

(no number – Zhang) 01/01/2013- 12/01/2017 (b) (4), (b) (6)
Ministry of Science $51,277
Yunnan region is an important natural reservoir
Pathogen survey of Yunnan province
Role: PI

81260437 (Zhang) 01/01/2013 -12/01/2016 (b) (4), (b) (6)
NSF, China $108,561
Rat and mouse viral metagenome
Yunnan murine viral metagenome important viral epidemic status and related research
Role: PI

(no number – Zhang) 11/01/ 2012- 11/01/2015 (b) (4), (b) (6)
Talent Research Foundation $87,000
Health Study Ecology
Yunnan Provincial Health Hall "Ten hundred" health study of the ecology of Yunnan province.

PENDING

1R01AI110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4), (b) (6)
NIAID $3,362,339
Understanding the Risk of Bat Coronavirus Emergence
To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.
Role: Co-Investigator

OVERLAP: none

EcoHealth Alliance

January 15, 2014

JUST IN TIME REQUESTED INFORMATION

1R01AI110964 *Understanding the Risk of Bat Coronavirus Emergence* (PI, Daszak)

Dear reviewers,

1) **Other current support:** Our AOR/SRO has uploaded the other current support information for all senior/key personnel on our proposal via the eRA Commons' JIT page.

2) **Budgeted effort for modeler/statistician:** The only suggested critique for our proposal is: "Despite these strengths, it is noted that there is a limited effort for modeling and statistics." (summary statement, Resume and Summary of Discussion). As I suggested in a conversation with the Program Officer, Dr. Erik Stemmy on the 13th of January, should this proposal be awarded, we intend to modify our budget to increase effort (and corresponding salary support) for our modeler/statistician Hosseini by (b) (4), (b) (6) in each year of the proposed work. **This would be achieved without increasing the overall proposed budget, and by reducing other costs on the award.**

3) **IRB:** Our IRB with Tufts University Health Science, through our inter-institutional agreement with them, is in process and the FWA for this is **FWA00004517**. Human subject education for all key personnel is being completed currently and all details will be provided at each step of approval.

4) **IACUC:** Our IACUC approval is also pending with Tufts University through our inter-institutional agreement with them. The OLAW Assurance number listed (**A4059-01)** is correct. Once we have an IACUC date, we will inform NIH immediately.

If you have any other questions, please contact me anytime. We are very appreciative of your consideration and look forward to further details.

Yours sincerely,

(b) (6)

Dr. Peter Daszak
EcoHealth Alliance
460 West 34th Street, 17th Fl.
New York, NY 10001, USA
(b) (6)
(b) (6)

Just In Time Report

Report submitted on : 02/18/2014 12:49 PM

IRB Confirmation:

Human Subjects Assurance Number:

Human Subjects Education: No Human Subjects Education was provided

IACUC Confirmation:

Last	First	Role	Training	Training URL	Date of Training
Daszak	Peter	PD/PI	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Epstein	Jonathan H.	Co-Investigator	NIH Web based Training Protecting Human Subjects	http://phrp.nihtraining.com/users/login.php	04-Mar-09
Shi	Zheng Li	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	14-Feb-14
Zhang	Shu-Yi	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	14-Feb-14
Ke	Chang Wen	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Zhang	Yun Zhi	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Ge	Xing Yi	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Olival	Kevin J.	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Chmura	Aleksei	Admin	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	18-Feb-14

Just In Time Report

Report submitted on : 02/12/2014 09:54 AM

IRB Confirmation:

Human Subjects Assurance Number:

Human Subjects Education: No Human Subjects Education was provided

IACUC Confirmation:

EcoHealth Alliance

February 11, 2014

JUST IN TIME REQUESTED INFORMATION

1R01AI110964 *Understanding the Risk of Bat Coronavirus Emergence* (PI, Daszak)

Dear Laura Pone,

In response to your email from the 10th of February we have provided responses below to the information requested as below:

1) Human Subjects Assurance documentation. Include grant specific IRB approval date. Grant specific IRB approvals must include either the project title or grant number.
2) Documentation of the Required Education in the Protection of Human Subject Research Participants for all personnel involved.
3) IACUC verification statement/letter with approval date.
4) Response to Summary Statement Concern Regarding:
    a. Protection of Human Subjects
    b. Overlap
5) Copy of EcoHealth Alliance's most recent F&A rate agreement.

RESPONSES:

1) IRB: Our IRB with Tufts University Health Science through our inter-institutional agreement with them is in process and the FWA for this is **FWA00004517**.

2) EDUCATION IN THE PROTECTION OF HUMAN SUBJECT RESEARCH PARTICIPANTS for all personnel involved is underway and we will provide certificates for Daszak, Epstein, Ge, Shi, Zhu, Ke, Olival, Zhang, Olival, and Zhang **before the end of February**.

3) IACUC: Our IACUC approval is also pending with Tufts University through our inter-institutional agreement with them. The OLAW Assurance number listed (**A4059-01)** is correct. Once we have an IACUC date, we will inform NIH immediately.

4) A: PROTECTION OF HUMAN SUBJECTS: We have revised this and specifically included language to address the following: **(a)** the survey is totally voluntary and the subjects may withdraw at any time**, (b)** the survey is anonymous and there is no connection between the surveyed individual ID and the clinical samples, and **(c)** we have a signed confidentiality agreement with NIH that protects the PIs from having to disclose information about the study**.** The following addresses the SRG concerns about protection of human subjects and applies to both human studies described in the proposal:

a. Survey of people highly exposed to wildlife in Guangxi, Yunnan, and Fujian provinces

b. Survey of cases of respiratory illness within the Shanghai CDC influenza-like illness surveillance program

[Study description from proposal with new material highlighted and in bold] *Expanding on our work in Guangdong, we will develop a voluntary study of animal vendors and hunters in Guangxi, Yunnan, and Fujian provinces in cooperation with local Bureaus of Public Health and CDCs. We will develop a survey to identify people with high exposure to wildlife, particularly bats, and will recruit volunteers, collect blood, sputum, and stool sample from each enrolled participant. We will screen sera for antibodies to SARS-CoV, other alpha & beta coronaviruses including MERS-CoV, and novel bat-CoVs. We will screen stool from CoV seropositive participants for CoV nucleic acid. We will also develop specific bat-CoV serological assays and share these with our Chinese collaborators. In each province in southern China we will aim to include 10 markets and survey 20 vendors per market; 20 additional wildlife hunters per province (220 case subjects); 400 control subjects from the general population near the markets in each province (total of 620 people per province). For Shanghai, we will enroll 200 acute respiratory illness cases and 400 non-respiratory controls (600 total), The total number of human subjects will be 2460. The study will be conducted in Guangxi, Yunnan, Fujian and Shanghai provinces*

HUMAN SUBJECTS RESEARCH

1. Risk to subjects: This project is a study of human exposure to animal coronaviruses in southern China. Subjects will be enrolled on a voluntary basis and a single interview and sample collection will be conducted. Informed consent will be obtained. People found to be infected with an animal coronavirus will be followed up after 6 months with a secondary interview and collection of biological specimens to determine whether infection is persistent and exposure is ongoing. Primary subjects will be male or female adults who are highly exposed to wildlife through hunting, butchering, or general handling in the context of live animal markets or restaurants that prepare and serve wild animals. The study population will be selected in Shanghai, Yunnan, Fujian, and Guangxi provinces, China, and will be open to people of all ethnicities that fit the subject criteria. We will target human subjects, comprising 220 subjects (market workers and hunters) and 400 controls from the general population in Yunnan, Fujian, and Guangxi provinces plus 600 subjects in Shanghai (total enrolled: 2460). The market types are defined in Specific Aim 1, Human exposure to CoVs. There are no data to suggest an ethnic bias for coronavirus exposure or infection, therefore subjects will be enrolled based on exposure criteria, though subjects will not be excluded based on ethnicity or gender. We will endeavor to have an equal number of men and women, if the composition of animal vendors in markets allows.

Sources of Materials: Samples to be collected and screened for coronaviruses include blood, saliva and stool samples. 10 mL of blood will be collected from each subject. Subjects will also be asked to provide saliva and stool in sterile containers. An initial sample collection and interview will be performed by trained medical personnel from the local CDC under the provincial Public Health Bureau. Sample collection will be done once in years 2-4 of the study. Samples will be screened for coronaviruses using PCR and an ELISA at the appropriate CDC microbiology lab or at the Wuhan Institute of Virology. Samples that test positive for coronavirus or antibodies to coronavirus will be followed up after 6 months with a secondary interview designed to determine the current level of

exposure to wild animals, and whether exposure at the current level was consistent between the first and subsequent interview. Repeated clinical samples will also be collected and tested for coronaviruses. In all instances, volunteers will be given a medical exam and informed of their test results.

Potential risks: The potential risks to study participants resulting from study participation are minimal. ***The volume of blood being collected is within normal safety limits. The interview questions will be designed to assess exposure risk, and may ask personal questions, but surveys will be done in private and anonymized to protect privacy. Some of the questions may include information about selling or trading animal species that are prohibited by local or federal laws. The participants may be reluctant to answer questions that implicate them in criminal activity and may become nervous following participation if their answers implicate them in potentially illegal activities. Participation in the survey and study is completely voluntary, and a participant may withdraw from the study at any time, or decline to participate in any aspect of the study, including declining to answer specific questions.***

There may be information contained in the surveys that implicates an individual or place of business in illegal trade activities. This could potentially have real or perceived negative legal or financial impacts on the respondent, their place of business, or the larger marketplace from which the information was obtained.

There may be some stress to subjects who are informed that they have been exposed to an animal virus, but counseling will be available and options for medical care will be included in the discussion.

2. Adequacy of protection against risks: Recruitment and informed consent: Prospective study participants will be identified by the research team at each site in partnership with provincial CDC personnel. The team will be thoroughly trained on communicating the research objectives and will be able to address any questions that potential subjects may have. Both written and oral descriptions of the study will be provided in Chinese (in Mandarin or via an interpreter in local dialect if necessary) as part of the informed consent process. Contact details of the collaborators at local CDCs and the study PI will be provided to all subjects, and CDC personnel on the research team will be available on site to answer questions from the study subjects. Test results will be communicated to each subject and counseling offered to minimize stress.

Subjects will be informed, via written consent forms and oral explanation of the consent forms, that their participation is entirely voluntary and that they will have the right to decline to participate in any part of the study, and may decline to answer any questions in the survey. Further, the participant's identity will remain anonymous. They will be assigned a coded ID number that will link their responses to the questionnaire to their clinical specimens, but any identifying information will be kept separate from these data and held in a secure cabinet by the local investigator. For the purposes of achieving the aims of this study, data derived from questionnaires can be analyzed in aggregate by region within a province, without revealing the name or location of specific markets. This will serve to minimize the legal and economic risks to specific markets or vendors that may provide information about potentially unlawful actions.

The PI has entered into a confidentiality agreement with NIH to further protect study subjects from the release of any personally identifying information. Confidentiality for all participants will be protected to the greatest possible extent by law. Consent forms and the front page of the

questionnaire containing the name of the participants will be stored separately from the rest of the data and held by the Local Project Manager on site. Access to personal identifiers by the Project Coordinator is allowed only for the purposes of contacting the participant of their results and participation in follow-up studies if they desire. For research purposes and data analysis, test results and questionnaires will be linked by coded numbers, and only by code numbers. Researchers and investigators handling the data will not have access to participant names. The page containing identifiers will be separated from the rest of the questionnaire and stored separately in a locked facility on site. Only the Project Director and site Coordinators will have access to such information for follow-up, identification (such as photographs) and the offering of counseling services. Only unidentifiable-linked questionnaire data, accident report information, and corresponding test results will be made accessible to project investigators. The participants' identifiable data and contact information will be kept until the end of the study and then destroyed. Results given to the Ministry of Health will be reported in aggregate form only; no individual names will ever be reported or published. Results will not be included in the individual's general health record.

3. Potential benefits to Subjects and Others: There are potential benefits to the study subjects including receiving a physical exam/health check from a medical officer and the potential benefit of identifying an occupational health hazard. At the conclusion of the study, we will deliver an educational workshop for high risk individuals (open to study subjects and non-study subjects) describing the health benefits of using PPE and hand-washing during animal handling activities throughout the day.

4. The importance of knowledge to be gained. There are valuable potential benefits to the general public from the knowledge to be gained by this study, as it may identify sources of zoonotic coronaviruses in the market system or which are commonly hunted. Avoidance of these animals or extra care when handling them may substantially reduce the risk of CoV (and other zoonotic pathogen) transmission.

Inclusion of Women: This proposal will enroll men and women as study subjects. Depending on local gender composition of animal vendors, we will make every effort to have men and women equally represented in this study.

Inclusion of minorities: Subjects will be enrolled in this study without regard to ethnicity. Occupational exposure to wildlife in a market, hunting, or butchering context will be the primary criteria for identifying subjects.

*Inclusion of Children: Children **(subjects below age 18)** will not be included in this study. Children do not normally work in wildlife markets, and are not normally involved in the wildlife trade in China.*

Total planned enrollment: See enrollment table

4) B: OVERLAP: The summary statement requested that: "[Budgetary] Overlap with PREDICT and other R01 funded projects should be better defined". The first (PREDICT) is a contract from USAID with the goal of building capacity in developing countries to identify and address new pandemic threats. The work funded by this contract covers 24 countries, and aims to 1) identify regions of high risk for viral spillover from wildlife to humans, conduct preliminary surveillance of wildlife, take blood samples, and conduct RT-PCR assays to identify new viruses present in them; and 2) to work with local agencies to

build laboratory capacity for viral work within the countries. The surveillance conducted in this project was used to build preliminary data for our proposal. However, this is primarily a capacity building project and is specifically defined as a non-research project so that none of the hypotheses in our current proposal are being tested. Furthermore, fieldwork for this project has been designated by USAID to end by June 2014 and the project completely ends on September 30th 2014. Work in China is now being conducted on birds, rats and primates only. Three other R01 projects were current at the time of submission:

1) R01GM100471 ("Modeling anthropogenic effects in the spread of infectious diseases") is an economic modeling grant that uses mathematical equations to describe the economic impact of disease spread, and therefore has no overlap

2) 2R01TW005869 ("The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh") focuses the vast majority of its work on Nipah virus within Bangladesh, but some of the funding was used with permission from the Fogarty International Center to build collaborations with our Chinese partners by conducting bat testing within China. This grant is now in a 6th year no-cost extension to finish human survey work in Bangladesh and no further work in China is planned or budgeted. The no-cost extension year ends on June 1st 2014

3) 1R01AI079231 ("Risk of viral emergence from bats") was focused on detailed surveys of bat species in 10 countries globally and viral diversity analyses (PCR-based), as well as hotspot modeling for bat-origin viruses. The grant ended on 8/31/2013 and the final report has been filed. This award was also used to build preliminary data for our current proposal. No other grants have been applied for or awarded that have any other overlap with the current proposed work.

5) **F&A RATE AGREEMENT:** We have already uploaded the latest EcoHealth Alliance F&A rate agreement via the Just In Time interface in eRA Commons.

If you have any other questions, please contact me anytime. We are very appreciative of your consideration and look forward to further details.

Yours sincerely,

(b) (6)

Aleksei Chmura
Program Coordinator & AOR
EcoHealth Alliance
460 West 34th Street, 17th Fl.
New York, NY 10001, USA
(b) (6)
(b) (6)

Just In Time Report

Report submitted on : 02/10/2014 04:38 PM

IRB Confirmation:

Human Subjects Assurance Number:

Human Subjects Education: No Human Subjects Education was provided

IACUC Confirmation:

ORIGINAL

NONPROFIT RATE AGREEMENT

EIN: 311726494

ORGANIZATION:
EcoHealth Alliance
460 West 34th St., 17th Fl.
New York, NY 10001-2320

DATE:04/03/2013

FILING REF.: The preceding agreement was dated 03/23/2012

The rates approved in this agreement are for use on grants, contracts and other agreements with the Federal Government, subject to the conditions in Section III.

SECTION I: INDIRECT COST RATES

RATE TYPES: FIXED FINAL PROV. (PROVISIONAL) PRED. (PREDETERMINED)

EFFECTIVE PERIOD

TYPE	FROM	TO	RATE(%)	LOCATION	APPLICABLE TO
FINAL	07/01/2011	06/30/2012	44.10	On-Site	All Programs
PROV.	07/01/2012	Until Amended			Use same rates and conditions as those cited for fiscal year ending June 30, 2012.

*BASE

Total direct costs excluding capital expenditures (buildings, individual items of equipment; alterations and renovations), that portion of each subaward in excess of $25,000 and flow-through funds.

ORGANIZATION: EcoHealth Alliance
AGREEMENT DATE: 4/3/2013

SECTION I: FRINGE BENEFIT RATES**

TYPE	FROM	TO	RATE (%)	LOCATION	APPLICABLE TO
FINAL	7/1/2011	6/30/2012	32.30	All	Full-Time Employees
PROV.	7/1/2012	Until amended			Use same rates and conditions as those cited for fiscal year ending June 30, 2012.

** DESCRIPTION OF FRINGE BENEFITS RATE BASE:
Salaries and wages.

SECTION II: SPECIAL REMARKS

TREATMENT OF FRINGE BENEFITS:

The fringe benefits are charged using the rate(s) listed in the Fringe Benefits Section of this Agreement. The fringe benefits included in the rate(s) are listed below.

TREATMENT OF PAID ABSENCES

Vacation, holiday, sick leave pay and other paid absences are included in salaries and wages and are claimed on grants, contracts and other agreements as part of the normal cost for salaries and wages. Separate claims are not made for the cost of these paid absences.

Fringe benefits include FICA/Medicare, health insurance, life insurance, dental insurance, short/long term disability insurance, retirement, workers' compensation and unemployment and other.

Equipment means an article of n onexpendable, tangible personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit.

SECTION III: GENERAL

A. LIMITATIONS:

The rates in this Agreement are subject to any statutory or administrative limitations and apply to a given grant, contract or other agreement only to the extent that funds are available. Acceptance of the rates is subject to the following conditions: (1) Only costs incurred by the organization were included in its indirect cost pool as finally accepted; such costs are legal obligations of the organization and are allowable under the governing cost principles; (2) The same costs that have been treated as indirect costs are not claimed as direct costs; (3) Similar types of costs have been accorded consistent accounting treatment; and (4) The information provided by the organization which was used to establish the rates is not later found to be materially incomplete or inaccurate by the Federal Government. In such situations the rate(s) would be subject to renegotiation at the discretion of the Federal Government.

B. ACCOUNTING CHANGES:

This Agreement is based on the accounting system purported by the organization to be in effect during the Agreement period. Changes to the method of accounting for costs which affect the amount of reimbursement resulting from the use of this Agreement require prior approval of the authorized representative of the cognizant agency. Such changes include, but are not limited to, changes in the charging of a particular type of cost from indirect to direct. Failure to obtain approval may result in cost disallowances.

C. FIXED RATES:

If a fixed rate is in this Agreement, it is based on an estimate of the costs for the period covered by the rate. When the actual costs for this period are determined, an adjustment will be made to a rate of a future year(s) to compensate for the difference between the costs used to establish the fixed rate and actual costs.

D. USE BY OTHER FEDERAL AGENCIES:

The rates in this Agreement were approved in accordance with the authority in Office of Management and Budget Circular A-122, and should be applied to grants, contracts and other agreements covered by this Circular, subject to any limitations in A above. The organization may provide copies of the Agreement to other Federal Agencies to give them early notification of the Agreement.

E. OTHER:

If any Federal contract, grant or other agreement is reimbursing indirect costs by a means other than the approved rate(s) in this Agreement, the organization should (1) credit such costs to the affected programs, and (2) apply the approved rate(s) to the appropriate base to identify the proper amount of indirect costs allocable to these programs.

BY THE INSTITUTION:

EcoHealth Alliance

(INSTITUTION)

(b) (6)

(SIGNATURE)

(b) (6)

(NAME)

(b) (6)

(TITLE)

4/8/2013

(DATE)

ON BEHALF OF THE FEDERAL GOVERNMENT:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

(AGENCY)

(b) (6)

(SIGNATURE)

Darryl W. Mayes

(NAME)

Regional Director, Division of Cost Allocation

(TITLE)

4/3/2013

(DATE) 1227

HHS REPRESENTATIVE: Regina DiGennaro

Telephone: (b) (6)

From: Aleksei Chmura
To: Pone, Laura (NIH/NIAID) [E]
Cc: Peter Daszak; Jon Epstein
Subject: Re: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER
Date: Tuesday, April 15, 2014 7:08:24 PM
Importance: High

Dear Laura,

Apologies for the delayed response. Here are the justifications for Local Reimbursement and Driver:

LOCAL REIMBURSEMENT: Once all permits are in place in Years 2 to 4, technician-consultants trained in phlebotomy and employed by EcoHealth Alliance partner institutions Yunnan Center for Disease Control, Wuhan Institute of Virology, or Guangdong Center for Disease Control will conduct interviews as part of the human wildlife contact survey as well as collect blood samples from volunteers in animal markets. No funds are requested to support these technician-consultants, since their respective institutions will support them. Each technician will be required to complete the Collaborative Institutional Training Initiative via the University of Miami. Shipping and maintenance of cold-chain from provincial areas to Wuhan Institute of Virology are already supported in the funding requests for our subwardees: East China Normal University and Wuhan Institute of Virology. We will provide reimbursement for the technician-consultant's allowable room/transportation/food costs that are expected to average monthly at food ($24.50), room ($25), and transportation ($56): $105.50 x 3 technicians x 3 months = $950 per year. In year 5 sampling will have ended, but partial support is requested for only two technician-consultants at $550.

DRIVER: In year 1, we have requested $7,200 for driver ($600 per month x 12 months). The driver will provide daily transportation for our field team from local lodging to field, market, and other locations including transport to/from local laboratories. The rates are estimated to remain constant, but the amount requested for the driver will be pro-rated to 8-months in year 2 ($4,800), 6-months in year 3 ($3,600), 4-months in year 4 ($2,400), and 3-months in year 5 ($1,800).

If you have further questions, please let me know.

Many thanks!

Aleksei Chmura
Program Coordinator
EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
(b) (6) (China)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

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On 15 Apr 2014, at 16:41:52, Pone, Laura (NIH/NIAID) [E] (b) (6). wrote:

Hi Aleksei,

I do not see a response to the email below. Please provide it as soon as possible.

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

please consider the environment before printing this e-mail.

From: Aleksei Chmura
To: Pone, Laura (NIH/NIAID) [E]
Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject: Re: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER
Date: Wednesday, March 05, 2014 3:53:10 PM
Attachments: JIT Other Support 1R01AI110964_Updated.pdf
ATT00001.htm

Dear Laura,

Apologies for the discrepancies between the proposal budget and the JIT Other Support file. These were the result of copy-pasting errors. The budgeted amounts are correct and we have no changes to them. Please find a corrected and updated Other Support file attached. The efforts for the following senior personnel are as follows:

Dr. ZL Shi - (b) (4), (b) (6)
Dr. SY Zhang - (b) (4), (b) (6)
Dr. JH Epstein - (b) (4), (b) (6)
Dr. KJ Olival - (b) (4), (b) (6)
Dr. PR Hosseini - (b) (4), (b) (6)
Dr. XY Ge - (b) (4), (b) (6)
Dr. GJ Zhu - (b) (4), (b) (6)
Dr. CW Ke - (b) (4), (b) (6)
Dr. YZ Zhang - (b) (4), (b) (6)

Dr. Chang Wen Ke and Dr. Yun Zhi Zhang are not listed in our budget, since in order to save costs they are not taking any salary, but will be dedicating (b) (4), (b) (6) (b) (4), (b) (6) each per year to liaise regularly with Co-Investigators, PD/PI, and other staff as well as collaborate on research design and papers.

Please let me know, if you have any further questions most,

Sincerely,

Aleksei Chmura
Program Coordinator and Authorized Organizational Representative
EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(mobile)
(b) (6) (China)
Aleksei MacDurian (Skype)

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EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

Yes

Publications Reported for this Reporting Period

Public Access Compliance	Citation
Complete	Luo CM, Wang N, Yang XL, Liu HZ, Zhang W, Li B, Hu B, Peng C, Geng QB, Zhu GJ, Li F, Shi ZL. Discovery of Novel Bat Coronaviruses in South China That Use the Same Receptor as Middle East Respiratory Syndrome Coronavirus. Journal of virology. 2018 July 1;92(13). PubMed PMID: 29669833; PubMed Central PMCID: PMC6002729; DOI: 10.1128/JVI.00116-18.
Complete	Field HE. Evidence of Australian bat lyssavirus infection in diverse Australian bat taxa. Zoonoses and public health. 2018 September;65(6):742-748. PubMed PMID: 29785730; PubMed Central PMCID: PMC6249124; DOI: 10.1111/zph.12480.
Complete	Wu Z, Lu L, Du J, Yang L, Ren X, Liu B, Jiang J, Yang J, Dong J, Sun L, Zhu Y, Li Y, Zheng D, Zhang C, Su H, Zheng Y, Zhou H, Zhu G, Li H, Chmura A, Yang F, Daszak P, Wang J, Liu Q, Jin Q. Comparative analysis of rodent and small mammal viromes to better understand the wildlife origin of emerging infectious diseases. Microbiome. 2018 October 3;6(1):178. PubMed PMID: 30285857; PubMed Central PMCID: PMC6171170; DOI: 10.1186/s40168-018-0554-9.
Complete	Eskew EA, Olival KJ. De-urbanization and Zoonotic Disease Risk. EcoHealth. 2018 December;15(4):707-712. PubMed PMID: 30120670; PubMed Central PMCID: PMC6265062; DOI: 10.1007/s10393-018-1359-9.
N/A	Irving AT, Ng JJ, Boyd V, Dutertre C, Ginhoux F, Dekkers MH, Meers J, Field HE, Crameri G, Wang L. Optimizing dissection, sample collection and cell isolation protocols for frugivorous bats. Methods in Ecology and Evolution. 2019 October 30;11(1):150-158.
Complete	Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nature reviews. Microbiology. 2019 March;17(3):181-192. PubMed PMID: 30531947; PubMed Central PMCID: PMC7097006; DOI: 10.1038/s41579-018-0118-9.
Complete	Li H, Mendelsohn E, Zong C, Zhang W, Hagan E, Wang N, Li S, Yan H, Huang H, Zhu G, Ross N, Chmura A, Terry P, Fielder M, Miller M, Shi Z, Daszak P. Human-animal interactions and bat coronavirus spillover potential among rural residents in Southern China. Biosafety and health. 2019 September;1(2):84-90. PubMed PMID: 32501444; PubMed Central PMCID: PMC7148670; DOI: 10.1016/j.bsheal.2019.10.004.
Complete	Li HY, Zhu GJ, Zhang YZ, Zhang LB, Hagan EA, Martinez S, Chmura AA, Francisco L, Tai H, Miller M, Daszak P. A qualitative study of zoonotic risk factors among rural communities in southern China. International health. 2020 February 12;12(2):77-85. PubMed PMID: 32040190; PubMed Central PMCID: PMC7017878; DOI: 10.1093/inthealth/ihaa001.
Complete	Daszak P, Olival KJ, Li H. A strategy to prevent future epidemics similar to the 2019-nCoV outbreak. Biosafety and health. 2020 March;2(1):6-8. PubMed PMID: 32562482; PubMed Central PMCID: PMC7144510; DOI: 10.1016/j.bsheal.2020.01.003.

Complete	Albery GF, Eskew EA, Ross N, Olival KJ. Predicting the global mammalian viral sharing network using phylogeography. Nature communications. 2020 May 8;11(1):2260. PubMed PMID: 32385239; PubMed Central PMCID: PMC7210981; DOI: 10.1038/s41467-020-16153-4.
N/A	Barrett J, Höger A, Agnihotri K, Oakey J, Skerratt LF, Field HE, Meers J, Smith C. An unprecedented cluster of Australian bat lyssavirus in Pteropus conspicillatus indicates pre-flight flying fox pups are at risk of mass infection. Zoonoses and public health. 2020 June;67(4):435-442. PubMed PMID: 32311218; DOI: 10.1111/zph.12703.
Complete	Welbergen JA, Meade J, Field HE, Edson D, McMichael L, Shoo LP, Praszczalek J, Smith C, Martin JM. Extreme mobility of the world's largest flying mammals creates key challenges for management and conservation. BMC biology. 2020 August 21;18(1):101. PubMed PMID: 32819385; PubMed Central PMCID: PMC7440933; DOI: 10.1186/s12915-020-00829-w.
Complete	Latinne A, Hu B, Olival KJ, Zhu G, Zhang L, Li H, Chmura AA, Field HE, Zambrana-Torrelio C, Epstein JH, Li B, Zhang W, Wang LF, Shi ZL, Daszak P. Origin and cross-species transmission of bat coronaviruses in China. Nature communications. 2020 August 25;11(1):4235. PubMed PMID: 32843626; PubMed Central PMCID: PMC7447761; DOI: 10.1038/s41467-020-17687-3.
Complete	Wu Z, Han Y, Liu B, Li H, Zhu G, Latinne A, Dong J, Sun L, Su H, Liu L, Du J, Zhou S, Chen M, Kritiyakan A, Jittapalapong S, Chaisiri K, Buchy P, Duong V, Yang J, Jiang J, Xu X, Zhou H, Yang F, Irwin DM, Morand S, Daszak P, Wang J, Jin Q. Decoding the RNA viromes in rodent lungs provides new insight into the origin and evolutionary patterns of rodent-borne pathogens in Mainland Southeast Asia. Microbiome. 2021 January 21;9(1):18. PubMed PMID: 33478588; PubMed Central PMCID: PMC7818139; DOI: 10.1186/s40168-020-00965-z.
Complete	Iglesias R, Cox-Witton K, Field H, Skerratt LF, Barrett J. Australian Bat Lyssavirus: Analysis of National Bat Surveillance Data from 2010 to 2016. Viruses. 2021 January 27;13(2). PubMed PMID: 33513882; PubMed Central PMCID: PMC7911197; DOI: 10.3390/v13020189.

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
DASZAK	Y	Daszak, Peter	BS,PHD	PD/PI	1.0	0.0	0.0			NA

Glossary of acronyms:
S/K - Senior/Key
DOB - Date of Birth
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RE - Reentry Supplement
DI - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

Yes

The grant is currently in suspension. As per instructions from our Grant Management Program Specialist, we have entered 1 calendar month for Dr. Peter Daszak solely to pass eRA Commons submission validation requirements - although NO work has been performed since the cancellation of our award on 24th April 2020.

D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

No

D.2.c Changes in Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

No

D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

D.2.e Multi-PI (MPI) Leadership Plan

Will there be a change in the MPI Leadership Plan for the next budget period?

NA

E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES? Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE? NOTHING TO REPORT
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER? Not Applicable
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)? NOTHING TO REPORT

F. CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

Current award is in suspension.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Sub-Project ID	Study ID	Study Title	Delayed Onset	Clinical Trial	NCT	NIH-Defined Phase 3	ACT
	266590	Understanding the Risk of Bat Coronavirus Emergence: Community and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences	NO	NO			

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Are there personnel on this project who are newly involved in the design or conduct of human subjects research?

No

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Does this project involve vertebrate animals?

Yes

G.8 PROJECT/PERFORMANCE SITES

Organization Name	DUNS	Congressional District	Address
Primary: EcoHealth Alliance	077090066	NY-010	ECOHEALTH ALLIANCE, INC. 520 EIGHTH AVENUE NEW YORK, NY 100184183

G.9 FOREIGN COMPONENT

No foreign component

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

No

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period? No

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?

