



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
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Office of Laboratory Animal Welfare  
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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

November 9, 2023

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

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 October 31, 2023, letter reporting an instance 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 September 28, 2023. According to the information provided, OLAW understands that an unapproved antibiotic was administered in water to twelve mice in a PHS-supported study. The Director of the Office of Animal Welfare instructed the Principal Investigator (PI) to euthanize the animals and halted the initiation of related studies. However, the PI failed to euthanize the animals when notified on the second day when the noncompliance was identified and instead euthanized the animals on the fifth day of the study. The PI did not conduct any work on his approved protocol in over two years and performed the antibiotic treatment in water for up to four days followed by euthanasia on the fifth day, as he has routinely done on a collaborator's approved protocol. The PI also stated that he misunderstood the Attending Veterinarian's notification as the assigned reviewer and did not realize that the amendment was not immediately approved upon submission.

The corrective actions consisted of the PI immediately reporting the noncompliance to the Attending Veterinarian and submitting an amendment to include the antibiotic treatment. The PI contacted the IACUC office to clarify the timeline for submissions and approvals and will review the protocol to ensure that it accurately reflects the work planned for future studies. The IACUC reminded the PI that only procedures described in the approved protocol could be performed. The IACUC also approved the submitted amendment for future studies, however data generated from the noncompliance could not be used in publications since the IACUC did not retro-actively approve the unapproved animal activity.

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: 2023.11.09 11:15:11 -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

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

A3245-5D

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, October 31, 2023 9:22 AM  
**To:** (b) (6)  
**Cc:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD); Morse, Brent (NIH/OD) [E]  
**Subject:** RE: UVA Compliance Report 2023-I and UVA Compliance Report 2023-L

Good morning,

Thank you for providing this update for A3245-5D. The new case submission (2023-L) has been assigned OLAW case A3245-5G. We will send 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](mailto:teagan.ware@nih.gov)

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**From:** (b) (6)  
**Sent:** Tuesday, October 31, 2023 9:11 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] UVA Compliance Report 2023-I and UVA Compliance Report 2023-L

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-I (see attached) which was assigned OLAW case number A3245-D and we also now report on UVA 2023-L which had not been assigned an OLAW case number. That is, UVA 2023-L is a new report.

Due to the nature and the timing of the issues as described in UVA 20232-L a preliminary report was not submitted. In this case the incident was reported to the IACUC by the UVA Attending Veterinarian who also serves as the directory of the UVA animal husbandry unit. At the time of this report, the AV summarized the incident and described the corrective actions taken to prevent recurrence. The IACUC reviewed the incident and the corrective actions and has determined that this matter is now resolved to their satisfaction. This happened so quickly that there really wasn't time to submit a preliminary report as the final report was already completed.

I have reviewed the IACUC final report and I agree with their recommendations.

(b) (6)

**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. Devora McCoy, 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-I**

**OLAW Case #: A3245-5D**

<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>	PI self-reported a protocol deviation to the Attending Veterinarian upon discovery. Animals were treated with antibiotic water for two days when the PI discovered that the treatment was not described in the protocol. The PI performed the same antibiotic treatment routinely on a collaborator's protocol but failed to realize the treatment was not included in their own protocol. The PI had not used their own protocol in >2yrs. The experiment involved treating animals (12) with antibiotic water for four days in order to disrupt the intestinal microbiome and then euthanizing the animals on day five. On the day of discovery, the PI immediately submitted a protocol modification to the IACUC. The Director of the Office of Animal Welfare was notified on the day of discovery and relayed to the PI that due to the protocol violation, the animals needed to be euthanized and similar experiments could not be initiated until fully described in the animal use protocol and approved by the IACUC.
<b>Action taken by IACUC:</b>	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). Prior to the meeting, the Director of the Office of Animal Welfare had asked the PI to prepare a corrective action plan to prevent reoccurrence of similar issues; therefore, the IACUC reviewed the plan at the same convened meeting. The IACUC required additional clarification from the PI because it appeared that the experiment was completed through day five instead of being terminated as requested (on day two).
<b>Action taken by PI:</b>	The PI responded to the IACUC concerns. The corrective actions taken by the PI included immediately reporting the issue to the Attending Veterinarian and submitting a protocol modification to include the antibiotic treatment. In the future, the PI will read through the protocol to ensure that it accurately reflects the work planned for future experiments. When asked why the experiment was completed, the PI indicated that once the protocol modification was submitted to the IACUC for review, the PI did not realize that the protocol was not immediately approved.

	The PI misunderstood the Attending Veterinarian's notification that the AV was assigned as the reviewer of the submitted modification. The PI contacted the IACUC office for clarification on the timeline for submissions and approvals to prevent future misunderstandings.
<b>Action taken by IACUC:</b>	The IACUC reviewed the additional information provided by the PI at the next convened monthly meeting. The IACUC reminded the PI that only work described in the approved protocol was permitted to be performed. Although the a protocol modification was submitted and later approved, the approval did not retro-actively approve the experiment that deviated from the protocol when performed, and 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 approved the protocol modification and considered the incident resolved.
<b>Federal Funding:</b>	1R01AT010253
<b>Notification of Final Disposition:</b>	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
<b>Institutional Official:</b> Dr. Frederick H. Epstein	(b) (6) Date: October 31, 202_



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

**A3245-5D**

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, October 2, 2023 10:21 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Preliminary Notification of Non-Compliance: UVA - #A3245-01 (Case #2023-I)

Good morning (b) (6)

Thank you for sending us this preliminary report, assigned OLAW case number **A3245-5D**. 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 9:51 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] Preliminary Notification of Non-Compliance: UVA - #A3245-01 (Case #2023-I)

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-I.

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 implemented a significant change to the IACUC-approved protocol without prior IACUC approval as required. Incident involved twelve mice.

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

(b) (6)