



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 1R]

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 failure of research personnel to complete required training, unauthorized personnel performing animal activities, and failure to meet occupational health requirements. The final report states field work involving bats was performed outside the United States in June and July 2023. A records review revealed the following findings:

- An individual assisting with field work had not completed required training.
- Some personnel assisting with field work were not identified in the approved protocol.
- Specific Occupational Health and Safety reporting expectations were not met.

The report states the Principal Investigator (PI) submitted an adverse event regarding the unexpected deaths of 15 bats over the course of the field work. It is further stated the cause of death could not be determined. In response to the incident, the PI received an education letter from the IACUC with the following corrective action plan:

- Submit a personnel change amendment to bring the protocol into compliance.
- Submit applicable amendments and gain approval prior to initiating new work.
- Ensure all personnel are fully trained prior to the next field work.
- Ensure adverse events are submitted in a timely manner.

It is noted the field work is supported by NSF funding (Award #: 2116748), OLAW surmises the OH&S expectations have been met as well. 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

Digitally signed by
Jacquelyn T. Tubbs -S

T. Tubbs -S

Date: 2024.05.09
11:15:53 -04'00'

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

cc: IACUC Contact

(b) (6)





RESEARCH AND INNOVATION
VIRGINIA TECH

A3208-1R

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 A-3208-1R Final Report").

This letter is written in response to Dr. Tubbs' questions and is intended to supplement the IO-OLAW A-3208-1R 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 June-July 2023.

Bat field work was conducted outside of the United States in June and July 2023. Subsequently, concerns about the field work were reported to the animal care and use program.

Based on review of records, it was found that all personnel assisting with the field work had fully completed the required training with the exception of one person; some personnel assisting with the field work were not identified in the approved protocol; and certain Occupational Health and Safety reporting expectations were not met.

The PI also submitted an adverse event report of the unexpected deaths of 15 bats over the course of the field work. It was reported that the cause of death could not be determined.

Question: Specific corrective actions

After discussion of the concerns and review at their December 2023 meeting, the IACUC sent an educational reminder letter to the PI containing the following corrective action plan: (1) submit a personnel change amendment to bring the protocol back into compliance, (2) submit applicable amendments and gain approval prior to initiating new work, (3) ensure all personnel are fully trained prior to the next field work, and (4) ensure adverse events are submitted timely. The required personnel change amendment was completed.

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)

(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

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

Hello Dr. Wolff,

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

A3208-1R



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 bats.

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).
(b) (6) During the call, Teagan provided A-3208-1R as the identifier for this report.

A thorough review of a field work expedition under the protocol was undertaken following receipt of reported concerns. During the review process, the PI submitted an adverse event report. 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 personnel training and animal welfare.

After discussion, the IACUC sent an educational reminder letter to the PI due to incongruencies relating to procedures and personnel with the approved protocol. To address the situation, corrective actions were taken including the submission of a personnel change amendment to bring the protocol back into compliance, and the amendment was approved by the IACUC.

The funding source of these animals is via the NSF (Federal Award #: 2116748). 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).
(b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

A rectangular grey box redacting the signature of the sender.

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

***Disclaimer:** 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>; (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?

Anonymous concern reported to IACUC for off-protocol work

Species involved: bats

Personnel involved:

Dates and times:

Animal deaths:

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

Finishing investigation and will include in final report

Projected submission to OLAW of final report from Institutional Official:

60-90 days

OFFICE USE ONLY

Case # _____