No

Section 1 - Basic Information (Study 266590)

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 03/31/2020

1.1. Study Title *

Understanding the Risk of Bat Coronavirus Emergence: Community and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	○ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	○ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	○ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

On 03 Mar 2014, at 16:23:19, Pone, Laura (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,

Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. **Wednesday, March 5th** is appreciated.

- Please confirm effort for these individuals:
  - Zheng li Shiï¿½s effort is listed as (b) (4), (b) (6) in the budget and (b) (4), (b) (6) in the other support.
  - Shu-Yi Zhangï¿½s effort is listed as (b) (4), (b) (6) in the budget and (b) (4), (b) (6) in the other support.
  - Jonathan Epsteinï¿½s effort is listed as (b) (4), (b) (6) in the budget and (b) (4), (b) (6) in the other support.
  - Kevin Olivalï¿½s effort is listed as (b) (4), (b) (6) in the budget and (b) (4), (b) (6) in the other support.
  - Parviez Hosseiniï¿½s effort is listed as (b) (4), (b) (6) in the budget and (b) (4), (b) (6) in the other support.
  - Xing-Yi Geï¿½s effort is listed as (b) (4), (b) (6) in the budget and (b) (4), (b) (6) in the other support.
  - Guang Jian Zhuï¿½s effort is listed as (b) (4), (b) (6) in the budget and (b) (4), (b) (6) in the other support.
  - Chang Wen Keï¿½s effort is not provided in the budget but is listed as (b) (4), (b) (6) in the other support.
  - Yun Zhi Zhangï¿½s effort is not provided in the budget but is listed as (b) (4), (b) (6) in the other support.

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)
e-Fax: 301-493-0597
Email: (b) (6)

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A. COVER PAGE

Project Title: Understanding the Risk of Bat Coronavirus Emergence	
Grant Number: 5R01AI110964-07	**Project/Grant Period:** 06/01/2014 - 06/30/2025
Reporting Period: 07/24/2019 - 06/30/2021	**Requested Budget Period:** 07/01/2021 - 06/30/2022
Report Term Frequency: Annual	**Date Submitted:** 06/09/2021
Program Director/Principal Investigator Information: PETER DASZAK , PHD BS **Phone Number:** (b) (6) **Email:** (b) (6)	**Recipient Organization:** ECOHEALTH ALLIANCE, INC. ECOHEALTH ALLIANCE, INC. 520 EIGHTH AVENUE NEW YORK, NY 100181620 **DUNS:** 077090066 **EIN:** 1311726494A1 **RECIPIENT ID:**
Change of Contact PD/PI: NA	
Administrative Official: ALEKSEI CHMURA 460 W 34th St., 17th Floor New York, NY 10001 **Phone number:** (b) (6) **Email:** (b) (6)	**Signing Official:** ALEKSEI CHMURA 460 W 34th St., 17th Floor New York, NY 10001 **Phone number:** (b) (6) **Email:** (b) (6)
Human Subjects: Yes **HS Exempt:** NA **Exemption Number:** **Phase III Clinical Trial:** NA	**Vertebrate Animals:** Yes
hESC: No	**Inventions/Patents:** No

B. ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Currently, this award is in suspension.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

There is no progress or plan because this award is in suspension.

New Publications Under This Award: R01AI110964

Reporting Period: 06/01/2018 – 05/31/2021

1. Li, H., Daszak, F., Chmura, A., Zhang, Y., Philip, T., Field, M. (2021) Knowledge, attitude and practice regarding zoonotic disease risk in wildlife trade, southern China. ***EcoHealth*** *(Accepted)*
2. Iglesias, R., Cox-Witton, K., Field, H., Skerratt, L. F., & Barrett, J. (2021). Australian Bat Lyssavirus: Analysis of National Bat Surveillance Data from 2010 to 2016. ***Viruses***, 13(2), 189. https://doi.org/10.3390/v13020189
3. Wu, Z., Han, Y., Liu, B. et al. Decoding the RNA viromes in rodent lungs provides new insight into the origin and evolutionary patterns of rodent-borne pathogens in Mainland Southeast Asia. ***Microbiome*** 9, 18 (2021). https://doi.org/10.1186/s40168-020-00965-z
4. Latinne, A., Hu, B., Olival, K. J., Zhu, G., Zhang, L., Li, H., Chmura, A. A., Field, H. E., Zambrana-Torrelio, C., Epstein, J. H., Li, B., Zhang, W., Wang, L. F., Shi, Z. L., & Daszak, P. (2020). Origin and cross-species transmission of bat coronaviruses in China. ***Nature communications***, 11(1), 4235. https://doi.org/10.1038/s41467-020-17687-3
5. Barrett, J., Höger, A., Agnihotri, K., Oakey, J., Skerratt, L. F., Field, H. E., ... & Smith, C. (2020). An unprecedented cluster of Australian bat lyssavirus in Pteropus conspicillatus indicates pre-flight flying fox pups are at risk of mass infection. ***Zoonoses and public health***, 67(4), 435-442. https://doi.org/10.1111/zph.12703
6. Albery, G. F., Eskew, E. A., Ross, N., & Olival, K. J. (2020). Predicting the global mammalian viral sharing network using phylogeography. ***Nature communications***, 11(1), 1-9. https://doi.org/10.1038/s41467-020-16153-4
7. Welbergen, J. A., Meade, J., Field, H. E., Edson, D., McMichael, L., Shoo, L. P., ... & Martin, J. M. (2020). Extreme mobility of the world's largest flying mammals creates key challenges for management and conservation. ***BMC biology***, 18(1), 1-13. https://doi.org/10.1186/s12915-020-00829-w
8. Daszak, P., Olival, K. J., & Li, H. (2020). A strategy to prevent future epidemics similar to the 2019-nCoV outbreak. ***Biosafety and health***, 2(1), 6–8. https://doi.org/10.1016/j.bsheal.2020.01.003
9. Li, H. Y., Zhu, G. J., Zhang, Y. Z., Zhang, L. B., Hagan, E. A., Martinez, S., ... & Daszak, P. (2020). A qualitative study of zoonotic risk factors among rural communities in southern China. ***International health***, 12(2), 77-85. https://doi.org/10.1093/inthealth/ihaa001
10. Peel, A. J., Wells, K., Giles, J., Boyd, V., Burroughs, A., Edson, D., Crameri, G., Baker, M. L., Field, H., Wang, L. F., McCallum, H., Plowright, R. K., & Clark, N. (2019). Synchronous shedding of multiple bat paramyxoviruses coincides with peak periods of Hendra virus spillover. ***Emerging microbes & infections***, 8(1), 1314–1323. https://doi.org/10.1080/22221751.2019.1661217
11. Li, H., Mendelsohn, E., Zong, C., Zhang, W., Hagan, E., Wang, N., Li, S., Yan, H., Huang, H., Zhu, G., Ross, N., Chmura, A., Terry, P., Fielder, M., Miller, M., Shi, Z., & Daszak, P. (2019). Human-animal interactions and bat coronavirus spillover potential among rural residents in Southern China. ***Biosafety and health***, 1(2), 84–90. https://doi.org/10.1016/j.bsheal.2019.10.004
12. Irving, A. T., Ng, J. H., Boyd, V., Dutertre, C. A., Ginhoux, F., Dekkers, M. H., ... & Wang, L.

F. (2020). Optimizing dissection, sample collection and cell isolation protocols for frugivorous bats. ***Methods in Ecology and Evolution***, 11(1), 150-158. https://doi.org/10.1111/2041-210X.13325

13. Cui, J., Li, F. & Shi, ZL. (2019). Origin and evolution of pathogenic coronaviruses. ***Nat Rev Microbiol*** 17, 181–192. https://doi.org/10.1038/s41579-018-0118-9
14. Luo, C. M., Wang, N., Yang, X. L., Liu, H. Z., Zhang, W., Li, B., Hu, B., Peng, C., Geng, Q. B., Zhu, G. J., Li, F., & Shi, Z. L. (2018). Discovery of Novel Bat Coronaviruses in South China That Use the Same Receptor as Middle East Respiratory Syndrome Coronavirus. ***Journal of virology***, 92(13), e00116-18. https://doi.org/10.1128/JVI.00116-18
15. Eskew, E.A., Olival, K.J. (2018). De-urbanization and Zoonotic Disease Risk. ***EcoHealth*** 15, 707–712. https://doi.org/10.1007/s10393-018-1359-9
16. Wu, Z., Lu, L., Du, J., Yang, L., Ren, X., Liu, B., Jiang, J., Yang, J., Dong, J., Sun, L., Zhu, Y., Li, Y., Zheng, D., Zhang, C., Su, H., Zheng, Y., Zhou, H., Zhu, G., Li, H., Chmura, A., … Jin, Q. (2018). Comparative analysis of rodent and small mammal viromes to better understand the wildlife origin of emerging infectious diseases. ***Microbiome*****,** 6(1), 178. https://doi.org/10.1186/s40168-018-0554-9
17. Field, H. E. (2018). Evidence of Australian bat lyssavirus infection in diverse Australian bat taxa. ***Zoonoses and public health***, 65(6), 742-748. https://doi.org/10.1111/zph.12480

Papers submitted or in preparation

- A strategy to assess spillover risk of bat SARS-related coronaviruses in Southeast Asia. ***Nature communications*** *(in preparation)*
- Li, H., Chen, Y., Machalaba, C., Tang, H., Chmura, A., Field, M., Daszak, P. (2021) Wild animal and zoonotic disease risk management and regulation in China. ***Zoonoses and public health*** *(under revision)*

C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

Yes

Publications Reported for this Reporting Period

Public Access Compliance	Citation
Complete	Luo CM, Wang N, Yang XL, Liu HZ, Zhang W, Li B, Hu B, Peng C, Geng QB, Zhu GJ, Li F, Shi ZL. Discovery of Novel Bat Coronaviruses in South China That Use the Same Receptor as Middle East Respiratory Syndrome Coronavirus. Journal of virology. 2018 July 1;92(13). PubMed PMID: 29669833; PubMed Central PMCID: PMC6002729; DOI: 10.1128/JVI.00116-18.
Complete	Field HE. Evidence of Australian bat lyssavirus infection in diverse Australian bat taxa. Zoonoses and public health. 2018 September;65(6):742-748. PubMed PMID: 29785730; PubMed Central PMCID: PMC6249124; DOI: 10.1111/zph.12480.
Complete	Wu Z, Lu L, Du J, Yang L, Ren X, Liu B, Jiang J, Yang J, Dong J, Sun L, Zhu Y, Li Y, Zheng D, Zhang C, Su H, Zheng Y, Zhou H, Zhu G, Li H, Chmura A, Yang F, Daszak P, Wang J, Liu Q, Jin Q. Comparative analysis of rodent and small mammal viromes to better understand the wildlife origin of emerging infectious diseases. Microbiome. 2018 October 3;6(1):178. PubMed PMID: 30285857; PubMed Central PMCID: PMC6171170; DOI: 10.1186/s40168-018-0554-9.
Complete	Eskew EA, Olival KJ. De-urbanization and Zoonotic Disease Risk. EcoHealth. 2018 December;15(4):707-712. PubMed PMID: 30120670; PubMed Central PMCID: PMC6265062; DOI: 10.1007/s10393-018-1359-9.
N/A	Irving AT, Ng JJ, Boyd V, Dutertre C, Ginhoux F, Dekkers MH, Meers J, Field HE, Crameri G, Wang L. Optimizing dissection, sample collection and cell isolation protocols for frugivorous bats. Methods in Ecology and Evolution. 2019 October 30;11(1):150-158.
Complete	Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nature reviews. Microbiology. 2019 March;17(3):181-192. PubMed PMID: 30531947; PubMed Central PMCID: PMC7097006; DOI: 10.1038/s41579-018-0118-9.
Complete	Li H, Mendelsohn E, Zong C, Zhang W, Hagan E, Wang N, Li S, Yan H, Huang H, Zhu G, Ross N, Chmura A, Terry P, Fielder M, Miller M, Shi Z, Daszak P. Human-animal interactions and bat coronavirus spillover potential among rural residents in Southern China. Biosafety and health. 2019 September;1(2):84-90. PubMed PMID: 32501444; PubMed Central PMCID: PMC7148670; DOI: 10.1016/j.bsheal.2019.10.004.
Complete	Li HY, Zhu GJ, Zhang YZ, Zhang LB, Hagan EA, Martinez S, Chmura AA, Francisco L, Tai H, Miller M, Daszak P. A qualitative study of zoonotic risk factors among rural communities in southern China. International health. 2020 February 12;12(2):77-85. PubMed PMID: 32040190; PubMed Central PMCID: PMC7017878; DOI: 10.1093/inthealth/ihaa001.
Complete	Daszak P, Olival KJ, Li H. A strategy to prevent future epidemics similar to the 2019-nCoV outbreak. Biosafety and health. 2020 March;2(1):6-8. PubMed PMID: 32562482; PubMed Central PMCID: PMC7144510; DOI: 10.1016/j.bsheal.2020.01.003.

Complete	Albery GF, Eskew EA, Ross N, Olival KJ. Predicting the global mammalian viral sharing network using phylogeography. Nature communications. 2020 May 8;11(1):2260. PubMed PMID: 32385239; PubMed Central PMCID: PMC7210981; DOI: 10.1038/s41467-020-16153-4.
N/A	Barrett J, Höger A, Agnihotri K, Oakey J, Skerratt LF, Field HE, Meers J, Smith C. An unprecedented cluster of Australian bat lyssavirus in Pteropus conspicillatus indicates pre-flight flying fox pups are at risk of mass infection. Zoonoses and public health. 2020 June;67(4):435-442. PubMed PMID: 32311218; DOI: 10.1111/zph.12703.
Complete	Welbergen JA, Meade J, Field HE, Edson D, McMichael L, Shoo LP, Praszczalek J, Smith C, Martin JM. Extreme mobility of the world's largest flying mammals creates key challenges for management and conservation. BMC biology. 2020 August 21;18(1):101. PubMed PMID: 32819385; PubMed Central PMCID: PMC7440933; DOI: 10.1186/s12915-020-00829-w.
Complete	Latinne A, Hu B, Olival KJ, Zhu G, Zhang L, Li H, Chmura AA, Field HE, Zambrana-Torrelio C, Epstein JH, Li B, Zhang W, Wang LF, Shi ZL, Daszak P. Origin and cross-species transmission of bat coronaviruses in China. Nature communications. 2020 August 25;11(1):4235. PubMed PMID: 32843626; PubMed Central PMCID: PMC7447761; DOI: 10.1038/s41467-020-17687-3.
Complete	Wu Z, Han Y, Liu B, Li H, Zhu G, Latinne A, Dong J, Sun L, Su H, Liu L, Du J, Zhou S, Chen M, Kritiyakan A, Jittapalapong S, Chaisiri K, Buchy P, Duong V, Yang J, Jiang J, Xu X, Zhou H, Yang F, Irwin DM, Morand S, Daszak P, Wang J, Jin Q. Decoding the RNA viromes in rodent lungs provides new insight into the origin and evolutionary patterns of rodent-borne pathogens in Mainland Southeast Asia. Microbiome. 2021 January 21;9(1):18. PubMed PMID: 33478588; PubMed Central PMCID: PMC7818139; DOI: 10.1186/s40168-020-00965-z.
Complete	Iglesias R, Cox-Witton K, Field H, Skerratt LF, Barrett J. Australian Bat Lyssavirus: Analysis of National Bat Surveillance Data from 2010 to 2016. Viruses. 2021 January 27;13(2). PubMed PMID: 33513882; PubMed Central PMCID: PMC7911197; DOI: 10.3390/v13020189.

