

Ward, Joan (NIH/OD) [E]

From: Ward, Joan (NIH/OD) [E]
Sent: Wednesday, May 24, 2023 7:35 AM
To: (b) (6)
Subject: RE: OLAW Case A3208-1L

Thank you (b) (6)

We received your confirmation and we will add this information to the file.

No additional letter will be forthcoming from OLAW unless the IACUC finds new items to report on the case.

Best regards,
Joan

From: (b) (6)
Sent: Tuesday, May 23, 2023 1:07 PM
To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>; Sui, Daniel <dsui20@vt.edu>
Cc: (b) (6)
Subject: [EXTERNAL] Re: OLAW Case A3208-1L

Hello to all,

As a follow up to this case, as requested in the letter from Dr. Wolff, the IACUC protocol was approved on May 18, 2023.

Please let me know if you require any additional information.

Thank you,

(b) (6)

(b) (6)

Ward, Joan (NIH/OD) [E]

From: Ward, Joan (NIH/OD) [E]
Sent: Wednesday, May 24, 2023 7:48 AM
To: (b) (6)
Cc:
Subject: FW: OLAW Case A3196-6T
Attachments: 4947_001.pdf

Dear (b) (6)

Attached please find Dr. Wolff's initial response to OLAW Case A3196-6T.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,
Joan

*Joan Ward
Program Specialist
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-496-7163
wardjoa@od.nih.gov*

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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

May 3, 2023

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

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 April 28, 2023 letter responding to my February 13, 2023 request for additional information regarding several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Virginia Polytechnic Institute and State University. According to the information provided, OLAW understands the following:

- 1) Following discussions between the Principal Investigator (PI) and key leadership of the animal care and use program, the previously terminated protocol has been resubmitted for Institutional Animal Care and Use Committee (IACUC) review. Currently pending documentation consists of the verification of personnel training and required wildlife permits.
- 2) The Co-PI stated that the wildlife permitting agency in Brunei did not require notification of the unexpected deaths of bats.
- 3) There were no reported human occupational health and safety incidents.
- 4) The level of post-approval monitoring has been enhanced and now requires weekly "Zoom" meetings with the investigators and IACUC, submission of weekly reports of animal activities, and including these oversight requirements as part of the protocol.

Based on its assessment of this additional information, OLAW has a better understanding of the actions taken by the IACUC to ensure compliance in a foreign field study. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy and we commend the enhanced post-approval monitoring procedures which were implemented. While OLAW will hereby close this investigation and notify the NSF representative, we request a final confirmation upon completion of the aforementioned action items in #1, including IACUC approval of the protocol. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
NSF Animal Welfare Officer



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

April 28, 2023

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Update report regarding adverse event at Virginia Tech [Assurance #A-3208-01] OLAW Case 1L

Dear Dr. Wolff:

This letter is in response to the OLAW letter received February 13, 2023 in reference to the final report for Animal Welfare Assurance A-3208-01 [OLAW Case 1L]. OLAW requested additional follow-up on several items, please see below. The below represents the results of multiple meetings involving the PI, IACUC, Veterinarians, Department Head, Associate Dean, and staff of the Animal Care and Use Program to ensure the PI has a clear understanding of the expectations of the IACUC if this protocol is to be approved.

1. Status of new protocol: The protocol is currently still under review by the IACUC. The IACUC is waiting for final personnel training and wildlife permits.
2. Actions required by the permitting agency: Per the PI, the Co-I has confirmed that there was no need to report the deaths of the bats to the wildlife permit agency in Brunei. Hence, he has not done this and no actions were required from the Brunei side.
3. Human occupational health and safety incidents: None
4. Level of post-approval monitoring: Once animal activity begins the IACUC has required weekly zoom meetings along with the PI or designee will be sending weekly reports of animal activities. These requirements will be instituted for any week animal work is ongoing. This monitoring plan will be part of the approved IACUC protocol.

The funding source for these bats are via the NSF (Federal Award Numbers: *CBET 2002466* and *OISE-1954172*).

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

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Monday, May 1, 2023 8:50 AM
To: (b) (6)
Subject: RE: OLAW Case A3208-1L

Thank you for this response, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Monday, May 1, 2023 8:43 AM
To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Subject: [EXTERNAL] Re: OLAW Case A3208-1L

Good morning, Joan,

Attached find the follow-up response to Case A3208-1L as requested by Dr. Wolff.

Please let me know if you have any additional questions and if you could please confirm receipt.

Best,
(b) (6)

(b) (6)

From: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Sent: Monday, March 20, 2023 12:08 PM
To: (b) (6)
Subject: RE: OLAW Case A3208-1L

Good afternoon (b) (6)

I hope all has been well.
Dr. Wolff is ok with your request for extension.

Best regards,
Joan

From: (b) (6)
Sent: Monday, March 20, 2023 11:11 AM
To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] Re: OLAW Case A3208-1L

Good morning,

I also left a bit of a long message on your phone. In essence we would like an extension until May 1, 2023, to respond to Dr. Wolff's request in the letter for case A3208-1L. The IACUC has been working with the PI on a new protocol submission and recently discussed the protocol and additional requirements at the March 16, 2023, meeting. The IACUC has requested additional revisions and information to be presented at the April 20, 2023, IACUC meeting. Since this date is past the requested April 14, 2023, the IACUC respectfully requests an extension until May 1, 2023.

