Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, November 20, 2020 3:35 PM
To: Don Sibley; NIH guidelines
Cc: Laurence Vonkalm; Renee Michel; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report filing

Dear Dr. Don Sibley,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). 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
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Don Sibley <Don.Sibley@ucf.edu>
Sent: Friday, October 23, 2020 2:52 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Laurence Vonkalm <lvonkalm@ucf.edu>; Renee Michel <Renee.Michel@ucf.edu>
Subject: Incident report filing

Good afternoon,

Please find attached an incident report concerning non-exempt research involving recombinant nucleic acid molecules conducted by Hao Yu, Ph.D. without obtaining IBC approval. Dr. Yu is the President and CEO of OncoTroy Inc., which is conducting research is a private concern leasing space operated by the UCF Business Incubator Program. The UCF IBC and the Department of Environmental Health and Safety provide research compliance and occupational health and safety oversight for research conducted within the UCF business incubator.

If you have any questions concerning this incident report or the UCF response to the incident please contact me.

Sincerely,

Don Sibley

Don Sibley, Ph.D., RBP
Biological Safety Officer
University of Central Florida
P 407-823-1526
C Redacted by agreement
F 407-823-1219
Don.Sibley@ucf.edu
3512 Perseus Loop Bldg 48, Office 132
Laboratory and Environmental Support
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National Institutes of Health
Office of Science Policy

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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)

April, 2019

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Does this incident involve research subject to the *NIH Guidelines*?	X YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Central Florida
Date of Report:	10/20/20
Reporter name and position:	Don Sibley, Biological Safety Officer
Telephone number:	407-823-1526
Email address:	Don.Sibley@ucf.edu
Reporter mailing address:	3512 Perseus Loop Bldg 48, Office 132 Laboratory and Environmental Support Orlando, FL 32816-3500
Date of incident:	9/17/2018 – 9/23/2020
Name of Principal Investigator:	Hao Yu
Is this an NIH-funded project?	☐YES X NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

What was the nature of the incident?	☐ Failure to follow approved containment conditions X 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 X NO If yes, date of approval:
What was the approved biosafety level of the research?	☐ BL1 X BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Experiments involving the use of infectious DNA/RNA Viruses **OR** Defective DNA/RNA viruses in the presence of helper virus in tissue culture systems. **(III-D-3)**
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.)	PI was modifying Vesticular Stomatitis virus to be used for targeting human tumor cells for lysis by the recombinant VSV. E. coli K-12 strains were used as expression vectors for plasmids containing the tumor receptor protein sequence. The VSV used was replication incompetent virus which was propagated using BHK cells co-infected with MVA as a helper virus and co-transfected with the tumor target plasmid using a lipofectamine system. All studies were conducted in vitro using a certified BSC and BSL-2 containment practices.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

This case was uncovered in an UCF incubator facility involving a tenant operating a private lab under the corporate name of OncoTroy Inc. Dr. Yu, President/CEO, Oncotroy was unaware of the IBC registration requirements by NIH guidelines for research involving recombinant or synthetic nucleic acid molecules. Once the research involving human tumor cell lines was identified in conjunction with the review of a biological permit with EHS, the PI was asked to register the work with the IBC. During the follow up inspection of his laboratory associated with the registration process it was determined that Dr. Yu had been conducting non-exempt recombinant DNA studies since the fall of 2018. It was later determined that Dr. Yu sent a protocol describing this work to the IBC on September 17,2018. The original protocol was not presented to the IBC or acted upon at that time. During this time, the IBC chair and the BSO had resigned and the positions were being filled. Dr. Von Kalm was named IBC chair during this time period and Dr. Sibley was hired as BSO on November 30 2018. Dr. Yu admitted that he had not heard back from the IBC concerning the protocol but failed to follow up on its approval. On September 23, 2020 the IBC met to consider Dr. Yu's case and ordered Dr. Yu's research to be suspended and his lab to cease all work. Dr. Yu complied with the IBC and immediately ceased all work on September 23. Dr. Sibley met with Dr. Yu on September 25 to explain the reasons his lab was shut down and what actions were required to reopen his laboratory. Dr. Yu was required to complete the UCF training course covering the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, and the bloodborne pathogens training for laboratory personnel. He completed both courses on September 29. Since this time Dr. Sibley has worked with Dr. Yu to draft an exempt registration protocol to allow him to begin working with his K-12 E. coli strains and plasmids. This exempt protocol was reviewed and approved by the BSO and IBC chair as a step toward reopening his laboratory in a manner fully compliant with the NIH guidelines and UCF policy. Dr. Yu has agreed to work closely with Dr. Sibley and the IBC to make certain he remains in full compliance with all regulations concerning research safety in the future.

Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	The Pi was not knowledgeable of the NIH guidelines and the requirements for IBC approval for non-exempt work. In addition, the University has stepped up its oversight of these incubator facilities and the operations of the organizations leasing these spaces.

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

The University is evaluating the lease agreements to assure UCF authority over the approval process for use of these spaces and the onboarding process for tenants leasing these spaces. In conjunction with these processes the University is stepping up the oversight and inspection processes for tenants in these incubator laboratories. Since this incident, the EHS Director implemented a requirement for all tenants to follow the same onboarding process as used for new faculty, requiring a detailed hazard assessment and the appropriate laboratory safety training for all personnel working in these spaces. It is also likely additional changes may be implemented by UCF administration once a full review and evaluation of the leasing program for these incubator laboratories has been completed.

- **Additional information may be requested by NIH OSP after review of this report**

depending on the nature of the incident.

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**