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
DASZAK	Y	Daszak, Peter	BS,PHD	PD/PI	1.0	0.0	0.0			NA

Glossary of acronyms:
S/K - Senior/Key
DOB - Date of Birth
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RE - Reentry Supplement
DI - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

Yes

The grant is currently in suspension. As per instructions from our Grant Management Program Specialist, we have entered 1 calendar month for Dr. Peter Daszak solely to pass eRA Commons submission validation requirements - although NO work has been performed since the cancellation of our award on 24th April 2020.

D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

No

D.2.c Changes in Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

No

D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

D.2.e Multi-PI (MPI) Leadership Plan

Will there be a change in the MPI Leadership Plan for the next budget period?

NA

E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES? Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE? NOTHING TO REPORT
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER? Not Applicable
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)? NOTHING TO REPORT

F. CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

Current award is in suspension.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Sub-Project ID	Study ID	Study Title	Delayed Onset	Clinical Trial	NCT	NIH-Defined Phase 3	ACT
	266590	Understanding the Risk of Bat Coronavirus Emergence: Community and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences	NO	NO			

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Are there personnel on this project who are newly involved in the design or conduct of human subjects research?

No

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Does this project involve vertebrate animals?

Yes

G.8 PROJECT/PERFORMANCE SITES

Organization Name	DUNS	Congressional District	Address
Primary: EcoHealth Alliance	077090066	NY-010	ECOHEALTH ALLIANCE, INC. 520 EIGHTH AVENUE NEW YORK, NY 100184183

G.9 FOREIGN COMPONENT

No foreign component

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

No

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period? No

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?

No

Section 1 - Basic Information (Study 266590)

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 03/31/2020

1.1. Study Title *

Understanding the Risk of Bat Coronavirus Emergence: Community and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	○ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	○ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	○ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 266590)

2.1. Conditions or Focus of Study

- Emerging zoonotic disease from bat Coronavirus

2.2. Eligibility Criteria

Participants to be enrolled in this study will be people living, working, or visiting the high-risk sites: 1) of likely divergence of SARSr-CoVs; 2) with a high diversity of SARSr-CoVs within the S protein sequence divergence of 5-25%; and 3) with high rates of human-wildlife interactions in four provinces of Yunnan, Guangxi, Guizhou, and Guangdong in China, who meet the inclusion criteria outlined below. Study sites are prioritized according to ecological and epidemiological conditions associated with a high risk for SARSr-CoVs spillover.

Research participants will be enrolled in two settings of community and hospital or clinic.

Community
People living, working, or visiting targeted high-risk communities (as defined above) who have close contact with bats, we anticipate interviewing and collecting biological samples from individuals with a range of exposure to bats. Enrolled research participants will be asked to provide biological samples and complete a questionnaire that is designed to obtain information about living circumstances (e.g. distance between the living house and closest bat roost, observed bats in house), income or livelihood, experience with SARI and ILI-like illness and involvement in activities with direct or indirect (e.g. via livestock) contact with bats.

Additional inclusion criteria for community participants
- Adults (18 years of age or older) who provide informed consent
- Pregnant women will be considered eligible for inclusion

Exclusion criteria for community participants
- Adults (18 years of age or older) who are unable to provide informed consent, including individuals with physiologically or medically induced cognitive impairments
- Individuals under 18 years of age
- Prisoners

Hospital or clinic
Patients at clinics or hospitals presenting with clinically defined symptoms of severe/acute respiratory illness (SARI/ARI) and/or influenza-like illness (ILI) with unknown origin. As with the community-based group, biological samples will be collected from the patients, and the patients or his/her designate will complete a questionnaire. We will follow up with these participants 35 days after enrollment to collect another biological sample to assess the development of IgG and collect additional data on the course of symptoms in the interim period.

Additional inclusion criteria for hospital or clinic participants
- Adults (18 years of age or greater) who provide informed consent
- Children aged 12 years or older with an accompanying parent or guardian who is able to provide informed consent, with the assent of children 12 years or older also required
- Pregnant women will be considered eligible for inclusion

Exclusion criteria for hospital or clinic participants
- Individuals over the age of 12 years who refuse to provide informed consent
- Adults unable to provide informed consent, including individuals with physiologically or medically induced cognitive impairments
- Children, aged 12-17, without an accompanying parent or guardian who is able to provide informed consent, or a child aged 12 to 17 who is unable or unwilling to provide assent
- Children < 12 years of age
- Prisoners

2.3. Age Limits	Min Age: 12 Years Max Age: N/A (No limit)
2.4. Inclusion of Women, Minorities, and Children	NIAID_COV_2019_Inclusion_of_Women_Minorities_Children_Final.pdf
2.5. Recruitment and Retention Plan	NIAID_COV_2019_Recruitment_Retention_Final.pdf
2.6. Recruitment Status	Not yet recruiting
2.7. Study Timeline	NIAID_COV_2019_Study_Timeline_Final.pdf

INCLUSION OF WOMEN AND MINORITIES:

This proposal will enroll men and women as study participants without regard to ethnicity.

- At community sites, exposure to bats in working and living environments will be the primary criteria for identifying participants in community. We will make every effort to have men and women equally represented in this study and no individuals will be excluded based on ethnicity.

- At clinic sites, only patients who present at the health facility who meet the clinical case definition of 1) severe/acute respiratory illness (SARI/ARI) of unknown origin; or 2) Influenza-like illness (ILI) of unknown origin will be recruited for this study, and no patients will be excluded (or included) based on ethnicity or gender.

INCLUSION OF CHILDREN:

Children aged 12 years or older will be included in the clinical syndromic study.

- Previous clinic-based studies have shown that children are one of the major populations who are affected by the severe/acute respiratory illness (SARI/ARI) and/or Influenza-like illness (ILI).
- Children aged 12 years or older are post-primary school and are able to respond to the questionnaire on their own which increases the reliability of responses.
- Our human research team at the Institute of Pathogen Biology are all well-trained and have extensive experience working with children at this age, as well as their parents, in a clinical setting since 2009.
- Every effort will be made to protect the privacy, dignity, and well-being of children who participate in this study.
- Inclusion of children in the study would increase the sample size to allow for the estimation of effect sizes of behavioral risk factors by two-fold (2X) or greater with 80% power.

We will not include children in the community-based surveillance because children in target communities are mainly school children who have very limited exposures to bats or other wild animals under the scenarios of interest to the study, prolonged time spent in the forests or markets.

RECRUITMENT AND RETENTION PLAN

In order to improve recruitment within target communities, introductory visits will be made by project staff to each of the selected sites. These visits will be advertised through word of mouth and a project description letter to town/city leaders that can be posted in a central community location. The letter will inform the community that a team will be coming on a particular day(s) to discuss health issues related to animal contact. The letter will not be advertised for recruitment purposes. It will only be used to inform the community of the research visits. The project description letter will be written in the local language with a Flesch–Kincaid readability score equivalent to a 7th grade and up level (post-primary in China), to assure that potential community participants understand the study purpose, eligibility, and inclusion guidelines.

During community visits, discussions and meetings will be held firstly with local authorities and community leaders to introduce our project, and when appropriate and following approval from local authorities, the study team will post flyers to inform the community when the team will be coming back to speak about enrollment. This “town hall” style meeting will be completely voluntary, and, based on our experience, those interested would likely attend. Although local authorities may be present to introduce the study team members, they will not be involved in the recruitment and/or consent of the participants for the study. If research visits or recruitment are held at a workplace, subjects will be clearly informed during this recruitment process that their participation in the study is voluntary and will not impact their employment, nor will information discussed be shared with employers. With the local permission and accompanied will local authorities or community leaders, study team members will also engage in community ‘walkabouts’ during which they will discuss study details, as well as dates, times, and locations for enrollment and participation in the study.

Participation in the study will be strictly voluntary and will require signed informed consent for all participants and signed assent for clinical participants aged 12-17 along with parent or guardian consent. Participants will be given a consent form prior to being asked to participate in this study. Our research staff will read the consent form to potential participants, and they will review the consent form with the research staff and be given time to ask questions. After reviewing the consent form, study staff will explain details of the study including: why they were selected, what the study procedures are and what will be expected from them, potential risks and benefits of their participation, that their participation is completely voluntary, and that they can withdraw their participation at any time. Responses will be kept strictly confidential. Measures will be taken to assure the privacy, dignity, and respect of each participant. During training of research staff, we will emphasize the importance of avoiding coercion and protecting the privacy of participants.

Community-based recruitment: Participants from the community will be recruited through town hall meetings and community ‘walkabouts’ as described above. Meeting dates, times, and locations for enrollment and participation will be shared during these activities, and participants who wish to enroll can volunteer to participate at these times and locations.

Clinic-based recruitment: Patients eligible for enrollment will be identified at intake areas or in the emergency room, ward, or intensive care unit of each participating clinic and hospital by clinic staff, according to standard operating procedures at collaborating sites. Employed staff at each location will identify potential participants meeting the clinical case definition of severe/acute respiratory illness (SARI/ARI) and/or influenza-like illness (ILI) with unknown origin. Patients will be screened for eligibility according to the inclusion/exclusion criteria based on available clinical information. For larger provincial-level hospitals, interval sampling will be implemented by selecting every Nth case at the site among those individuals who meet enrollment criteria. The interval will be determined by local implementing partners based on an evaluation of the expected number of cases presenting at the site within a given year in order to best meet study design and sample size criteria. In terms of retention, we will express our gratitude to subjects for their participation and discuss the importance of the follow-up data collection. Nonetheless, we expect to have an approximate 40% loss to follow up and have included this in our sample size calculations.

STUDY TIMELINE

Patients/participants will be asked to volunteer approximately 1 hour of their time for participation in the study, including providing biological samples and completing the questionnaire at each sampling time point.

This will be an ongoing, five-year project (June 01, 2019 -- May 31, 2024). We anticipate to starting human subject enrollment on June 01, 2020, and completion of preliminary analyses is expected in 2024.

Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
IER 264238	Foreign	Local community and hospital/clinic in Yunnan, Guangdong, Guangxi, Guizhou Provinces

Inclusion Enrollment Report 264238

Using an Existing Dataset or Resource* : ○ Yes ● No

Enrollment Location Type* : ○ Domestic ● Foreign

Enrollment Country(ies): CHN: CHINA

Enrollment Location(s): Local community and hospital/clinic in Yunnan, Guangdong, Guangxi, Guizhou Provinces

Comments: This is a renewal, the cumulative enrollment from the previous funding period 5R01AI110964-05 is 980 females and 616 males, in total 1,596 Asians.
We don't plan to use the existing dataset.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	4675	4675	0	0	9350
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	4675	4675	0	0	9350

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 266590)

3.1. Protection of Human Subjects	NIAID_COV_2019_Protection_Human_Subjects_Final.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	○ Yes ● No ○ N/A
If yes, describe the single IRB plan	
3.3. Data and Safety Monitoring Plan	
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	○ Yes ● No
3.5. Overall structure of the study team	

PROTECTION OF HUMAN SUBJECTS:

1. Risks to Human Subjects

1.1 Human Subjects Involvement, Characteristics, and Design
This project is a study of human exposure to animal coronaviruses in southern China. Subjects will be enrolled on a voluntary basis and informed consent will be obtained from all participants. Consenting participants will provide biological samples and complete a questionnaire. Subjects will be individuals: 1) who are highly exposed to bats in community settings, including through hunting, butchering, or general handling within the context of their living or working environment (≥ 18 years old); and 2) patients admitted to hospitals and clinics presenting with disease symptoms of clinically-defined severe/acute respiratory illness (SARI/ARI) or Influenza-like illness (ILI) of unknown origin (≥ 12 years old).

The study population will be selected from the Yunnan, Guangxi, Guangdong, and Guizhou provinces of China. We will aim to enroll: 1) in 12 clinic sites across the four provinces, 2,750 individuals (accounting for an estimated 40% loss from follow-up); and 2) in 8 community sites, 1,650 individuals per each of the four provinces, pooled across two sites for each province for a total of 6,660 (1,650*4) participants, allowing us to make province-level comparisons of differing effects (one time data collection, no follow-up among community participants). The community and clinical sites are further defined in **"Specific Aim 2: Using community-based and clinical biological-behavioral surveys to identify SARSr-CoV spillover, routes of exposure and public health consequences of human infection"**.

There are no data to suggest a gender or ethnic bias for coronavirus exposure or infection, therefore subjects will be enrolled based on exposure criteria, and subjects will not be excluded based on ethnicity or gender. We will also stratify sampling to ensure representation of sex, demographic, and socio-economic factors in each community site.

1.2 Sources of Materials
Samples to be collected and screened for coronaviruses include whole blood and nasal/oropharyngeal swabs. Samples will be collected and a questionnaire will be administered by trained medical personnel from the local CDC, hospitals, and clinics. In community sites, whole blood samples (only) will be collected once during Years 2-4 of the study, and samples will be screened for coronaviruses using developed ELISA at the Institute of Pathogen Biology and the Wuhan Institute of Virology. In clinic sites, both whole blood samples and nasal/oropharyngeal swabs will be collected at enrollment, and samples will be screened for coronaviruses using ELISA and consensus PCR (cPCR). Patients who test positive for coronavirus or antibodies to coronavirus will be followed up 35 days after enrollment, when additional blood samples will be collected for serological testing with ELISA.

At the enrollment, a standardized questionnaire will be administered at both community and clinic sites to collect data on living circumstances (e.g. distance between the living house and closest bat roost, observed bats in house), income or livelihood, experience with SARI and ILI-like illness and involvement in activities with direct or indirect (e.g. via livestock) contact with bats. During the follow-up with clinic study participants, a standardized questionnaire supplement will be administered to collect additional data on the course of symptoms in the interim period. All electronic data will be password protected, and all hardcopy files and biological samples will be stored in secure storage facilities. All consent forms will be stored separately from any data in separated locked filing cabinets.

1.3 Potential Risks
The potential risks to study participants resulting from study participation are minimal. The volume of blood being collected is within normal safety limits. The questionnaire will be designed to assess exposure risk, and may ask personal questions, but they will conducted in private and confidentially to protect privacy. There may be some stress to subjects who are informed that they have been exposed to an animal virus, but counseling will be available and options for medical care will be included in the discussion.

2. Adequacy of Protection against Risks

2.1 Recruitment and Informed Consent

Potential study participants at each site will be identified by well-trained in-country research team in partnership with local CDC staff (for community participants) and medical personnel (for clinic participants). The team will be thoroughly trained on communicating the research objectives, what is being asked of participants, any risks or benefits, and will be able to address any questions that potential subjects may have. Both written and oral descriptions of the study details will be provided in Chinese Mandarin (or orally via an interpreter in local dialects if necessary) as part of the informed consent process. Contact details of the collaborators at the local CDC or hospital and the study PI will be provided to all subjects, and CDC or hospital personnel on the research team will be available onsite to answer questions from the study subjects. Test results will be communicated to each subject and counseling offered to minimize stress.

2.2 Protection against Risks

After the informed consent process, the questionnaire will be conducted in private, ensuring that others cannot overhear responses. Individual sessions will be held in areas where there are no other individuals within a 10-foot distance. A barrier will be created so that no other individuals can view the participants during their interview. Depending on the location, this could be a private room, behind a building or fence, or behind a line of trees, obstructing view so that confidentiality may be maintained. The interview team will take care to pair interviewers and respondents by sex to the best of their ability to increase the level of comfort of the participant and the team will ensure the privacy and confidentiality of responses. Children will not be interviewed in the absence of a parent or guardian. This study will not involve greater than minimal risk, and every effort will be made to ensure the privacy, dignity, and well-being of children who participate in this study.

3. Potential Benefits to Subjects and Others

There are potential benefits to the study subjects including receiving a physical exam/health check from a medical officer and the potential benefit of identifying a health hazard. At the conclusion of the study, we will deliver an educational workshop for high risk individuals (open to study subjects and non-study subjects) describing the health benefits of using PPE and hand-washing during animal handling activities throughout the day, as well as to share other prevention interventions that emerge from the research data.

