



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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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

November 28, 2023

Re: Animal Welfare Assurance
A3245-01 (OLAW Case 4Y)

Frederick H. Epstein, Ph.D.
Professor & Interim Vice President for Research
University of Virginia
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 24, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Virginia. Your letter supplemented the information contained in an initial email report to this office on September 28, 2023. According to the information provided, OLAW understands that two cages of mice were found with incomplete post-operative cage cards. The cards were from different surgeons and did not include the required number of post-operative observations. The error was found during a semiannual facility inspection. The veterinarian was present and deemed the animals healthy. The mice involved in this incident were supported by PHS funds.

Corrective and preventive measures were initiated. The principal investigator (PI) reported that one of the surgeons was no longer with the laboratory. The second surgeon was warned that inadequate monitoring would not be tolerated, and a second finding would result in removal from the protocol. The PI also reviewed the guidelines for completing surgery cage cards with all current animal handlers. The PI and laboratory manager will monitor each surgeon, and surgeons will be required to email them daily when completing surgery cage cards. Any surgeon found noncompliant will be removed from the protocol. The animal handler tasked with taking the daily census will also monitor the surgery cage cards for completion. Finally, the PI and laboratory manager will perform daily checks of the colony.

OLAW appreciates the consideration of this matter by the University of Virginia, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M.
Engel -S
Date: 2023.11.28 08:29:33 -05'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact

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-D
OLAW Case #: A3245-4Y

Nature of Incident(s):	Failure to monitor animals post-procedurally as necessary to ensure well-being
Summary of Incident:	During the semi-annual facility inspection, a member of the Institutional Animal Care and Use Committee (IACUC) found two cages of post-operative mice with incomplete surgery cage cards. The cards were from two different surgeons and both were incomplete for the required number of post-operative observations. According to the veterinarian, the animals appeared to be okay at the time of the inspection.
Action taken by IACUC:	The IACUC discussed the incident at a convened meeting and determined that the incident was a significant deficiency because of the <i>potential</i> impact on animal welfare and the deviation from the protocol and IACUC policy. The Committee was concerned about the training and oversight being provided by the PI. The IACUC sent a letter to the PI notifying him of the deficiencies and required a written corrective action plan addressing: how the current surgeons will be retrained, how future surgical training will be modified to ensure compliance, and methods for improving the oversight of all surgeries.
Action taken by PI:	<p>The PI responded to the IACUC concerns and reported that one of the surgeons was no longer employed by the PI. The second surgeon received a strong warning that inadequate monitoring would not be tolerated and if found, the individual would be removed from the protocol. In addition to discussing the specific incident with the surgeon, the PI also reviewed the guidelines for completing surgery cage cards with all the current animal handlers.</p> <p>In order to provide additional oversight, the PI and lab manager will monitor each surgeon, and surgeons will be required to email the PI/lab manager daily when completing surgery cage cards. Any surgeon found non-compliant will be removed from the protocol. The animal handler tasked with taking the daily census will also monitor the surgery cage cards for completion. The PI and lab manager will perform daily checks of the colony.</p>

Action taken by IACUC:	The IACUC felt that the PI responded appropriately and no further action was deemed necessary.
Decision/Resolution:	The IACUC accepted the corrective action plans as submitted by the PI and considered the incident resolved.
Federal Funding:	R56NS099586
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Frederick H. Epstein	Date: October 24, 2023 (b) (6)

Ware, Teagan (NIH/OD) [E]

A3245-44

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 24, 2023 10:51 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Morse, Brent (NIH/OD) [E]
Subject: RE: Animal Care and User Report - UVA - #A3245-01 (Case #2023-D (A3245-4Y) and 2023-E (A3245-Z)

Hello (b) (6)

Thank you for these two updates and 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

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From: (b) (6)
Sent: Tuesday, October 24, 2023 10:45 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] Animal Care and User Report - UVA - #A3245-01 (Case #2023-D (A3245-4Y) and 2023-E (A3245-Z)

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 a preliminary notification (attached) on two compliance matters, UVA 2023-D which was assigned OLAW case number A3245-4X, and UVA 2023-E which was assigned OLAW case number A2345-Z.

Appropriate corrective actions have been taken and the IACUC has determined that these two matters are now resolved to their satisfaction. I have received copies of their final reports and I agree with their recommendations.

(b) (6)

Ware, Teagan (NIH/OD) [E]

A3245-44

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 2, 2023 10:08 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Notification of Non-Compliance: UVA - #A3245-01 (Case #2023-C, 2023-D, 2023-E)

Good morning (b) (6)

Thank you for sending us these preliminary reports and we look forward to receiving the final reports once completed. I have documented the UVA tracking numbers along with our assigned case numbers (added below), so please references either the UVA tracking number or OLAW case number when sending the final reports.

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

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From: (b) (6)
Sent: Thursday, September 28, 2023 5:55 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-C, 2023-D, 2023-E)

Dear OLAW Division of Compliance Oversight,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) identified three significant deficiencies during the semi-annual inspection of the program. The UVA tracking numbers are listed below. Each issue is under review by the IACUC, and they are working towards resolution. The IO will send a separate compliance report for each of the bulleted points once resolved.

- (OLAW case number A3245-4X)- 2023-C: failure to maintain appropriate animal-related husbandry records. A gap in the animal husbandry records was identified in one rodent room

- **(OLAW case number A3245-4Y)- 2023-D:** failure to monitor animal post-procedurally as necessary to ensure well-being. Rodent surgery cage cards were incomplete from two different surgeons on the same animal use protocol.
- **(OLAW case number A3245-4Z)- 2023-E:** researcher inadvertently administered expired anesthetic to rodents

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

Sincerely,

(b) (6)