



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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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

February 5, 2024

Re: Animal Welfare Assurance  
A3245-01 [OLAW Case 5F]

Frederick H. Epstein, Ph.D.  
Professor and Interim Vice President for Research  
University of Virginia - Charlottesville  
P.O. Box 400301  
136 Hospital Drive  
Charlottesville, VA 22904

Dear Dr. Epstein,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 30, 2024, letter reporting as series of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Virginia, following up on an initial email notification on October 2, 2023. According to the information provided, OLAW understands that when a student injected an approved hazard into thirteen mice, the following protocol noncompliance issues related to this PHS-supported animal activity were identified:

- the age and reproductive status of the animals used;
- blood withdrawal;
- behaviors studies; and
- location and method of euthanasia.

The corrective actions consisted of the Director of the Office of Animal Welfare counseling the Principal Investigator (PI) regarding the oversight and training provided to laboratory animal users. Compliance expectations were also reviewed with the PI and laboratory personnel. The PI and student were informed that they were prohibited from performing any additional unapproved animal activities and that data generated during the noncompliance could not be used for publication. The PI completed a review of the approved protocol and IACUC policies with laboratory staff and laboratory personnel attended the orientation seminar as mandated by the IACUC. In addition, the PI developed and implemented an on-boarding training plan for new laboratory animal users and described retraining for current animal users. Provision of additional laboratory oversight by the PI will be accomplished by meeting weekly with each animal user and discussing the approved protocol at least once a month. Prior to initiating any animal work, the laboratory will ensure that all animal activities have been approved in the protocol.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed of this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee -S

Digitally signed by Neera V.  
Gopee -S  
Date: 2024.02.05 10:30:44 -05'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Associate Director, Animal Welfare Policy  
Office of Laboratory Animal Welfare  
National Institutes of Health

cc: IACUC Chair

**University of Virginia**  
**Animal Care and Use Compliance Report**  
*PHS Assurance # A3245-01*

The Institutional Animal Care and Use Committee (IACUC) discovered the following compliance issue and found that it was associated with NIH funds. A preliminary email notification was sent to the OLAW Division of Compliance Oversight by the Director of the Office of Animal Welfare. Teagan Ware, Program Analyst, acknowledged receipt. It was understood that a full report would be submitted following IACUC review. This document is a summary of the incident, actions taken, and final resolution.

**UVA Case #: 2023-K**  
**OLAW Case #: A3245-SF**

<b>Nature of Incident(s):</b>	Implementation of a significant change to the IACUC-approved protocol without proper IACUC approval as required (mice)
<b>Summary of Incident:</b>	During protocol review, it was determined that an unapproved experiment had been performed by a student in the laboratory. The student discussed and planned this experiment with the PI, and several members of the laboratory assisted the student with the experiment. Thirteen mice were injected with a biohazard and later verified, through blood analysis, that the animals were no longer hazardous. The animals were then taken to the behavioral suite and a single day of behavioral experiments were performed followed by immediate euthanasia. The use of the biohazard was approved in the protocol; however, the age and reproductive status of the animals used, blood withdrawal, behavior experiments, location and method of euthanasia were not described in the protocol. Several IACUC policy infractions were noted during the performance of the unapproved animal work.
<b>Action taken by IACUC:</b>	<p>The Director of the Office of Animal Welfare met with the PI to discuss oversight and training provided to animal handlers in the laboratory. The PI and student were told that they were not permitted to perform any additional animal experiments that were not explicitly detailed and approved in the animal use protocol, and any data obtained from animal experiments not approved in the animal use protocol were not to be used for publication. Training and oversight were found to be inadequate and the PI was told to begin re-evaluating and strengthening the training provided to her animal handlers.</p> <p>The IACUC discussed the incident at the next convened meeting and determined that the incident was a significant deficiency because of the protocol violation (deviation). They were very concerned about the student's lack of familiarity with the protocol and multiple IACUC policies, and unfamiliarity with fundamental components of compliance. It appeared that several members of the laboratory, including the PI, were aware of the experiment occurring yet no one recognized the protocol or policy noncompliance. The IACUC determined that there was a lack of appropriate oversight from the PI. The IACUC required that the entire laboratory and PI complete the orientation seminar, review several IACUC policies, and ensure that they had a deep understanding of the</p>