4. The Importance of Knowledge to be Gained

There are valuable potential benefits to the general public from the knowledge to be gained by this study, as it may identify sources of zoonotic coronaviruses in the market system or through hunting. Avoidance of these animals or extra care when handling them may substantially reduce the risk of CoVs (and other zoonotic pathogen) transmission.

Section 4 - Protocol Synopsis (Study 266590)

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

Type	Name	Description

4.2.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ❍ No

4.2.e. Intervention Model

4.2.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.2.g. Allocation

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description

4.4. Statistical Design and Power

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.7. Dissemination Plan

Section 6 - Clinical Trial Milestone Plan (Study 266590)

6.1. Have there been any anticipated or unanticipated serious adverse events?	❍ Yes	❍ No	❍ Not Applicable
6.2. Have adverse events occurred with greater than 5 percent frequency within any area of the clinical trial?	❍ Yes	❍ No	❍ Not Applicable
6.3. Study Start Date			
6.4. Study Primary Completion Date			
6.5. Study Final Completion Date			
6.6. Enrollment and randomization			
Enrollment of the first subject	06/01/2020	Anticipated	
25% of planned enrollment recruited by			
50% of planned enrollment recruited by			
75% of planned enrollment recruited by			
100% of planned enrollment recruited by			
6.7. Completion of primary endpoint data analysis			
6.8. Completion of secondary endpoint data analysis			
6.9. Reporting of results in ClinicalTrials.gov			
6.10. Is this an applicable clinical trial under FDAAA?	❍ Yes	❍ No	

NIH-NIAID Progress report, Year 5 and FINAL report; July 2012- August 2013
Grant Number: 5R01AI079231-05
Project Title: Risk of Viral Emergence from Bats
PI: Dr. Peter Daszak
Institution: EcoHealth Alliance

24 November 2013

Major Milestones and Highlights 2009-2013. Categorized by Original Primary Aims

We will expand on each of these primary findings below.

We published over 50 peer-reviewed papers from this award, including in *Nature*, *Lancet*, *PNAS*, *Emerging Infectious Diseases*, *MBio*, *PLOS Pathogens*, *Journal of Virology*, *Journal of General Virology*, and others. Full list provided at the end of this report.

Aim 1. Predictive modeling of bat viral diversity and risk of future emergence.

1. Produced models and maps of global 'hotspots' of bat viral diversity and bat zoonoses risk; paper Submitted to *Proc Roy Soc B*.
2. Pandemic risk model based on bat viral hotspots and global travel and trade. *PLoS ONE* paper published; other models developed.
3. First ever estimate of the number of unknown viruses in bats (and mammals) using exhaustive sampling and ecological methods for species diversity. *MBio* paper published.
4. Modeled future spread of bat zoonoses under different global climate change projections using ecological niche models. *PNAS* paper published.
5. Created database with >45,000 bat parasite/pathogen records from last 100 years of literature. This year we updated to include specific analyses of bat viral discovery efforts over past 5 years – meta-analyses of 95 studies.
6. Built bat species-specific and virus-specific models to identify species and pathogens of the highest risk for emerging bat zoonoses.

Aim 2. Bat viral pathogen identification using a staged strategy.

7. Over 100 putative new viruses discovered; screened over 40,000 specimens from bats from over 120 species globally. Numerous papers published including: *Nature*; *Emerging Infectious Diseases*; *PLoS Pathogens*; *Journal of Virology*; and *Journal of General Virology*.
8. Phylogenetic analyses of all novel bat viruses identified together with related viruses.
9. Developed and optimized conserved family-level viral PCR assays for 16 viral families; and optimized next-generation sequencing pipelines for viral discovery in bats.
10. Developed sampling protocols for optimal, non-invasive collection of bat specimens; trained over 250 participants from 8 countries using these protocols.

Aim 3. Bat viral pathogenesis

11. Attempted viral isolation on 100s of PCR positive samples.
12. Demonstrated proof of concept for bat viruses isolation and in vitro investigations of host range using cell lines from multiple species – i.e. SARS-like CoV study from China published in *Nature*.

Major Findings from Last 12 months of Grant, 2012-13:

- In the last 12 months we sampled over 3500 individual bats from our target countries, including: Bangladesh, China, Guatemala, Malaysia, Mexico, Thailand, and the United States.
- We have screened over 8,000 bat specimens for pathogen discovery.
- Ran over 16,000 PCRs to estimated the total viral diversity in a bat species for the first time. Discovered over 50+ new viruses in one species, published in *MBio*.
- Launched a pathogen discovery study of vampire bats in Guatemala and have preliminary results to suggest novel viruses of zoonotic potential circulating in bats that regularly feed on domestic cattle near human habitation.
- Discovered over 80 novel Astroviruses and 15 novel Coronaviruses from Thailand bats; and expanded deep sequencing of Thailand bat samples for pathogen discovery using the Roche 454 Jr. platform.
- Identified coronaviruses related to MERS-CoV in Thailand bat guano harvested for agricultural use, published in *Emerging Infectious Diseases*.
- Isolated a bat coronaviruses for the first time, and identified the closest relatives to SARS-CoV to date. *In vitro* studies of host range for these new viruses using cell lines confirmed that these new viruses are the progenitors to SARS and use the ACE2 receptor, thus able to infect humans. Published in *Nature*.
- Expanded our modeling of bat zoonoses risk using spatial and species-specific approaches. Several manuscripts have been submitted others are In Prep for journals including: *Nature*; *Proceedings of the Royal Society B-Biological Sciences*; and *Oecologia*.

Details for Major Milestones and Primary Results 2009-13, including country specific findings from last 12 months:

1. Mapping global 'hotspots' of bat viral diversity and bat zoonoses risk

Using an extensive database of over 45,000 records of bat viruses and other bat parasites and pathogens from the literature, we created a hotspot map of bat viruses (**Fig 1**).

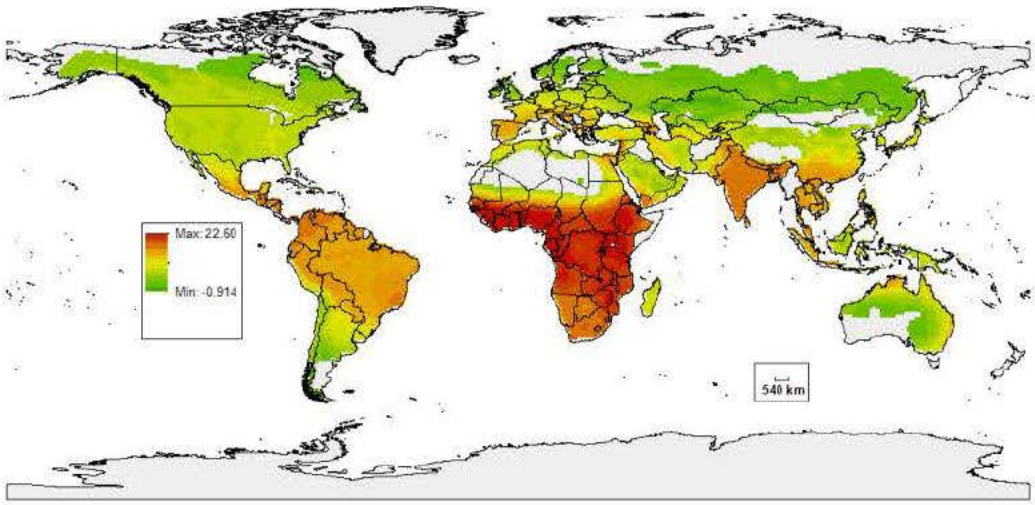


Figure 1: Fitted model, risk map for zoonotic bat-borne viruses "bat virus hotspot map". Red and orange are areas of higher risk for bat zoonoses (Brierley *et al.* In Review).

We identified a number of global predictors of bat-human viral sharing. Coefficients for log-transformed covariates can be interpreted as the increase in viruses predicted by an e-fold (2.718) increase in the covariate. All variables in bold were significant in the model, and covariates are listed in decreasing order of significance. **Table 1** below.

Model Component	Coefficient	95% confidence interval for coefficient	P value
(intercept)	3.299	2.369 to 4.228	3.466e-12
log(bat species richness)	2.872	2.795 to 2.949	< 2.2e-16
log(annual rainfall range)	0.629	0.543 to 0.716	< 2.2e-16
log(bat publication authors)	-0.157	-0.191 to -0.122	< 2.2e-16
log(GDP per capita)	-0.350	-0.437 to -0.263	3.109e-15
log(human density)	0.079	0.056 to 0.102	1.547e-11
bushmeat activity	0.579	0.404 to 0.754	8.443e-11
log(pig stocks)	0.026	0.015 to 0.038	9.542e-06
log(sheep stocks)	0.023	0.011 to 0.034	1.049e-04
arcsin(% crop/pasture cover)	0.106	-0.027 to 0.239	0.119
monthly temperature range	-0.008	-0.035 to 0.019	0.563

By evaluating previous research effort for bat viral discovery globally, we also used these models to identify geographic areas that have been historically either oversampled or undersample for bat viruses. Thus, identifying areas for cost-effective, future viral discovery in bats (**Fig 2**).

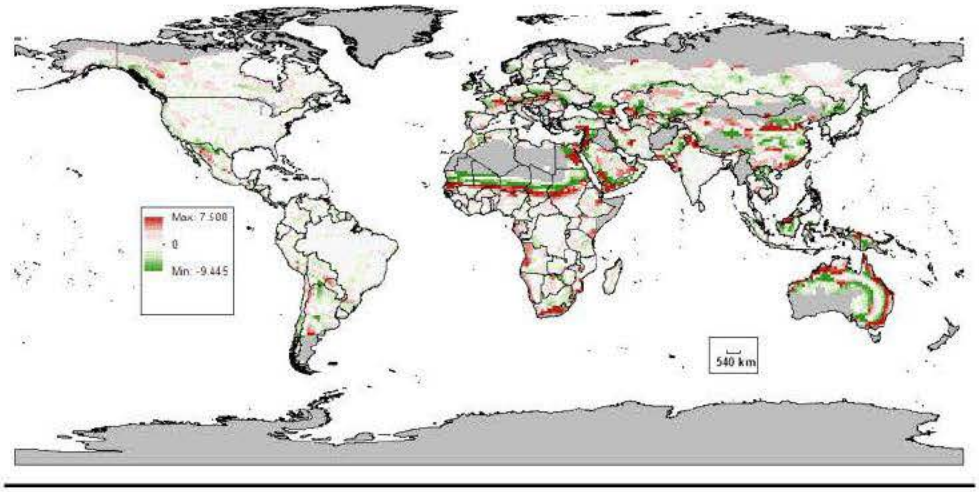


Figure 2. Map showing residuals of bat virus hotspot model. Positive residuals values (red) are where the model under-predicts the actual bat viral diversity, and negative values (green) are where the model over-predicts bat viral diversity. We are using this modeling technique to explore geographic areas (e.g. negative values in red) that are

likely to be more cost-effective in yielding novel bat viruses with devoted sampling efforts.

2. Pandemic risk model based on bat viral hotspots and global travel and trade.

We modeled the global vulnerability from the emergence of all bat transmitted zoonotic viruses using airline travel data from the International Air Transport Association, zoonotic disease hotspot risk maps (Jones et al. 2008), and per capita health care (as a correction, i.e. probability of detecting a disease before it gets on an airplane). Our basic model in the two figures that follow is outlined below. This work was published in PLoS One.

$$\phi_j = \sum_{\text{all } i} \frac{C_{ij} \cdot E_i}{H_i}$$

- Calculating index
- E_i = Zoonotic disease hotspots
- C_{ij} = Est. Number of passengers
- H_i = Healthcare spending per capita
- i = source of risk
- j = destination of risk

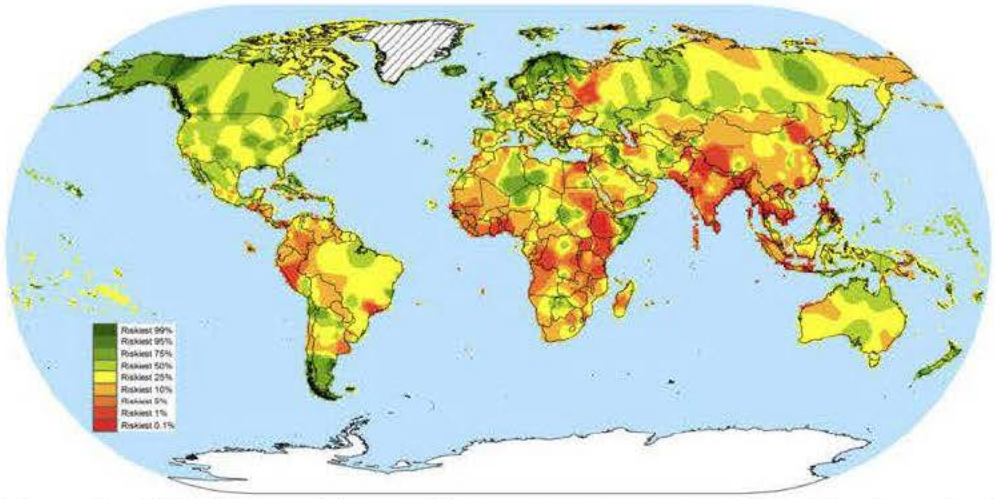


Figure 3. Global vulnerability **outflow** map, areas of greatest risk of pandemic origin for a bat-borne disease based on global travel and trade data. The spread of Middle Eastern Respiratory Syndrome coronavirus (MERS-CoV) to Europe via airline travel highlights this real risk.

Further, as part of our attempts to ground truth these global travel and trade risk assessments for bat-borne viruses, we have been working with US authorities (US Fish and Wildlife; US CDC; National Wildlife Health Center; NY Port Authorities) to screen confiscated bat samples coming into the US. We have documented a large number of bats, most preserved dried, coming into the US both legally and illegally (**Fig 4** below). No viruses have yet been discovered in these specimens.

Figure 4. Bat specimens confiscated at US ports; highlighting risk of bat-borne viruses via the global wildlife trade.

3. First ever estimate of the number of unknown viruses in bats (and mammals) using ecological modeling approaches

Using extensive sampling for one bat species, *Pteropus giganteus*, we estimated asymptotic viral richness for 9 viral families (**Fig 5).** Using data from observed virus detections, we applied three statistical models: Chao2, ICE and Jackknife, typically used to estimate vertebrate or invertebrate species richness in terrestrial ecosystems. This allowed us to estimate the viral richness in this species and, importantly, determine what level of sampling effort it would take to discover all the viruses in a given species. Total viral richness for this species was estimated to be 58 viruses and the required sampling effort to discover all 58 was estimated to be 7079 samples (i.e., ~7 times what we achieved). We identified 55 of these 55 predicted novel viral species using our PCR assays. This study was published in ***MBio***, Anthony et al. 2013, and received considerable media attention.

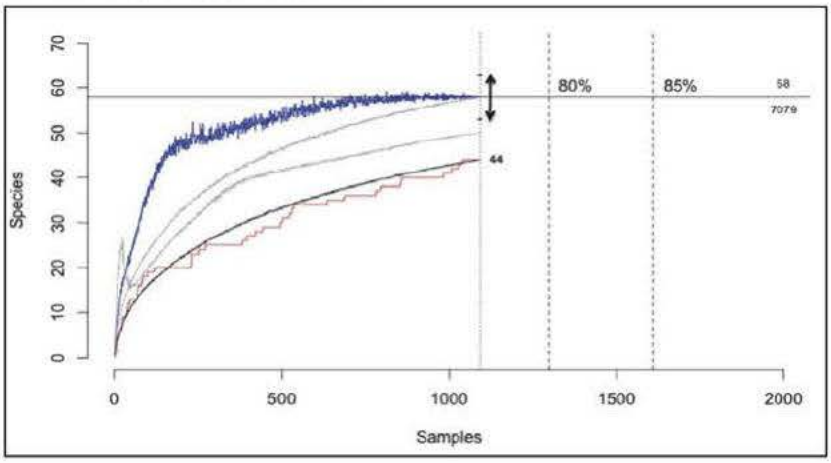


Figure 5. Non-parametric viral richness estimates for *P. giganteus*. Red line = collector curve; Black line = accumulation curve; Blue line = Chao2 richness estimator. The number of samples (vertical dashed lines) needed to detect given % of total viral richness estimated is shown.

