

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

May 9, 2024

Re: Animal Welfare Assurance A3208-01 [OLAW Case 10]

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

> FOR EXPRESS MAIL: Office of Laboratory Animal Welfare

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 16, 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 an animal lacking access to food. The final report states on January 6, 2024, animal care staff found a dead mouse in a cage that was singly housed. It is stated no food was present in the cage, but the lixit was determined to be functioning properly. A review of the incident determined the mouse presented as clinically normal on January 2nd during cage change. It is understood the review concluded food may not have been replenished for 1-3 days after cage change.

In response to the finding, all remaining mice in the housing room were evaluated by vivarium leadership and no additional concerns were observed regarding food, water, or health status of the animals. Per the report, on January 8th and 9th, the animal care staff and technicians supporting the facility were retrained on the relevant animal husbandry SOP. The corrective measure was reviewed and approved by the IACUC at the February 2024 meeting.

It is noted the animal was 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 Jacquelyn Tubbs, Date: 2024.05.09 10:47:33 -04100 Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

208-10



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

800 Drillfield Drive	
Blacksburg, Virginia 2	4061
P: ((b) (6)	(b) (6)
research.vt.edu	

April 16, 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 1R56AG080735-01A1 Final Report").

This letter is written in response to Dr. Tubbs' questions and is intended to supplement the IO-OLAW 1R56AG080735-01A1 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 January 2024.

On January 6, 2024, animal care staff discovered one deceased mouse, singly housed, which death was not expected. No food was present at the time of discovery. The water lixit serving the cage was found to be properly functioning and water available.

A review of the incident found that the mouse had presented as clinically normal during a cage change on January 2, 2024. The review concluded that replenishment of food may have been inadvertently missed for one to three days after the cage change.

Question: Specific corrective actions

Immediately following the discovery, vivarium leadership assessed all other mice in the housing room and no other concerns were identified as to food, water, or health status.

On January 8 and 9, 2024, the animal care staff and technicians serving the facility were retrained on the relevant animal husbandry SOP (Housing and Care of Mice and Rats).

The IACUC reviewed the corrective actions taken and approved the actions at their February 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)

Sincerely.

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

(b) (6)

From: 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) <<u>olawdco@od.nih.gov</u>>

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

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

 Cc: 1
 (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) <<u>olawdco@od.nih.gov</u>> 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.

208-10



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

800 Drillfield Drive Blacksburg, Virginia 24061 P: (b) (6) (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)

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 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 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 #: 1R56AG080735-01A1). 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.

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY An equal opportunity, affirmative action institution 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: Cc:	(b) (6) OLAW Division of Compliance Oversion	
Subject:	RE: Final Reports	jiit (ivii i) 00)

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: <u>teagan.ware@nih.gov</u>

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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>; Subject: [EXTERNAL] Final Reports

Hello Dr. Wolff,

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

Thank you,

(b) (6)

A3208-10



Initial Report of Noncompliance

By: TDW

Date: 1/31/24	Time: 1:18PM
Name of Perse Teleph Fax #: Email:	none #: (b) (6)
Name of Insti Assurance nu	tution: _ Virginia Tech mber: A3208-01
Funding con	nvolve PHS funded activity? _Yes nponent: component contacted (if necessary):
What happene One mouse Fl	
Species inv Personnel i Dates and t Animal dea	imes:
	a and schedule for correction/prevention (if known): gating cause of death
Projected sub 60-90 days	mission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #____