

## Hunter, Renee (NIH/OD) [C]

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**From:** McKinney, Michelle (NIH/OD) [E]  
**Sent:** Monday, June 1, 2020 9:07 AM  
**To:** O'Meara, Helen; NIH guidelines  
**Cc:** Williams, Marshall; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]  
**Subject:** RE: NIH Guideline incident report from the Ohio State University

Dear Helen O'Meara,

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](mailto:harriskath@od.nih.gov) or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP  
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Mobile: Redacted by agreement  
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**From:** O'Meara, Helen <[omeara.15@osu.edu](mailto:omeara.15@osu.edu)>  
**Sent:** Tuesday, May 19, 2020 7:49 AM  
**To:** NIH guidelines <[NIHguidelines@od.nih.gov](mailto:NIHguidelines@od.nih.gov)>  
**Cc:** Williams, Marshall <[williams.70@osu.edu](mailto:williams.70@osu.edu)>  
**Subject:** NIH Guideline incident report from the Ohio State University

Attached is an incident report from the IBC Chair at The Ohio State University. This involved work that was conducted by an investigator prior to IBC approval.

Please let me know if you have any questions.

Best,

Helen O'Meara



**Helen O'Meara, MS, CPIA**  
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**COVID-19 and Animal Research:** [Click Here](#)

**COVID-19 and Biosafety Reviews:** [Click Here](#)

<b>Does this incident involve research subject to the <i>NIH Guidelines</i>?</b>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If no, this incident does not require reporting to OSP
<b>Institution Name:</b>	The Ohio State University
<b>Date of Report:</b>	05/12/2020
<b>Reporter name and position:</b>	Marshall V. Williams, JR., PhD Chair, Institutional Biosafety Committee
<b>Telephone number:</b>	614-293-6175
<b>Email address:</b>	Williams.70@osu.edu
<b>Reporter mailing address:</b>	300 Research Administration 1960 Kenny Rd Columbus, Ohio 43210-1063
<b>Date of incident:</b>	April 2020
<b>Name of Principal Investigator:</b>	Shan-Lu Liu
<b>Is this an NIH-funded project?</b>	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, please provide the following information (if known)  <i>NIH grant or contract number:</i> <i>NIH funding institute or center:</i> <i>NIH program officer (name, email address):</i>

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<b>What was the nature of the incident?</b>	<input type="checkbox"/> Failure to follow approved containment conditions <input checked="" type="checkbox"/> Failure to obtain IBC approval <input type="checkbox"/> Incomplete inactivation <input type="checkbox"/> Loss of containment <input type="checkbox"/> Loss of a transgenic animal <input type="checkbox"/> Personnel exposure <input type="checkbox"/> Spill <input type="checkbox"/> Other (please describe):
<b>Did the Institutional Biosafety Committee (IBC) approve this research?</b>	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, date of approval:
<b>What was the approved biosafety level of the research?</b>	<input type="checkbox"/> BL1 <input type="checkbox"/> BL2 <input type="checkbox"/> BL2+ <input type="checkbox"/> BL3 <input type="checkbox"/> BL3+ <input type="checkbox"/> BL4 BSL2+ will be the containment level once approved
<b>What section(s) of the <i>NIH Guidelines</i> is the research subject to?</b>	Section III-D1
<b>Has a report of this incident been made to other agencies? If so, please indicate</b>	<input type="checkbox"/> CDC <input type="checkbox"/> Funding agency/sponsor <input type="checkbox"/> USDA <input type="checkbox"/> State or local Public Health <input type="checkbox"/> FDA <input type="checkbox"/> Law enforcement <input type="checkbox"/> EPA <input type="checkbox"/> Other (please describe): <input type="checkbox"/> OSHA
<b>Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)</b>	Lentiviral pseudotypes bearing the SARS-CoV-2 spike protein were produced and used to develop an assay for the detection of neutralizing antibodies to SARS-CoV-2 in COVID-19 patients.

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)



On April 30, information was received by the IBC regarding work that had been conducted to produce a pseudotyped lentivirus containing the gene encoding the SARS CoV-2 S protein. This pseudotyped virus is being used as a surrogate in infection assays for testing neutralizing antibodies in COVID-19 clinical samples. The PI has an approved IBC protocol to conduct similar work with a variety of other viral genes.

The production of pseudotyped lentivirus containing the SARS-CoV-2 spike protein had not yet been approved by the IBC. While the unapproved work was being conducted, appropriate containment procedures were followed and there is no evidence of a potential release or exposure. The PI was notified by the IBC Chair in an email dated 05.01.2020 that the conduct of the work was in violation of the NIH regulations and could not continue until his amendment is approved.

<p><b>Has the IBC reviewed this incident?</b></p>	<p><input checked="" type="checkbox"/> YES      <input type="checkbox"/> NO</p>
<p><b>Please describe the root cause of this incident:</b></p>	<p>Public pressure to quickly develop and advance methodology to combat the COVID-19 pandemic.</p>

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):

The PI has ceased work relating to the development of this assay until approval is obtained from the IBC. The amendment for adding the SARS-CoV-2 S protein-pseudotyped lentivirus was reviewed by the full committee of the IBC on May 5, 2020 and approved on May 7, 2020.

Communication from the IBC Chair regarding the incident and the need for IBC approval has been sent to Senior Leadership at the University and the Medical Center. The requirement for IBC approval particularly before initiating any studies related to SARS-CoV-2 has been reiterated to leaders and investigators. This information has also been posted on the COVID-19 Research Information site maintained by the Office of Research.