Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Tuesday, June 30, 2020 3:00 PM
To: Coulson, Garry Brian; NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident Report

Dear Dr. Garry Coulson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, June 8, 2020 12:18 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: NIH Incident Report

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a minor spill involving recombinant DNA that occurred in a BSL-3 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599

Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of North Carolina at Chapel Hill
Date of Report:	6/08/2020
Reporter name and position:	Garry Coulson, Biosafety Officer
Telephone number:	919.962.5722
Email address:	garry.coulson@ehs.unc.edu
Reporter mailing address:	Environment, Health and Safety 1120 Estes drive Campus Box 1650 Chapel Hill, NC 27599
Date of incident:	6/06/2020
Name of Principal Investigator:	Dr. Ralph Baric
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant number: U19AI100625 / U19AI142759 /* Task order 75N93020F00001 for contract HHSN272201700036I *NIH funding institute or center: NIAID* *NIH program officer (name, email address):Qian Liu / Maureen Beanan / Eric Stemmy and Chelsea Lane*

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☒Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO Date approved: 3/5/2020
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☒BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Recombinant infectious clone of SARS-CoV-2 in which orf7 is replaced by the reporter gene NanoLuc luciferase.

Description of the incident:

At approximately 9:00 am on Saturday, June 06, 2020 the Researcher was performing viral neutralizing assays when the incident occurred. The Researcher was working within a biological safety cabinet (BSC) inside a BSL-3 laboratory. For personal protective equipment (PPE), the Researcher was wearing the required protection for the BSL-3 laboratory, which included scrubs, lab shoes, shoe covers, Tyvek suit, hood, purified air powered respirator (PAPR), apron and 2 pairs of gloves. No other researchers were in the laboratory at the time of the incident.

When the Researcher was loading the multi-channel pipette with tips, the tip box slid on the working surface of the BSC and hit a 96-well neutralization assay plate, possibly due to excess residual 75% ethanol (EtOH) used to surface decon the BSC and tip box when bringing it into the BSC. The neutralization assay plate contained various dilutions of neutralizing mouse serum and the recombinant SARS-CoV-2 NanoLuc virus. The collision created a small spill (< 1ml) inside the BSC and the Researcher also noticed about 5 – 10 drops on his waterproof apron. It is unknown whether the drops came from control wells without virus or experimental wells with virus.

Immediately after the spill, the Researcher sprayed down his gloves and apron with 75% ethanol. Following the procedures for small spills in the BSC, the Researcher used paper towels in the BSC completely saturated with 75% ethanol to cover the spill area and waited for 10 min for aerosols in the BSC to clear. Additionally, while no droplets were observed to have spilled out of the BSC onto the floor, the Researcher also sprayed down the area immediately proximal to the BSC, including the chair and the floor, with 75% EtOH. During the 10-minute wait, the Researcher sprayed down his gloves again and changed into a new pair of outer gloves. Used gloves were disposed of in the biohazard trash. After the wait, the Researcher placed all contaminated materials, including the 96- well plate, the paper towels and the pipette tip box into a decon tray containing disinfectant inside the BSC. The Researcher removed all other materials, including pipette and three other 96-well plates outside of the hood following a surface decon with 75% ethanol. The Researcher then deconned and exited out of the lab as per laboratory SOP and returned to his lab space and informed the PI and EHS via email at 10:17am on 6/6/2020. The Department of Environment, Health, and Safety (EHS) reviewed the email notification Sunday 6/07/2020 at 11:58 am and immediately followed up with the Researcher for a detailed description of the incident and communicated the incident to the Medical Director of the University Employee Occupational Health Clinic (UEOHC).

Given that the spill outside of primary containment was classified by the Researcher as small, and that the Researcher verified that there was no breach in PPE or respiratory protection, the assessed risk for actual personnel exposure by the Researcher was considered low. Consequently, the procedures for a Potential Exposure, as outlined in the BSL-3 Medical

Surveillance Laboratory Standard Operating Procedures (SOP) were followed. A determination was made that self-quarantine was not medically indicated. The Researcher is required to continuously monitor temperatures and perform symptom monitoring for the next 14 days. Any changes in health, or development of symptoms must be reported to the UEOHC immediately.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC is aware of the incident and will discuss the incident at the next IBC meeting (7/1/2020).
Please describe the root cause of this incident:	The excess EtOH on the stainless steel working surface likely created a slippery interface with the pipette tip box leading to the incident. Additionally, having the 96-well plate cover open during the loading of the pipette tips likely contributed to the incident.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As part of the corrective and preventative actions to be taken, an internal Incident Report will be submitted by the Department of Environment, Health and Safety (EHS) to the Principal Investigator (PI) detailing the incident and including recommendations for the lab to follow to mitigate future reoccurrence of the incident.

The affected Researcher was trained in performing neutralizing assays, was performing all duties according to established laboratory procedures, and was wearing the appropriate PPE for the procedure. As part of the recommendations, the PI will be instructed to discuss this incident with his lab, specifically focusing on procedures for addressing spills inside the BSC and spills outside the BSC. The PI will also discuss the importance of immediately reporting any incidents or exposures in the BSL-3 lab to the Biosafety Officer (BSO)/Associate Biosafety Officer (ABSO) by telephone or emergency pager.

The PI will be required to investigate ways to avoid reoccurrence of the incident through procedural work practice controls. This may include options such as i) limiting the volume of EtOH used to surface decon objects in the BSC, ii) keeping the lid on all plates while loading pipette tips, iii) physically distancing pipettes and plates in the BSC; or iv) using a hand to hold and stabilize the pipette tip box while loading tips onto the pipette with the other hand.

The expected date of completion for recommendations is 6/15/2020.