We also found a large number of intra and inter-familial viral co-occurrences in *P. giganteus* and showed that as many as five different viruses can exist in a single sample (**Fig 6**). Significant intraspecific co-detections were identified in the families *Herpesviridae* (HV) and *Adenoviridae* (AdV). This revealed information about the carrying capacity and composition of discrete viral niches within an individual bat, and also the number of different viruses that could potentially spillover to a new host from a single exposure event.

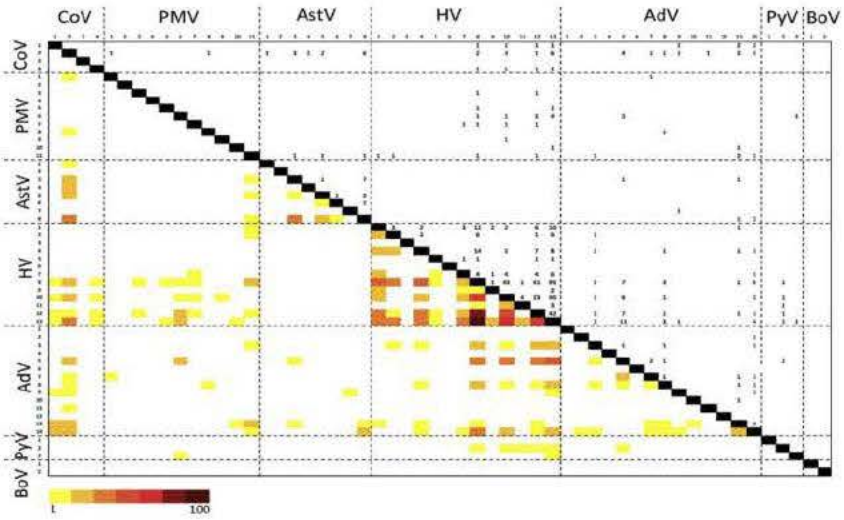


Figure 6. Viral Co-occurrence Analysis in a bat species. Patterns of Herpesvirdae (HV) co-occurrence were non-random (p=<0.001 with C-score and positive pairwise associations were observed between certain virus pairs, particularly within the HVs.

Using these data, we estimate that there is a minimum of **320,000 mammalian viruses awaiting discovery within these nine viral families**, assuming all species harbor a similar number of viruses, with minimal turnover between host species. We **estimate the cost of discovering these viruses** to be ~$6.3 billion (or ~$1.4 billion for 85% of the total diversity), which if annualized over a 10-year study time frame would represent a small fraction of the cost of many pandemic zoonoses.

4. Predicting future spread of bat zoonoses under different global climate change projections using ecological niche models.

As a proof of principle, we used Ecological Niche Models and ensemble methods that aggregate across Global Climate Models (GCMs) to model the future geographic change in bat species distribution and their associated viruses. Our initial model was based on bat species known to harbor Paramxyoviruses, including those hosts we have recently identified with novel Paramxyoviruses from Bangladesh, Malaysia, and Thailand (**Fig 7**).

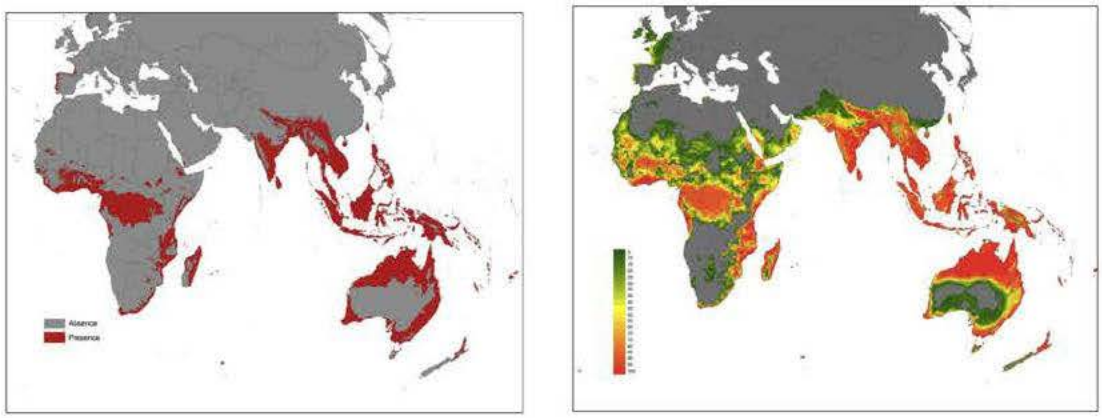


Figure 7. Modeling potential spread of novel henipa-like paramyxoviruses using IPCC (A2 - conservative) climate change scenario models. **Left**, current distirubiton of bat host species for known henipaviruses. **Right**, future projection (2050's) of henipa and henipa-like viruses, based on 50% Global Climate Model agrement using ensembal methods.

5. Database created for all known bat pathogens and parasites from past ~100 years of literature. In 2013, conducted focused meta-analysis of bat viral discovery studies from last 6 years.

We created a database including over 45,000 records for all bat virus, bacterial, fungal, and parasite references from the past 100 years. **These data were used to create our global bat virus 'hotspot' maps, and viral data were additionally used to model species-specific viral diversity and zoonoses risk (see #6 below).**

In 2013, we also conducted a specific analysis of bat viral discovery efforts over past 5 years – **this meta-analysis included 95 bat viral discovery studies published over the course of our grant,** including those from our research group.

The first aim of this study was to evaluate trends in viral discovery by study design, using generalized linear models (GLM) to fit response variables to explanatory study-level variables. Separate models were explored using two response variables, the number of novel and total viruses found per study. Explanatory variables included in the full model were: number of species tested, proportion of bats killed, number of total bats in the study, number of total samples in the study, and number of viral families tested in the study.

We also used GLMs to assess the probability of viral detection given variables specific to sample type, detection method, viral family and study design. Models were fit for the entire dataset, as well as for subsets of data by molecular detection methods only and by viral family.

Over the last six years, 44,322 bats comprising 17 families, 110 genera, and 340 species were sampled across 94 published studies. Overall, a total of 5,946 (9.91%) of all samples tested were found to be virus or antibody positive, with 534 viruses (24 families) identified overall and 248 described as "novel" viruses. Half of studies used lethal sampling methods, with a total of 19,484 individual bats killed across these studies.

The best-fit model for predicting whether a sample would be positive for a given virus included sample type, detection method category, viral family, host family, number of samples tested, and number of viral families tested in the study (AIC=1937.6). There was no significant difference between viral discovery rates in bats that were killed vs. those specimens collected using non-invasive protocols (Fig 8). **We use these results to specifically highlight how the non-lethal sampling protocols we developed during this grant are both effective and conservation minded.**

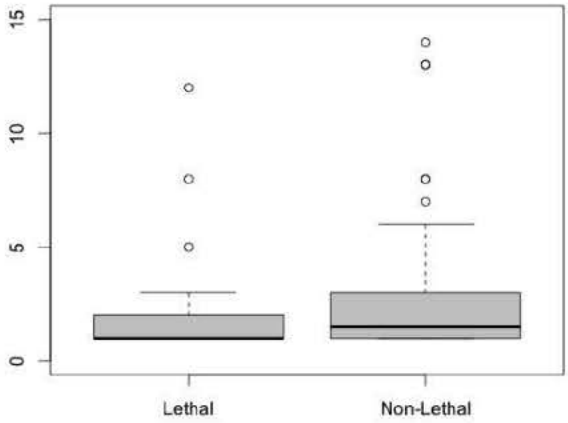


Figure 8. Total number of viruses discovered in a given study (n=95 studies), comparing those studies that used lethal bat sampling vs. those that did not. No significant difference.

6. Built species-specific and virus-specific predictive models to identify species and pathogens of the highest risk for emerging bat zoonoses.

We compiled our data on estimates of average viral prevalence from our efforts and from the literature to examine viral prevelance and diversity viral family and host taxonomy (**Fig 9 and 10**). We are using these analyses and comparing our results to those in the published literature to better quantify the progress of our research over the course of this grant award.

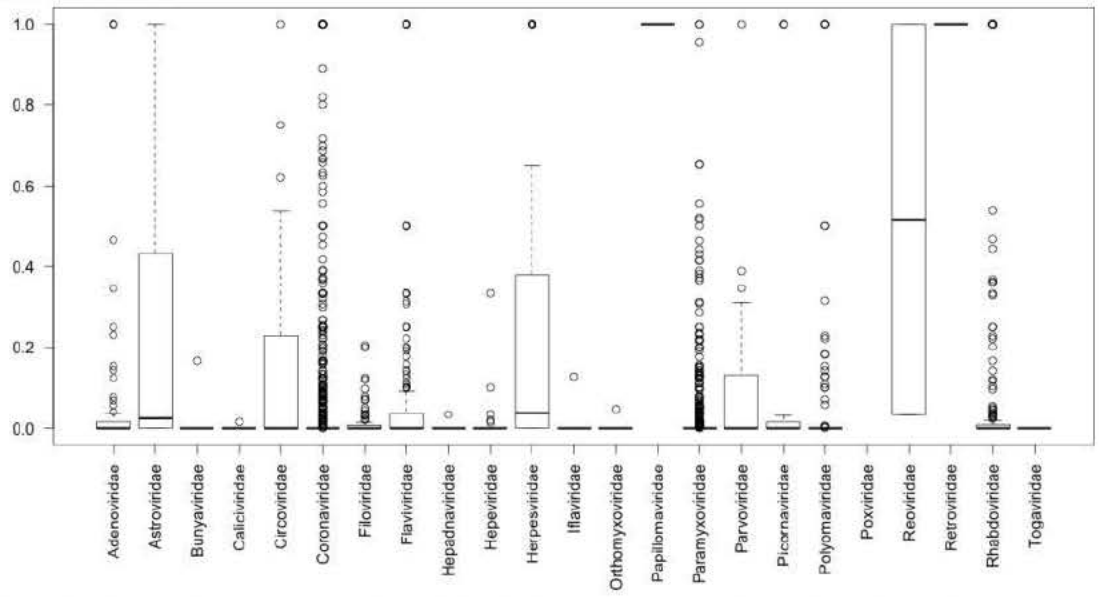


Figure 9. Boxplots of prevalence by viral family from individual sample data collated from 95 bat viral discovery studies published in the last 5 years. Data from both

serological studies and molecular studies are shown together here, but were also analyzed separately.

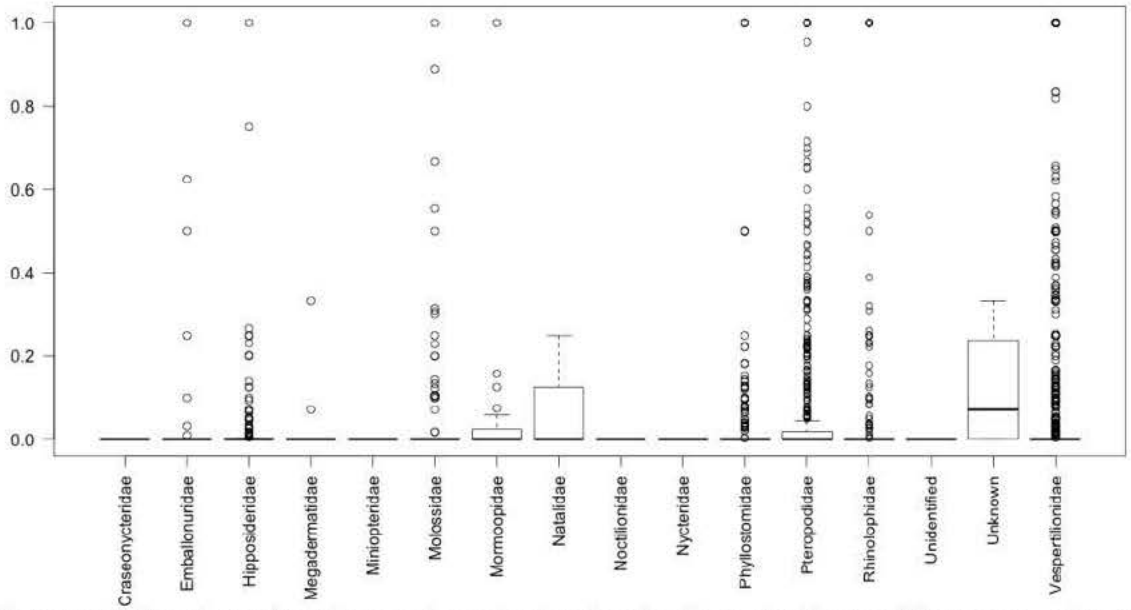


Figure 10. Boxplots of viral prevalence by bat family. Few significant differences exist on a per species analysis, and most of these can be explained by sampling bias by host taxa.

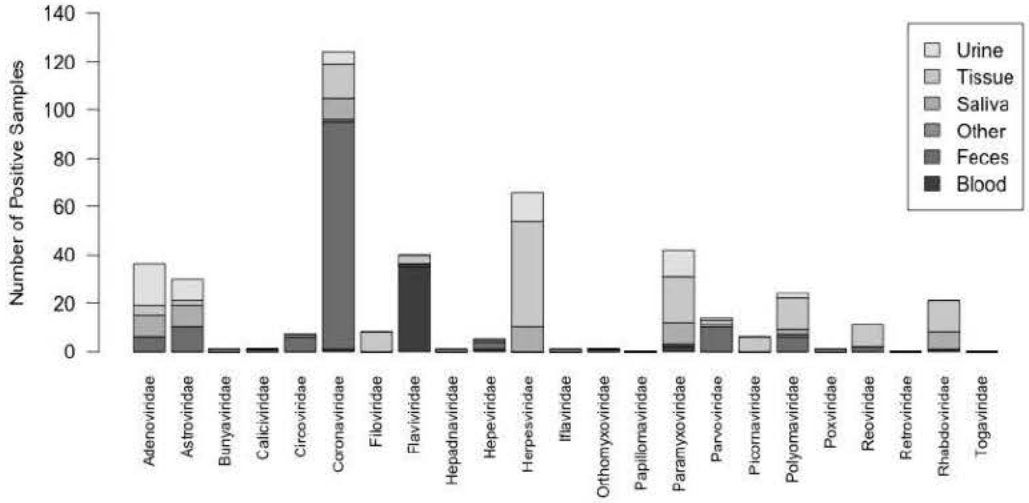


Figure 11. Specimens PCR Positive by Sample Type and Viral Family. This graph, and accompanying GLM models show that some types of viruses are more likely to be found in certain sample types, e.g. CoVs in fecal samples, and are useful for understanding transmission risk and virus tropism.

6. Built species-specific and virus-specific predictive models to identify species and pathogens of the highest risk for emerging bat zoonoses.

