



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

November 28, 2023

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

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 mice received expired anesthetic to immobilize them for a laboratory procedure. The anesthetic expired 15 days prior to use. The post-doctoral student responsible for labeling and disposal of controlled substances had recently left the institution and the graduate student who used the expired drug was not aware of the expiration date. The mice involved in this incident were supported by PHS funds.

Corrective and preventive measures were initiated. The principal investigator (PI) and all authorized users were retrained on the labeling, usage documentation, and disposal practices for controlled substances. All users were reminded that the use of expired substances is never permitted. The PI instituted annual retraining of animal handlers on proper use and disposal of controlled substances. Further, the expiration dates of substances will be placed in a shared laboratory calendar with notification reminders to dispose of expired substances and mixtures.

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. However, in future reports please indicate whether the animals were negatively affected by the noncompliance.

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 10:37:31 -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-E

OLAW Case #: A3245-4Z

Nature of Incident(s):	Administration of expired anesthetic
Summary of Incident:	During the semi-annual facility inspection, a member of the Institutional Animal Care and Use Committee (IACUC) found a bottle of expired anesthetic and upon further review determined that the substance was used beyond the expiration date. According to the controlled substance usage documentation, a working solution of anesthetic was made using the expired anesthetic stock solution and two mice were administered the anesthetic mix. The solution was used approximately 15 days past the expiration date. The anesthetic was used to immobilize the animals for a laboratory procedure.
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. The IACUC sent a letter to the PI notifying them of the deficiency and reminded them that using expired anesthesia for any purpose is prohibited. The PI was required to dispose of the expired material and provide a written corrective action plan to prevent reoccurrence.
Action taken by PI:	The PI responded to the IACUC concerns and reported that the expired anesthetic and all solutions made with the expired anesthetic were immediately labeled for disposal. The PI indicated that the post-doc responsible for controlled substance labeling and disposal left the institution suddenly and the graduate student using the controlled substance was not aware of the expiration date. All authorized users were provided immediate retraining on the following: the IACUC policy for labeling and monitoring vials of anesthetic; reminded that the use of expired substances is never permitted; and reviewed methods for completing usage and disposal documentation. The PI instituted annual retraining of animal handlers at the start of every fall semester on proper usage and disposal of controlled substances. The expiration dates of substances will be placed in a shared laboratory calendar with notification reminders to dispose of expired substances and mixtures.

Action taken by IACUC:	The IACUC felt that the PI responded appropriately; however, the Committee required that the PI complete one-on-one training with the director of the Office of Animal Welfare on the labeling, usage documentation, and disposal practices for controlled substances.
Decision/Resolution:	Following the required training, the IACUC felt that no further action was deemed necessary and accepted the corrective action plans as submitted by the PI. The IACUC considered the incident resolved.
Federal Funding:	R01-DC013773
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]

A3245-4Z

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

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: (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]

A3245-42

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

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: (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)