

#### 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

May 9, 2024

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

Daniel Sui, Ph.D.
Vice President for Research and Innovation
Virginia Polytechnic Institute and State University
800 Drillfield Drive,
Blacksburg, VA 24061

Dear Dr. Sui,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 15, 2024 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Virginia Polytechnic Institute and State University (Virginia Tech) following up on an initial January 31, 2024 notification by telephone.

According to the information provided, this office understands that the Virginia Tech Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to conditions that jeopardized the health/well-being of animals resulting in harm to animals. The final report states on October 16, 2023, four mice were found dead by animal care staff in a cage. It is stated the lixit was determined to be dislodged from the automated water supply line, but food was present in the cage. It is also stated the root cause of the lixit malfunction could not be determined, however the lixit was verified to be functional during the most recent cage change.

In response to the finding, all other lixits were confirmed to be functional on the rack and it was confirmed there were no health concerns with the remaining mice on the rack. On October 20, 2023, a corrective action plan was submitted to the IACUC for review by vivarium leadership. It is understood the corrective measures were approved by the committee at the January 2024 meeting. In summary, the corrective action plan included the following:

- Retraining animal care staff on relevant animal husbandry SOP.
- · Retraining animal care staff on how to check lixits.
- Retraining research staff on lixit verification testing.
- Reminding all vivarium users on proper cage handling and lixit verification.

It is noted the research project is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the Virginia Polytechnic Institute and State University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

Page 2 – Dr. Sui May 9, 2024 OLAW Case A3208-1P

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn Digitally signed by Jacquelyn T. Tubbs -S
T. Tubbs -S
Date: 2024.05.09
10:50:56-04'00'

Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact





Daniel Sui Senior Vice President for Research and Innovation

(b) (4)

800 Drillfield Drive Blacksburg, Virginia 24061

(b) (6)

research.vt.edu

April 15, 2024

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

Re: Supplemental Information - adverse event at Virginia Tech [Assurance #A-3208-01]

Dear Dr. Wolff:

Virginia Tech received an email from Dr. Jacquelyn Tubbs on March 14, 2024, outlining several questions for clarification based on her review of the final report dated March 1, 2024, submitted by Virginia Tech ("IO-OLAW 7R01AG077783-02 Final Report").

This letter is written in response to Dr. Tubbs' questions and is intended to supplement the IO-OLAW 7R01AG077783-02 Final Report.

Question: Description of the incident (i.e., when the incident occurred, individuals involved, nature of the animal welfare concern, etc.)

The incident occurred in October 2023.

On October 16, 2023, animal care staff discovered four deceased mice that were group housed, which deaths were not expected. It was noted that the cage lixit was dislodged from the automated water supply line. Food was noted to be present.

The cause of the lixit equipment malfunction could not be determined although the lixit was checked and verified to be functional at the most recent cage change.

#### Question: Specific corrective actions

Immediately following the discovery, vivarium leadership verified all other lixits on the rack were properly functioning and further confirmed that there were no concerns with the health status of any other mice.

On October 20, 2023, vivarium leadership submitted a summary of the corrective action plan including: (1) retraining animal care staff on relevant animal husbandry SOP (Housing and Care of Mice and Rats); (2) retraining animal care staff on checking lixits; (3) retraining research staff on lixit verification testing; and (4) reminding all vivarium users on proper cage handling and lixit verification testing.

The IACUC reviewed the corrective actions taken as well as the corrective action plan and approved the actions at their January 2024 meeting.

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 supplemental information, please contact (b) (6)

| S | in | C | e | re | el | ٧ |  |
|---|----|---|---|----|----|---|--|
|   |    |   |   |    |    |   |  |

(b) (6)

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

## Ware, Teagan (NIH/OD) [E]

From:

Tubbs, Jai (NIH/OD) [E]

Sent:

Monday, April 22, 2024 6:59 AM

To:

(b) (6) OLAW Division of Compliance Oversight (NIH/OD); iacucpam

Subject:

**RE: Final Reports** 

Follow Up Flag:

Follow up

Flag Status:

Flagged

Good morning,

Thank you for the additional information, I'll provided a response soon.

Kind Regards,

J. Tubbs

From:

(b) (6)

Sent: Friday, April 19, 2024 3:58 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; iacucpam <iacucpam@vt.edu>

Cc: Tubbs, Jai (NIH/OD) [E] < jacquelyn.tubbs@nih.gov>

Subject: [EXTERNAL] Re: Final Reports

Dr. Tubbs,

Thank you for your patience. Attached, please find the requested supplemental documents.

If you have any questions, please feel free to contact.

Best,

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov>

Sent: Thursday, March 14, 2024 1:58 PM

To: iacucpam < iacucpam@vt.edu >; OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov >

(b) (6) Cc: Tubbs, Jai (NIH/OD) [E] < jacquelyn.tubbs@nih.gov>

Subject: RE: Final Reports

### Good afternoon,

I am reviewing the submitted final reports and have additional questions for clarification. Two final reports state there was a thorough review of husbandry procedures following receipt of a reported event. A third report states "A thorough review of vivarium husbandry procedures and methods of communication with research personnel was undertaken following receipt of reported event." However, none of these reports include a description of the incident (i.e., when the incident occurred, individuals involved, nature of the animal welfare concern, etc.) or the specific corrective actions taken to address the matter. The fourth final report also lacks a description of the incident that occurred and detailed corrective action plan in response.

Please provide the requested information for each final report. If you would like to discuss anything via telephone, please let me know and we can arrange a time and date to chat.

## Kind Regards,

Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: iacucpam < iacucpam@vt.edu> Sent: Monday, March 4, 2024 2:21 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: iacucpam <iacucpam@vt.edu>;

Subject: [EXTERNAL] Final Reports

Hello Dr. Wolff,

Please find four final reports attached from our IO. Please confirm receipt.





Daniel Sui Senior Vice President for Research and Innovation (b) (4)

800 Drillfield Drive Blacksburg, Virginia 24061

(b) (6)

research.vt.edu

March 1, 2024

Axel Wolff, DVM
Acting 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. Wolff:

Virginia Tech, in accordance with Assurance A-3208-01 and PHS Policy IV.F.3., provides this report of animal-related activities that were determined to be potentially non-compliant with the associated IACUC-approved protocol. This animal research study involves mice.

This incident was first reported to Teagan Ware. Animal Welfare Program Analyst. OI AW on January 31, 2024 via a telephone call led by

A thorough review of vivarium husbandry procedures was undertaken following receipt of reported event. The results of the review were provided to the IACUC in December 2023. The IACUC reviewed and discussed the facts, circumstances, and potential non-compliances with the approved protocol including with respect to animal welfare.

After discussion, the IACUC sent an educational reminder letter to the vivarium leadership with respect to animal husbandry. To address the situation, corrective actions were taken including the re-training of husbandry staff on relevant SOPs for the species.

The funding source of these animals is via the NIH (Federal Award #:7R01AG077783-02). Per PHS requirement, the PI has been informed that they must cooperate with their grant administrator to determine if any funding related actions 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)

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

# Ware, Teagan (NIH/OD) [E]

OLAW Division of Compliance Oversight (NIH/OD)

OLAW Division of Compliance Oversight (NIH/OD)

Monday, March 4, 2024 2:27 PM

'iacucpam' (b) (6)

**RE: Final Reports** 

Thank you for providing these 4 final reports. We will send our official responses soon.

From:

Sent: To:

Cc: Subject:

Best, Teagan

Good afternoon,

Teagan Ware, MS, PMP

Phone: 301-435-2390

Animal Welfare Program Analyst Division of Compliance Oversight Office of Laboratory Animal Welfare

National Institutes of Health

| Email: teagan.ware@nih.gov  |
|---|
| <b>Disclaimer</b> : Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender. |
| From: iacucpam <iacucpam@vt.edu></iacucpam@vt.edu>  |
| Sent: Monday, March 4, 2024 2:21 PM   |
| To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>  |
| cc. lacucpant \lacucpant@vt.edu>  |
| Subject: [EXTERNAL] Final Reports   |
| Hello Dr. Wolff,  |
| Please find four final reports attached from our IO. Please confirm receipt.  |
| Thank you (b) (6)   |
| (0) (0)   |
|   |
|   |
|   |
|   |
|   |
|   |
|   |
|   |
|   |



# **Initial Report of Noncompliance**

By: TDW

| Date: 1/31/24   | Time: 1:18PM  |
|---|---|
| Name of Person report<br>Telephone #:<br>Fax #:<br>Email:                             | ting: (b) (6) (b) (6)   |
|   | _Virginia Tech<br>A3208-01  |
| Funding component:  | PHS funded activity? _Yesent contacted (if necessary):                          |
| What happened?<br>One mouse found mor   | ibund, had to be EU.  |
| Species involved: m<br>Personnel involved:<br>Dates and times:<br>Animal deaths: yes, |   |
|   | edule for correction/prevention (if known):ee of moribundity for this one mouse |
| Projected submission t<br>60-90 days  | to OLAW of final report from Institutional Official:                            |
| OFFICE USE ONLY Case #  |   |