



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

October 19, 2022

Re: Animal Welfare Assurance  
A3208-01 [OLAW Case 1K]

Daniel Sui, Ph.D.  
Vice President for Research and Innovation  
Virginia Polytechnic Institute and  
State University – Blacksburg  
800 Drillfield Drive,  
Burruss Hall, (b) (4)  
Blacksburg, VA 24061

Dear Dr. Sui,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated October 6, 2022 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Virginia Tech University. Your letter supplements the information in the preliminary telephone report on August 2, 2022. According to the information provided, OLAW understands that on March 11, 2022, your institution was notified that a cohort of 22 hamsters developed lesions after intraperitoneal injections with an unapproved diluent. The funding source for these hamsters is the NIH. Per PHS requirement, the PI has been informed that she must work with her grant administrator to determine any funding related actions that must be taken.

Corrective and preventive actions include:

1. Hamsters were examined by a veterinarian, did not require treatment, and proceeded through the remainder of the study as normal.
2. Re-training was performed by a veterinarian on injection technique.
3. An amendment was submitted updating the protocol to include the diluent.
4. The PI was counseled.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. As you have noted, PHS-related animal expenses directly associated with this incident should not be charged to the related grant. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

**Brent C. Morse**

-S

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

Digitally signed by Brent C.

Morse -S

Date: 2022.10.19 09:40:14

-04'00'

*Page 2 – Dr. Sui*  
*October 19, 2022*  
*OLAW Case A3208-1K*

cc: IACUC contact  
Dr. Robert M. Gibbens, USDA, APHIS, AC

A3208-1K



RESEARCH AND INNOVATION  
VIRGINIA TECH

Daniel Sui  
Senior Vice President for Research and Innovation  
Burruss Hall, (b) (4)  
800 Drillfield Drive  
Blacksburg, Virginia 24061  
(b) (6)  
research.vt.edu

October 6, 2022

Brent Morse, DVM  
Director, Divisions of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Final report regarding adverse event at Virginia Tech [Assurance #A-3208-01]

Dear Dr. Morse:

Virginia Tech, in accordance with Assurance A-3208-01 and PHS Policy IV.F.3., provides this report of an adverse event regarding an incident of hamsters receiving an unapproved substance on an IACUC approved protocol. This incident was initially reported to you on August 2, 2022 after verification of NIH funding.

On March 11, 2022, the IACUC office was notified that a cohort of hamsters developed lesions after intraperitoneal injections with an unapproved diluent. The IACUC discussed the incident at the July 21, 2022 convened meeting, approved corrective steps taken, and requested additional corrective actions from the PI:

1. Corrective actions outlined by the PI and accepted by the IACUC include (1) hamsters were examined by an Animal Resources and Care Division (ARCD) veterinarian, did not require treatment, and proceeded through the remainder of the study as normal; (2) re-training by the ARCD veterinarian on injection technique; and (3) an amendment was submitted updating the protocol to include the diluent
2. The IACUC issued a minor noncompliance letter for administering a substance not approved on the protocol and reminded the PI in the future to adhere to the approved protocol. The IACUC additionally reminded the PI to submit an amendment further updating the Appendix G and receive approve prior to administering any new or changes substances.

The funding source for these hamsters is the NIH (Federal Award Number: 1R01NS124204-01). Per PHS requirement, the PI has been informed that she must work with her grant administrator to determine any funding related actions that must be taken.

Virginia Tech is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have

any questions regarding this report, please contact  
(b) (6)

(b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dr. Daniel Sui  
Senior Vice President for Research and Innovation  
Institutional Official  
Virginia Tech

**McCoy, Devora (NIH/OD) [E]**

---

**From:** iacucpam <iacucpam@vt.edu>  
**Sent:** Thursday, October 6, 2022 10:19 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6) iacucpam  
**Subject:** [EXTERNAL] Final Report on Adverse Event  
**Attachments:** IO-OLAW 1R01NS124204-01 Letter.pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hello Dr. Morse,

This is a follow-up to our phone conversation on August 2, 2022. Please find a letter attached from our IO, which contains information regarding the IACUC's decision. Please confirm receipt.

Thank you,

(b) (6)

**McCoy, Devora (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, October 6, 2022 11:34 AM  
**To:** iacucpam  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report on Adverse Event

Good morning (b) (6)

Thank you for sending us this final report and we will send an official response soon.

Best,  
Devora

Devora McCoy, BS, MBA  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
301-435-2390

---

**From:** iacucpam <iacucpam@vt.edu>  
**Sent:** Thursday, October 6, 2022 10:19 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) iacucpam <iacucpam@vt.edu>  
**Subject:** [EXTERNAL] Final Report on Adverse Event

Hello Dr. Morse,

This is a follow-up to our phone conversation on August 2, 2022. Please find a letter attached from our IO, which contains information regarding the IACUC's decision. Please confirm receipt.

Thank you.

(b) (6)







## Initial Report of Noncompliance

By: BCM

Date: 8/2/2022

Time: 3:30

Name of Person reporting: [redacted] (b) (6)

Telephone #: [redacted] (b) (6)

Fax #:

Email:

Name of Institution: Virginia Tech.

Assurance number: A3208-1K

Did incident involve PHS funded activity?   ? (checking)   

Funding component:   ?   

Was funding component contacted (if necessary):   

hamsters  
Twenty-two mice administered substance in DMSO. DMSO not approved in protocol.

Species involved: ~~mouse~~ hamster

Personnel involved: Researcher

Dates and times: 3/9/2022

Animal deaths: no

Projected plan and schedule for correction/prevention (if known):   

Investigating.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY

Case #