Thank you for the consideration. Please let me know if you have any questions or if I should submit the extension request differently.

Best,
(b) (6)

(b) (6)

(b) (6)

From: Sui, Daniel <dsui20@vt.edu>

Sent: Monday, February 13, 2023 9:23 AM

To: (b) (6)

(b) (6)

Subject: Fwd: OLAW Case A3208-1L

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From: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>

Sent: Monday, February 13, 2023 7:44:11 PM

To: Sui, Daniel <dsui20@vt.edu>

Cc: (b) (6)

Subject: FW: OLAW Case A3208-1L

Dear Dr. Sui,

Attached please find Dr. Wolff's response to OLAW case A3208-1L.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,
Joan

Joan Ward
Program Specialist
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-496-7163
wardjoa@od.nih.gov

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Follow Up Flag: Follow up
Flag Status: Flagged

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To: Sui, Daniel <dsui20@vt.edu>

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If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,
Joan

*Joan Ward
Program Specialist
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
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Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

February 13, 2023

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

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 February 3, 2023 letter reporting several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Virginia Polytechnic Institute and State University, following up on an initial telephone report on October 17, 2022. According to the information provided, OLAW understands that on a captive bat study individuals not listed on the protocol were handling the animals, husbandry was provided by students not approved by the Institutional Animal Care and Use Committee (IACUC), personal protective equipment was not being used, adequate veterinary care was unavailable, the species of bat housed had not been approved, humane endpoints were not followed, the euthanasia method was not listed on the protocol and was not an American Veterinary Medical Association approved method, and the Principal Investigator failed to inform the IACUC of any bat deaths. The noncompliance had already occurred when it was anonymously reported to the IACUC and there are no current animal activities ongoing. These activities were performed under NSF awards CBET 2002466 and OISE-1954172.

The corrective actions consisted of the IACUC terminating the protocol due to the magnitude of infractions. The IACUC is meeting with the Animal Care and Use Program staff and the veterinarians to assess the design of this project and how to ensure appropriate oversight prior to potential approval of a new protocol.

Based on its assessment of this explanation, OLAW concurs with the swift action taken by the IACUC to ensure animal welfare and compliance with the PHS Policy. OLAW will inform NSF but will keep this case open until a final decision is made as to whether this protocol is reinstated and until the measures taken to ensure compliance going forward can be evaluated. Please provide an update by **April 14, 2023** as to the actions being taken. Include information on any actions required by the permitting agency, whether there were any human occupational health and safety incidents, and the level of post-approval monitoring applied if this study resumes. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



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A3208-1L

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

February 3, 2023

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 multiple incidences of noncompliance on an IACUC approved protocol utilizing wild-caught bats. This incident was initially reported to you via phone call on November 17, 2022 after verification of NSF funding.

On October 11, 2022, the IACUC office was anonymously notified of concerns regarding appropriate training of protocol personnel and care of bats. Animal use on the protocol was not ongoing at the time of notification and animal use is not expected to re-initiate until summer 2023. The IACUC discussed the protocol at the December 15, 2022 convened meeting and requested corrective actions from the PI:

1. The IACUC issued a serious noncompliance letter and reminded the PI in the future to adhere to the approved protocol. The multiple noncompliance violations addressed in the letter included (1) individuals participated in bat handling who were not approved and listed on the protocol; (2) husbandry of captive bats were performed by Virginia Tech-associated students without IACUC approval or awareness; (3) PPE requirements were not enforced for individuals handling bats; (4) appropriate veterinary care was not available; (5) the majority of bats captured, held, and manipulated were not approved species; (6) humane endpoints were not followed – euthanasia by protocol personnel was not described on the protocol and the euthanasia method utilized was not an AVMA-approved method; (7) the PI did not notify the IACUC of bat deaths.
2. Due to multiple noncompliance violations and the absence of active animal use on the protocol, corrective actions required by the IACUC included (1) requesting the closure of the protocol within 48 hours of the receipt of the noncompliance letter, and (2) meeting with Animal Care and Use Program staff and Animal Resources and Care Division veterinarians to discuss project design, implementation and oversight prior to initiating a new protocol.

The funding source for these bats are via the NSF (Federal Award Numbers: *CBET 2002466* and *OISE-1954172*). Per PHS requirement, the PI has been informed that he must cooperate with his 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)

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: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 9, 2023 7:36 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 report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA (pronunciation)
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: iacucpam <iacucpam@vt.edu>
Sent: Wednesday, February 8, 2023 3:31 PM
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 November 17, 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: (b) (6)

Date: 10/17/22

Time: 1000

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: VIRGINIA Polytechnical Inst.

Assurance number: A3208

Did incident involve PHS funded activity? NSF

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Problems w/ husbandry at a primate site

Species involved: *Bats*

Personnel involved:

Dates and times:

Animal deaths:

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

Issue investigated by IACUC

Projected submission to OLAW of final report from Institutional Official:

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Case # _____