Using a our database of bat pathogens from the literature, combined with unpublished results of novel viruses from specific hosts, we used a GLM logistic regression approach, to model the probability of a host being infected with a given bat viruses. Results from our analysis of all known bat viruses support previous empirical work from individual viruses (e.g. bat rabies) that have shown host phylogeny is a significant predictor of cross species transmission (**Fig 12; Table 2 below**). We also found that some viral traits, e.g. replication in the cytoplasm (not shown) will also influence the number of hosts that a give virus infects. Also, sampling bias (when using data from the literature) can significantly bias findings (i.e. the more you look the more you find, **Fig 13**)

Host and Virus Traits	Estimate	Std. Error	z value	Pr(>|z|)
(Intercept)	-3.8292	0.19639	-19.498	<0.001***
Phylogenetic Distance to other bat hosts	-1.1709	0.07469	-15.676	<0.001***
Number of disease publications per host	0.43199	0.06618	6.528	<0.001***
Number of publications per virus	0.50347	0.08172	6.161	<0.001***
Species is hunted (IUCN)	-0.51859	0.19374	-2.677	0.007**
Species in artificial habitat (IUCN)	0.24513	0.17613	1.392	0.163
Virus is segmented	-0.85348	0.22687	-3.762	<0.001***
Virus is vector-borne	-1.0137	0.14334	-7.072	<0.001***

Table 2. Results from logistic generalized linear model (GLM), identifying significant host and virus traits that predict whether or not a virus will be shared among bat species. Those variables in bold were significant.

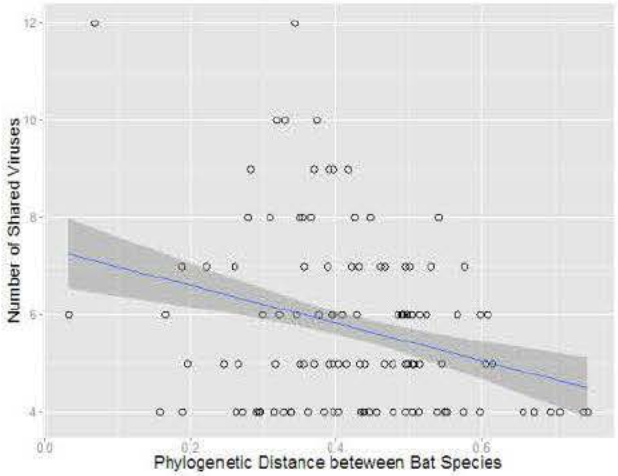


Fig 12. Scatterplot showing a general decrease in the number of shared viruses with decreasing pairwise phylogenetic distance between bat species. Dataset includes all bat species pairs with >3 shared viruses for ~200 pairwise comparisons. Phylogenetic distance based on tip-tip distances from a maximum likelihood tree from cytochrome B mtDNA (1140bp) data.

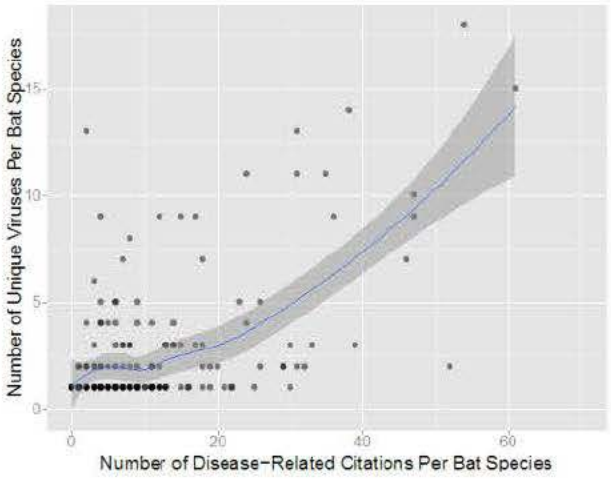
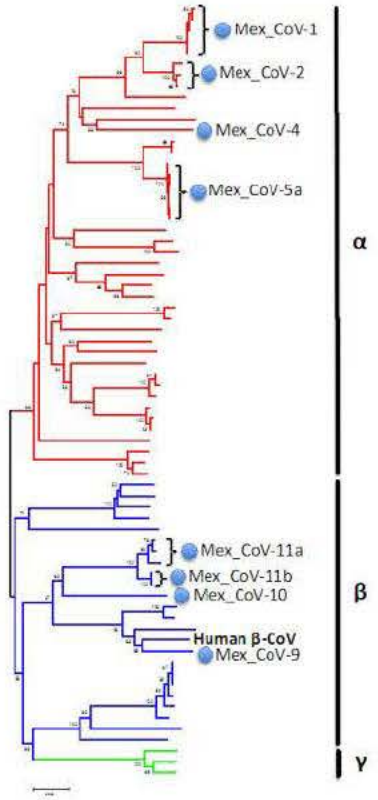


Fig 13. Scatterplot with LOESS curve shows the effect of research bias on known viral richness for ~200 bat species from the literature.

7. **Over 100 putative new viruses discovered; screened over 40,000 specimens from bats from over 120 species globally, and…**
8. **Phylogenetic analyses of all novel bat viruses identified.**



See papers published at end of this report and previous annual reports for more details on novel viral discoveries by family. We have published some of these findings in *Nature*; *MBio*; *Emerging Infectious Diseases*; *PLoS Pathogens*; *PLoS One*; *Journal of Virology*; and *Journal of General Virology*. **In Anthony et al. 2013 (*MBio*) we describe over 55 novel viruses from 9 viral families from bats in Bangladesh and present phylogenetic analyses for each family.** Other highlights include:

- Novel MERS-like viruses from bat guano in Thailand (Wacharapluesadee *et al.* 2013)
- 8 novel CoV from Bats in Mexico (Anthony et al. 2013a), including MERS-like Beta 2c CoVs **Fig 14**.
- **Isolation of SARS-like CoVs that use the ACE2 human receptor from China** (See #11 below).

Figure 14. Novel Coronaviruses discovered in a community of Mexican bats. Including a strain that clusters closely with the human beta 2c CoV, MERS.

9. **Developed and optimized conserved family-level viral PCR assays; and optimized next-generation sequencing pipelines for viral discovery**

We optimized laboratory protocols for viral discovery in bats, primarily utilizing a suite of consensus PCR assays for 14+ viral families (**Fig 15**). While the bulk of our screening was done at **Columbia University's Center for Infection and Immunity** and the **Australian Animal Health Lab**, we also **transferred this technology and protocols to 6 in-country partner labs** that supported work under this award.

Figure 1

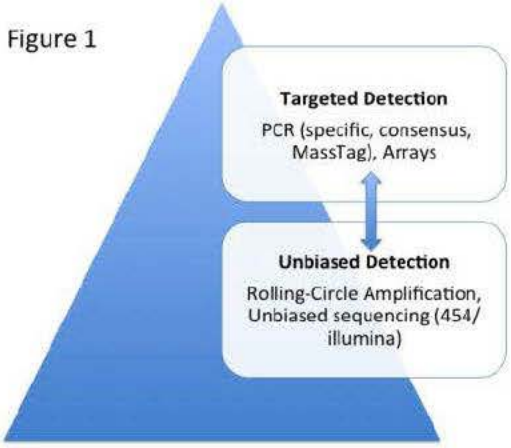


Fig 2. Consensus PCRs for bats

Figure 15. Viral discovery protocols developed, using a mixed approach for each set of samples – screening with consensus PCRs for 14+ viral families, and NGS on a subset of samples or pooled samples to capture the 'unknown' viral diversity undetectable using known pathogen assays.

We developed Next-Generation-Sequencing (NGS) protocols for unbiased detection of viral diversity in bats. This includes methods for viral purification and post-extraction processing that have increased our yield and success in identifying novel viruses (e.g. see Wacharapluesadee et al. 2012). In Thailand, we used the 454 Jr Roche platform with pooled bat urine, saliva and fecal samples from 2 bat species, *Pteropus lylei* and *Tadarida plicata*. These runs typically yielded 100,000s of reads, <1% of which were viral. Preliminary results from pooled saliva samples are shown in **Fig 16**.

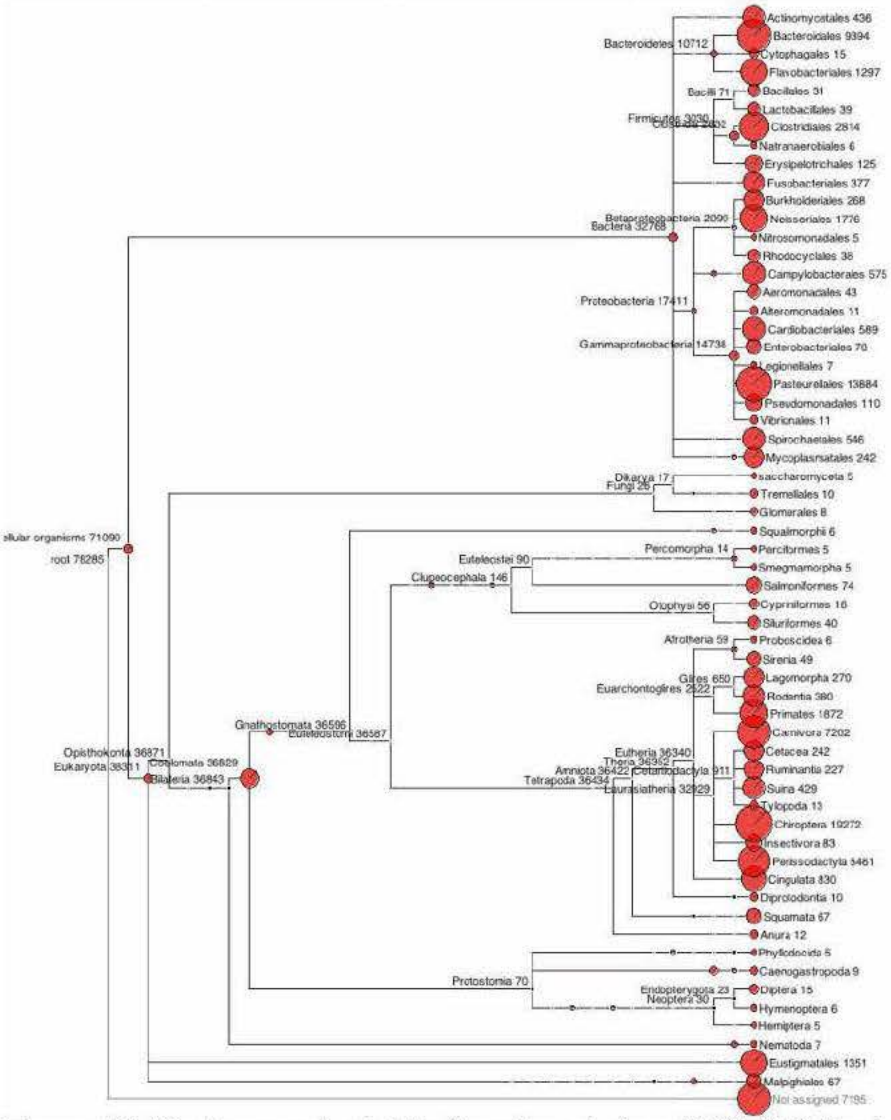


Figure 16. The taxonomic distribution of reads from NGS (454 Roche) sequences from 10 pooled bat saliva samples from Thailand. A majority of reads, 19,272 mapped to Chiroptera, but the taxonomic distribution shows that relatives of <u>many potential</u>

pathogens identified in other host taxa can also be found in bats with increased surveillance and pathogen discovery tools.

10. Developed non-invasive sampling protocols for optimal bat virus specimens; trained over 250 participants from 8 countries using these protocols.

We have developed and optimized field protocols to increase our yield of bat samples. Additional in-country training associated with this award has included hands-on training for methods of bat capture, safe handling, species identification, proper use of Personal Protective Equipment (PPE), and minimally-invasive sample collection. These protocols have been published, e.g. Smith *et al.* 2012 and Newman *et al.* 2012 (FAO manual below, **Fig 17**).

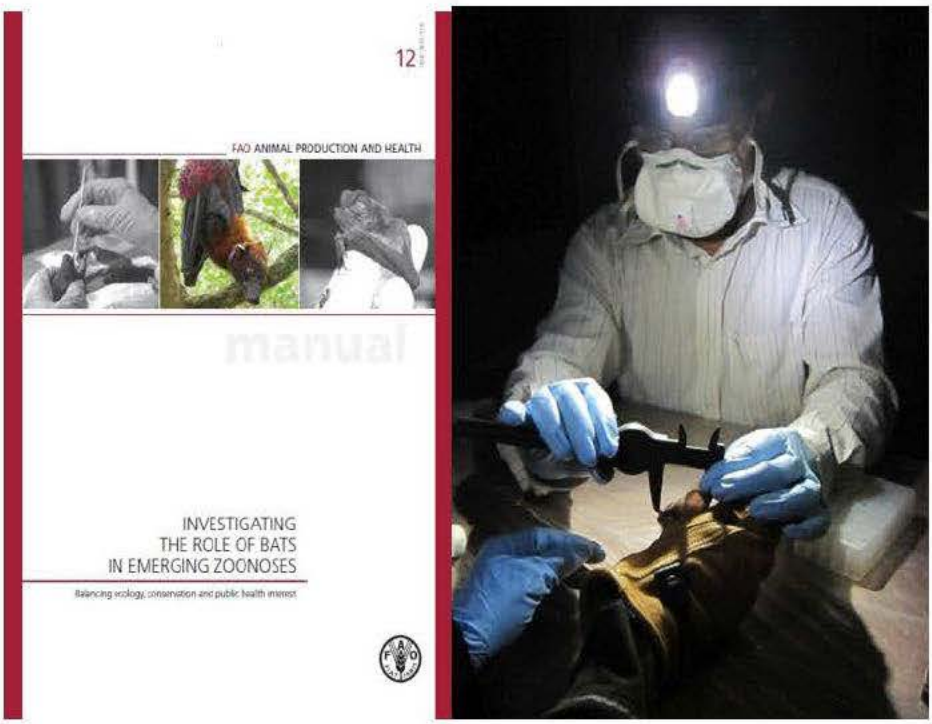


Figure 17. EcoHealth Alliance with FAO co-edited and published a volume on best practices for investigating zoonoses from bats which is freely available online (left); and Dr. Arif Islam (EcoHealth Alliance) demonstrating proper use of calipers for collecting morphological measurements to field team in Bangladesh (right).

11. Attempted viral isolation on 100s of PCR positive samples with limited success. As per the original aims of our grant, we attempted to obtain isolates for new Paramxyoviruses and Coronaviruses that we found from bats globally. Novel viruses were identified by PCR, sequencing, and deep sequencing and then duplicate samples from the same specimen and bat individual were sent to coPIs at the Australian Animal Health Laboratory for culture. For example, we identified 3 novel Paramxyoviruses, distinct from Henipaviruses, from *Pteropus giganteus* in Bangladesh (**Fig 18**) – and sent these samples for culture using a pipeline including human, hamster, and bat cell lines.

Unfortunately we were unable to culture these viruses despite concerted attempts using multiple samples. In light of these negative findings, we expanded our sequencing of these viruses using additional PCR assays and target gene regions to amplify more of the genome to better characterize these viruses.

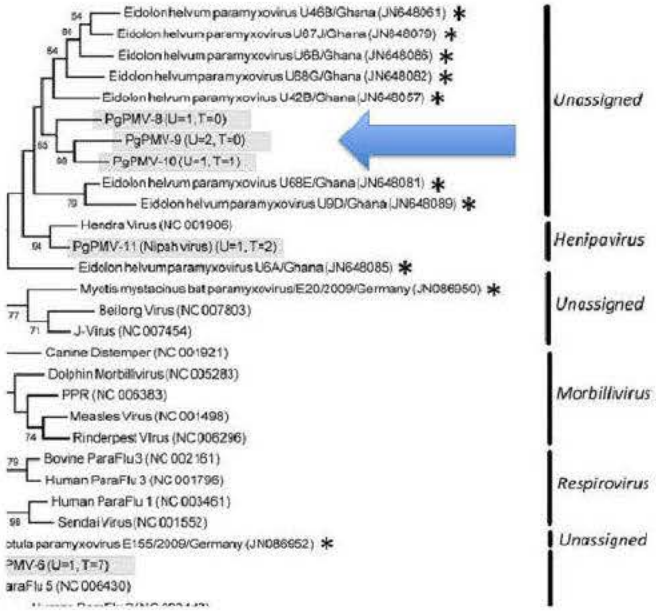


Figure 18. Novel Paramyxoviruses related to but distinct from all known Henipaviruses were found in *Pteropus* bats from Bangladesh using PCR. Unfortunately all the samples and over 50+ other PCR positive individual samples that we had in duplicate in viral transport media did not replicate in cell culture, and we were unable to obtain isolates for further screening.

