



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 10, 2024

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

Daniel Sui, Ph.D.
Vice President for Research and Innovation
Virginia Polytechnic Institute and State University
800 Drillfield Drive, (b) (4)
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 animals lacking access to food. The final report states on November 15, 2023, animal care staff identified 6 mice with no food present in their cage(s). In response to the finding, supplemental care was provided, but only 2 mice survived. It is stated the lack of access to food was due to a process error.

Per the report, the Principal Investigator (PI) created new forms and redundancy processes within the lab to reduce the likelihood of recurrence. Personnel have also been educated on the new processes and the IACUC determined these corrective measures were appropriate at the February 2024 meeting.

It is noted the animals are 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.

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

Sincerely,

Jacquelyn
T. Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2024.05.10
08:52:37 -04'00'

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

cc: IACUC Contact



RESEARCH AND INNOVATION
VIRGINIA TECH

A3208-1Q

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 ("Case #A-3208-1Q Final Report").

This letter is written in response to Dr. Tubbs' questions and is intended to supplement the Case #A-3208-1Q 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 November 2023.

On November 15, 2023, animal care staff discovered six mice without food present. Supplemental care was immediately provided (including food, heating pads, subcutaneous fluids, and veterinary care). Two of the mice survived.

A review of the incident found that the lack of food was due to a process error.

Question: Specific corrective actions

The PI developed new forms and redundancy processes within the lab to reduce the likelihood of recurrence.

Personnel have been educated on the new processes.

The IACUC reviewed the corrective actions taken at their February 2024 meeting and found the actions appropriate.

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)

Sincerely,

(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)



(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>
Cc: (b) (6) 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

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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>; (b) (6)
Subject: [EXTERNAL] Final Reports

Hello Dr. Wolff,

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

A3208-1Q



RESEARCH AND INNOVATION
VIRGINIA TECH

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, OLAW, on January 31, 2024 via a telephone call led by (b) (6). During the call, Teagan provided A-3208-1Q as the identifier for this report.

A thorough review of vivarium husbandry procedures and methods of communication with research personnel was undertaken following receipt of reported event. The results of the review were provided to the IACUC in February 2024. 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 PI with respect to communicating animal husbandry responsibilities. To address the situation, corrective actions were taken by the PI to improve communication internally, and the IACUC has requested the PI to follow-up with a finalized plan for communication between research and vivarium personnel.

The funding source of these animals is via the NIH (Federal Award #: 1R01DK133823-01). 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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 4, 2024 2:27 PM
To: 'iacucpam'
Cc: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Reports

Good afternoon,

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

Best,
Teagan

Teagan Ware, MS, PMP
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: teagan.ware@nih.gov

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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>; (b) (6)
Subject: [EXTERNAL] Final Reports

Hello Dr. Wolff,

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

Thank you

(b) (6)





Initial Report of Noncompliance

By: TDW

Date: 1/31/24

Time: 1:18PM

Name of Person reporting: (b) (6)
 Telephone #: (b) (6)
 Fax #:
 Email:

Name of Institution: Virginia Tech
 Assurance number: A3208-01

Did incident involve PHS funded activity? Yes
 Funding component: _____
 Was funding component contacted (if necessary): _____

What happened?
 2 mice FD and 2 had to be EU.

Species involved: 4 mice
 Personnel involved:
 Dates and times:
 Animal deaths: 2 dead, 2 EU

Projected plan and schedule for correction/prevention (if known): _____
 Still investigating cause of moribundity and cause of death in cohort

Projected submission to OLAW of final report from Institutional Official:
 60-90 days

OFFICE USE ONLY
 Case # _____