	contents of the approved animal use protocol. The PI was required to develop an on-boarding training program for new animal handlers. A written corrective action plan was required and needed to include the following: description of specific practices and procedures for preventing future compliance issues, methods for providing ongoing training to current animal handlers, and practices to improve oversight.
<b>Action taken by PI:</b>	The PI responded to the IACUC concerns and recognized the seriousness of the problems noted. The corrective actions taken by the PI included reviewing the protocol and IACUC policies (provided dates of completion). The group attended the next convened orientation seminar. The Director of the Office of Animal Welfare met with the PI and laboratory and reviewed compliance expectations. The PI developed and provided the on-boarding training plan for new animal handlers and described retraining of existing animal handlers. The PI described how they would provide additional oversight of the protocol and animal handlers on a routine basis.
<b>Action taken by IACUC:</b>	The IACUC reviewed the information provided by the PI at the next convened monthly meeting. The IACUC accepted the on-boarding training plan and required additional information specific to the frequency of retraining and oversight measures to be taken. The PI responded to the request and indicated that they meet with each animal handler weekly and they will discuss the animal use protocol at a minimum of once a month. They will ensure that all work is approved in the protocol prior to beginning work. The IACUC responded to the update and the PI was reminded that any data resulting from the unapproved animal activity should not be used for publication. The IACUC felt that the other actions taken by the PI to prevent future protocol deviations was appropriate and no further action was deemed necessary.
<b>Decision/Resolution:</b>	The IACUC considered the incident resolved.
<b>Federal Funding:</b>	1R01 DK122737-01A1
<b>Notification of Final Disposition:</b>	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
<b>Institutional Official:</b> Dr. Frederick H. Epstein	Date (b) (6)



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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, January 30, 2024 10:11 AM  
**To:** (b) (6)  
**Cc:** (b) (6); Epstein, Frederick H (fhe6b);  
(b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Compliance Report 2023-K for OLAW

Good morning,

Thank you for providing this final report for OLAW case **A3245-5F**. We will send an official response 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](mailto:teagan.ware@nih.gov)

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**From:** (b) (6)  
**Sent:** Tuesday, January 30, 2024 10:04 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; McCoy, Devera (NIH/OD) [E] <devora.mccoy@nih.gov>  
**Cc:** (b) (6); Epstein, Frederick H (fhe6b) <fhe6b@virginia.edu>; (b) (6)  
**Subject:** [EXTERNAL] Compliance Report 2023-K for OLAW

Dr. Brent Morse, Division Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health RKL 1, Suite 360, MSC 7982  
6705 Rockledge Dr., Bethesda, MD

Dr. Morse:

We previously submitted an email notification on a compliance matter, UVA 2023-K (see attached) which was assigned OLAW case number #A3245-5F.



The IACUC reviewed the incidents and the corrective actions and has determined that this matter is now resolved to their satisfaction.

I have reviewed their final reports and I agree with their recommendations.

(b) (6)

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

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**From:** Ware, Teagan (NIH/OD) [E]  
**Sent:** Wednesday, January 3, 2024 11:03 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** OLAW cases A3245-5E and A3245-5F

Good morning (b) (6)

During a recent QA of our records, it was discovered that we have two open cases in need of updates that were initially reported to OLAW via e-mail on September 28, 2023. I have provided additional information on these incidents below, for your reference.

Case **A3245-5E** (UVA #2023-J): several infractions that jeopardized the health and well-being of mice resulting in protocol suspension

Case **A3245-5F** (UVA #2023-K): significant changes to mouse protocol by a researcher and student without IACUC approval (13 mice)

Please provide updates for both of these incidents at your earliest convenience.

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](mailto:teagan.ware@nih.gov)

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, October 2, 2023 10:22 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Preliminary Notification of Non-Compliance: UVA - #A3245-01 (Case #2023-K)

Good morning (b) (6)

Thank you for sending us this preliminary report, assigned OLAW case number **A3245-SF**. I have documented the UVA tracking number along with our assigned case number, so please reference either the UVA tracking number or OLAW case number when sending the final report.

Thanks,  
Devora

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

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

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**From:** (b) (6)  
**Sent:** Thursday, September 28, 2023 9:52 PM  
**To:** Wolff, Axel (NIH/OD) [E] <[wolffa@od.nih.gov](mailto:wolffa@od.nih.gov)>; OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] Preliminary Notification of Non-Compliance: UVA - #A3245-01 (Case #2023-K)

Dear OLAW Division of Compliance Oversight,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) identified a significant deficiency related to mice. The UVA tracking number is 2023-K.

The issue is currently under investigation and review by the IACUC. We are working towards resolution with the researcher and the IO will send a separate compliance report once resolved. It appears that a researcher and their student implemented a significant change to the IACUC-approved protocol without prior IACUC approval as required. Incident involved thirteen mice.

Should you have any questions or concerns prior to receiving our final report, please do not hesitate to contact me.



Sincerely,

(b) (6)