12. Demonstrated proof of concept for bat viral isolation and *in vitro* investigations of host range using cell lines from multiple species – i.e. SARS-like Coronavirus study from China published in *Nature*.

While our attempts to culture novel Paramyxoviruses from AAHL failed, we were able to demostrate the circulation of at least seven different strains of SARS-like (SL-CoVs) within a single colony of *Rhinolophus sinicus* from China (**Fig 19**) and cultured two of these viruses. This work was recently published in Nature. Using cell lines we were able to test host range for these viral isolates (**Fig 20 and 21**) and found that they use human ACE2 receptor, suggesting that direct bat- to-human infection is a plausible scenario for some bat SL-CoVs. This study has important implications for public health control measures in the face of potential spillover of a diverse and growing pool of recently discovered SARS-like CoVs with a wide geographic distribution.

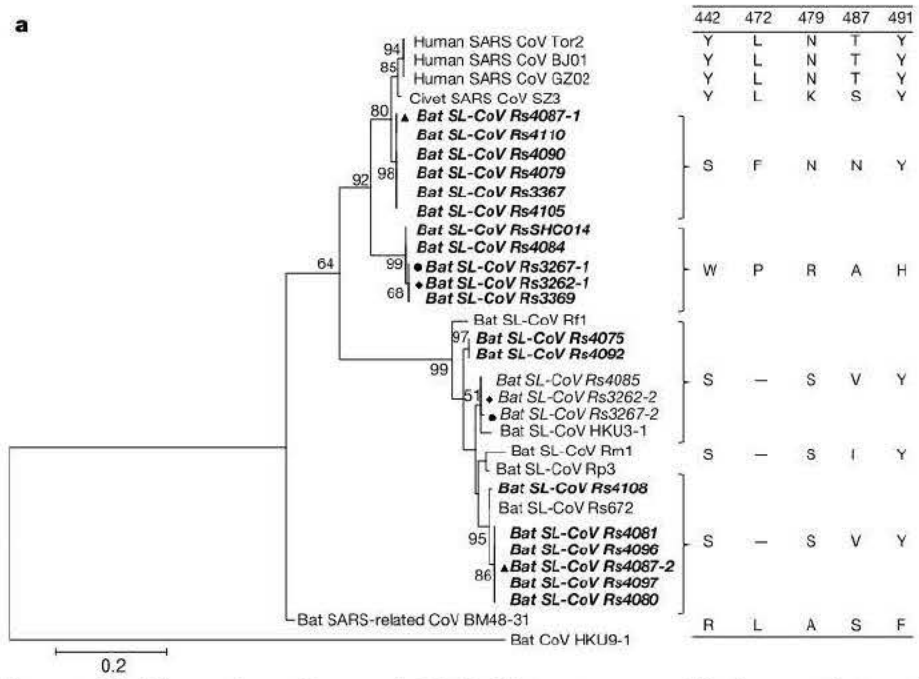


Figure 19. Figure from Ge *et al.* 2013 ***Nature*** paper. Phylogenetic tree based on amino acid sequences of the Spike RBD region and the two parental regions of bat SL-CoV Rs3367 or RsSHC014 found in China.

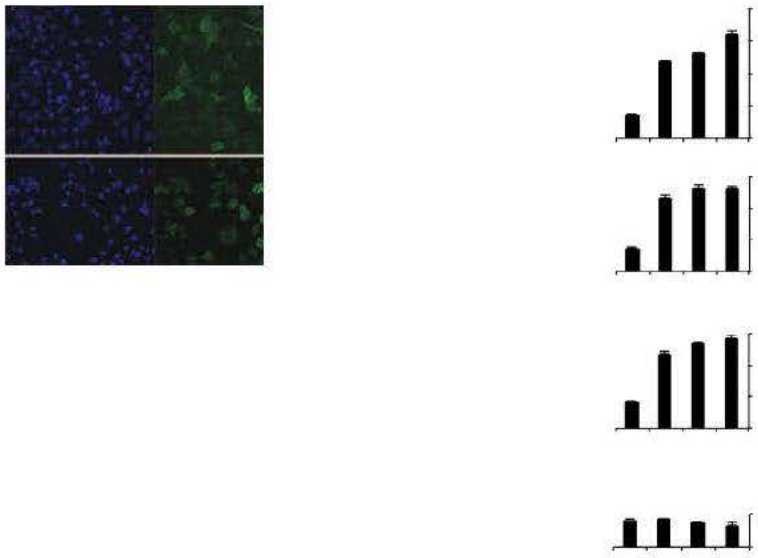


Figure 20. Analysis of receptor usage of SL-CoV-WIV1 determined by immunofluorescence assay and real-time PCR. Determination of virus infectivity in HeLa cells with and without the expression of ACE2: b, bat; c, civet; h, human. ACE2 expression was detected with goat anti-humanACE2 antibody followed by fluorescein

isothiocyanate (FITC)-conjugated donkey anti-goat IgG. Virus replication was detected with rabbit antibody against the SL-CoV Rp3 nucleocapsid protein followed by cyanine 3 (Cy3)-conjugated mouse anti-rabbit IgG. Nuclei were stained with DAPI (49,6-diamidino-2- phenylindole). The columns (from left to right) show staining of nuclei (blue), ACE2 expression (green), virus replication (red), merged triple-stained images and real-time PCR results, respectively. (n 5 3); error bars represent standard deviation.

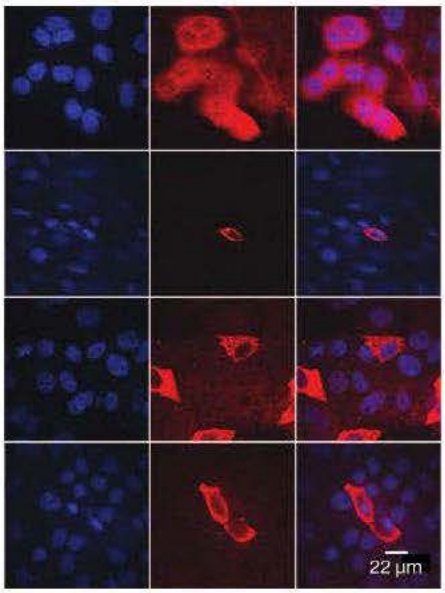


Figure 21. Analysis of host range of SL-CoV-WIV1 determined by immunofluorescence assay and real-time PCR. Virus infection in A549, RSKT, Vero E6 and PK-15 cells. Virus replication was detected as described Fig. 3. The columns (from left to right) show staining of nuclei (blue), virus replication (red), merged double-stained images and real-time PCR results, respectively. n 5 3; error bars represent s.d.

Additional Project Highlights from Last 12 months of Grant, 2012-13:

Guatemala

Of the 1200+ bat species globally, only 3 feed on blood. Vampire bats, *Desmodus rotundus*, frequently come into contact with humans and domestic animals, primarily cattle, and thus are of primary concern for the emergence of potentially zoonotic pathogens. In 2012, we launched a study in Guatemala to investigate this important interface. We collected over 500 specimens from 75 vampire bats, *Desmodus rotundus*, and have screened these for 12 viral families. Confirmation and analysis of PCR positive results are ongoing, but a number of new astroviruses and coronaviruses are likely to be described. When confirmed, our findings will have significance given the direct route of transmission between these bat species and humans.

As part of this study we also conducted basic ecological investigations on the bats we sampled in order to better understand their interface with humans and domestic animals. This included studying their roosting and foraging behaviors using radio telemetry. Six vampire bats were radio tracked for two weeks in July 2013. We found that foraging activity varied with phases of the moon (less foraging in full moonlight) and that bats had high fidelity for both roost sites and feeding sites over the study period. Further, bats were confirmed to be feeding on cattle in a paddock about 1km from their roost using radio telemetry data (**Fig 22, 23**).

Fig 22. Tracking vampire bats using radio telemetry in Guatemala. Inset: cave location were bats were sampled and found to be roosting (green dot) and the paddock where fed on cattle, ~1km away (red dot).

Fig 23. Below, vampire bat #BVE-004 captured for non-lethal sampling for viral discovery and radio tracking.

Philippines

In Year 3 we reported collecting specimens from bats in the Philippines; we sampled over 400 bats from 19 species. Since then we have screened over 3000 specimens (duplicate samples of saliva, urine, feces, sera) from these bats for several viruses at the Australian Animal Health Laboratory. Three individuals of one bat species were found to be PCR positive for viruses closely related to Reston Ebola Virus, only one nucleotide different from strains that had infected pigs and people years before (**Fig 24**). This is the first molecular evidence that REBOV is found in bats, and corroborates recent serological studies. A manuscript is in preparation entitled: "Molecular evidence of Ebola Reston virus infection in Philippine bats".

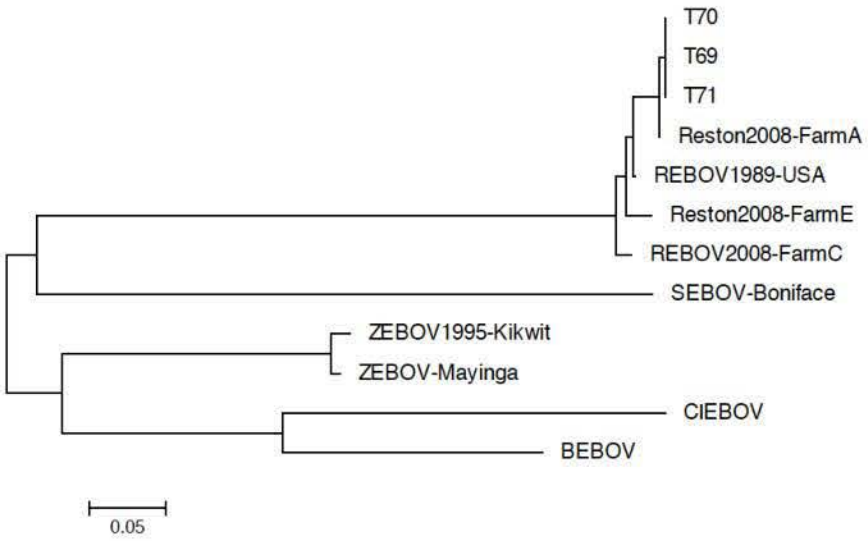


Figure 24. Phylogenetic analysis of viruses found in Philippine bats. Viruses nearly identical to REBOV were identified based on 575bp of NP gene (In Prep). Three different individuals (T69-T71) of *Miniopterus schreibersii* were found positive with identical sequences from the same cave at the same sampling point.

Over 50 Papers Published from this Award:

Below we have listed (alphabetically by first author), all papers published from work funded by this R01. This includes some papers currently under review, but not those in prep. Note that some of these papers (asterisked*) were not bat-specific studies, but utilized laboratory methods developed under this award and/or were supported by staff time in the laboratory or field.

1. Anthony, S. J., J. H. Epstein, K. A. Murray, I. Navarrete-Macias, C. M. Zambrana-Torrelio, A. Solovyov, R. Ojeda-Flores, N. C. Arrigo, A. Islam, S. Ali Khan, P. Hosseini, T. L. Bogich, K. J. Olival, M. D. Sanchez-Leon, W. B. Karesh, T. Goldstein, S. P. Luby, S. S. Morse, J. A. Mazet, P. Daszak and W. I. Lipkin (2013). "A strategy to estimate unknown viral diversity in mammals." ***MBio*** 4(5): e00598-00513.

2. Anthony, S. J., F. Ojeda-Flores, O. Rico-Chávez, I. Navarrete-Macias, C. M. Zambrana-Torrelio, M. Rostal, J. H. Epstein, T. Tipps, E. Liang, M. Sanchez-Leon, J. Sotomayor-Bonilla, R. Ávila, T. Goldstein, G. Suzán, P. Daszak and W. I. Lipkin (2013). "Coronaviruses in bats from Mexico." ***Journal of General Virology*** 94: 1028–1038.

3. Aziz, S. A., K. J. Olival, S. Bumrungsri, G. Richards and P. A. Racey (Submitted). "Mitigating the conflict between fruit bats and commercial fruit growers". ***Bats in the Anthropocene: Conservation of bats in a changing world.*** T. Kingston and C. C. Voight, Springer.

4. Bogich, T., S. Funk, T. Malcom, N. Chun, J. Epstein, A. Chmura, A. Kilpatrick, J. Brownstein, O. Hutchison, C. Doyle-Capitman, R. Deaville, S. Morse, A. Cunningham and P. Daszak "Using network theory to identify the causes of disease

outbreaks of unknown origin." ***Journal of the Royal Society Interface*** 10(81): 20120904.

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6. Brierley, L., M. Vonhof, K. E. Jones, K. J. Olival and P. Daszak (Submitted). "Global patterns of zoonotic bat viruses are associated with anthropogenic change." ***Proceedings of the Royal Society B-Biological Sciences***.

7. Burbelo, P. D., E. J. Dubovi, P. Simmonds, J. L. Medina, J. A. Henriquez, N. Mishra, J. Wagner, R. Tokarz, J. M. Cullen, M. J. Iadarola, C. M. Rice, W. I. Lipkin and A. Kapoor (2012). "Serology-enabled discovery of genetically diverse hepaciviruses in a new host." ***J Virol*** 86(11): 6171-6178.

8. Cui, J., M. Tachedjian, L. Wang, G. Tachedjian, L. F. Wang and S. Zhang (2012). "Discovery of retroviral homologs in bats: implications for the origin of mammalian gammaretroviruses." ***J Virol*** 86(8): 4288-4293.

9. Daszak, P. (2012). "Anatomy of a pandemic." ***Lancet*** 380: 1883-1884.

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12. Epstein, J., M. Baker, C. Zambrana-Torrelio, D. Middleton, J. Barr, E. DuBovi, V. Boyd, B. Pope, S. Todd, G. Crameri, A. Walsh, K. Pelican, M. Fielder, A. Davies, L.-F. Wang and P. Daszak (2013). "Duration of maternal antibodies against canine distemper virus and Hendra virus in pteropid bats." ***PLoS One*** 8(6): e67584.

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14. Epstein, J. H., J. A. Zambriski, M. K. Rostal, D. J. Heard and P. Daszak (2011). "Comparison of intravenous medetomidine and medetomidine/ketamine for immobilization of free-ranging variable flying foxes (Pteropus hypomelanus)." ***PLoS One*** 6(10): e25361.

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20. *Kapoor, A., M. Hornig, A. Asokan, B. Williams, J. A. Henriquez and W. I. Lipkin (2011). "Bocavirus episome in infected human tissue contains non-identical termini." ***PLoS One*** 6(6): e21362.

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24. *Kapoor, A., P. Simmonds, G. Gerold, N. Qaisar, K. Jain, J. A. Henriquez, C. Firth, D. L. Hirschberg, C. M. Rice, S. Shields and W. I. Lipkin (2011). "Characterization of a canine homolog of hepatitis C virus." ***Proc Natl Acad Sci U S A*** 108(28): 11608-11613.

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27. *Kapoor, A., R. B. Tesh, R. Duraisamy, V. L. Popov, A. P. Travassos da Rosa and W. I. Lipkin (2013). "A novel mosquito-borne Orbivirus species found in South-east Asia." ***J Gen Virol*** 94(Pt 5): 1051-1057.

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42. Olival, K. J., R. L. Hoguet and P. Daszak (2013). "Linking the Historical Roots of Environmental Conservation with Human and Wildlife Health." ***EcoHealth***: 1-4.

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