

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 11:12 AM
To: Gregory Park; NIH guidelines
Cc: Chris Cramer; Masato Yamamoto; Frances Lawrenz; Dan Voytas; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Guidelines-related incident report from U of MN

Dear Dr. Gregory Park,

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. However, it is recommended that you consider providing refresher training for the investigator on the requirements for IBC review and approval. 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: 301-742-5922
michelle.mckinney@nih.gov

From: Gregory Park <parkx479@umn.edu>
Sent: Thursday, January 30, 2020 11:41 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chris Cramer <cramer@umn.edu>; Masato Yamamoto <yamam016@umn.edu>; Frances Lawrenz <lawrenz@umn.edu>; Dan Voytas <voytas@umn.edu>
Subject: NIH Guidelines-related incident report from U of MN

Dear NIH-OSP,
Please find attached a cover letter with an NIH incident report. Do not hesitate to contact me if you have any further questions.
Regards,
Greg

--
Gregory Park, PhD
parkx479@umn.edu
+1 612-625-9153 (direct line)

Assistant Director
Office of Biotechnology Activities Oversight
<https://research.umn.edu/units/obao>
Office of the Vice President for Research
D192 Mayo Memorial Building MMC820
420 Delaware ST SE
University of Minnesota

Minneapolis, MN 55455
USA

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Harris, Kathryn (NIH/OD) [C]

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Sent: Thursday, January 30, 2020 11:41 AM
To: NIH guidelines
Cc: Chris Cramer; Masato Yamamoto; Frances Lawrenz; Dan Voytas
Subject: NIH Guidelines-related incident report from U of MN
Attachments: UMN NIH Incident 20200130.pdf

Dear NIH-OSP,
Please find attached a cover letter with an NIH incident report. Do not hesitate to contact me if you have any further questions.
Regards,
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UNIVERSITY OF MINNESOTA

*Office of the Vice President for Research
Institutional Biosafety Committee*

*420 Delaware ST SE
D192 Mayo MMC 820
Minneapolis, MN 55455*

*E-mail: ibc@umn.edu
Main line: 612-626-2161
Fax: 612-626-6061 (shared)*

January 29, 2020

Attention: Incident Reports
NIH Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20817
Phone: 301-496-9838
Email: NIHGuidelines@od.nih.gov

Dear NIH OSP Representative,

Please find attached an incident report from the University of Minnesota. The Incident Reporting Template has been completed.

The reported incident involved a failure to seek IBC approval for research activities subject to the NIH Guidelines.

If you have any questions about this information, please contact Gregory Park, Assistant Director of the Institutional Biosafety Committee Administration at 612-625-9153.

Thank you.

Sincerely,



Christopher J. Cramer, Ph.D.
Vice President for Research
Institutional Official

c: Gregory Park
Masato Yamamoto
Frances Lawrenz

Enc: NIH-OSP Final Incident Report

Does this incident involve research subject to the <i>NIH Guidelines</i>?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If no, this incident does not require reporting to OSP
Institution Name:	University of Minnesota
Date of Report:	01/29/2020
Reporter name and position:	Christopher Cramer, Vice President for Research, Institutional Official
Telephone number:	612-624-5054
Email address:	cramer@umn.edu
Reporter mailing address:	101 Pleasant ST SE 419 Johnston Hall Minneapolis, MN 55455
Date of incident:	01/14/2020
Name of Principal Investigator:	Daniel F. Voytas
Is this an NIH-funded project?	<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>

What was the nature of the incident?	<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):
Did the Institutional Biosafety Committee (IBC) approve this research?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, date of approval:
What was the approved biosafety level of the research?	<input checked="" type="checkbox"/> BL1 <input type="checkbox"/> BL2+ <input type="checkbox"/> BL2 <input type="checkbox"/> BL3+ <input type="checkbox"/> BL3 <input type="checkbox"/> BL4 <input type="checkbox"/> BL4
What section(s) of the <i>NIH Guidelines</i> is the research subject to?	III-E
Has a report of this incident been made to other agencies? If so, please indicate	<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
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Generation and use of recombinant <i>Agrobacterium tumefaciens</i> (GV3101) and transgenic <i>Nicotiana benthamiana</i> , <i>Arabidopsis thaliana</i> , <i>Rosa rubiginosa</i> , <i>Catharanthus roseus</i> , <i>Vitis vinifera</i> , <i>Solanum lycopersicum</i> , <i>Moricandia arvensis</i> , <i>Petunia axillaris</i> , <i>Solanum tuberosum</i> , <i>Helianthus annuus</i> , <i>Capsicum annuum</i> , and <i>Capsicum chinense</i>

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On 1/14/2020, the IBC Assistant Director discovered that research activities subject to the NIH Guidelines had been performed from 10/2017 to 12/2019 without IBC review and approval. An investigation into these activities revealed that a BSL1/BSL1-P laboratory had generated recombinants of *Agrobacterium tumefaciens* (strain GV3101), and subsequently used them for the infection, transduction, and generation of recombinant cells and transgenic plants. The Principal Investigator was notified to cease all unapproved activities and that he must seek IBC approval. An investigation into the work showed that all personnel involved (8 staff/students + PI) had the IBC required training, and that the PPE, procedures, and containment followed are in-line with expected IBC guidance. Waste disposal and decontamination procedures also followed standard IBC requirements. There were no reported injuries, illnesses, or other reported incidents from this investigator or his lab during the time period of the unapproved activities.

An application has been submitted and will be reviewed, as will this incident of non-compliance, at the next IBC meeting (2/17/2020).

Has the IBC reviewed this incident?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
Please describe the root cause of this incident:	Failure to seek IBC approval for research activities subject to the NIH Guidelines.

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):

Upon determination that research activities subject to the NIH Guidelines had taken place, the IBC Assistant Director instructed the PI to halt all on-going research activities that were not approved by the IBC. Because the IBC has not yet reviewed the incident, the IBC has not made recommendations to mitigate any problems identified. The IBC will review this incident on February 17, 2020. The Assistant Director will make recommendations for refresher training of all involved personnel in the requirements of the NIH Guidelines and our related University policies.