



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

October 31, 2023

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

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 24, 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 animal handler inappropriately euthanized a rat, weighing less than 200 g, by failing to assure death following carbon dioxide asphyxiation on a PHS-supported study. The responsible handler assured death in two remaining rats by performing bilateral thoracotomy but failed to assure death by a secondary method in the third animal.

The corrective actions consisted of the Principal Investigator (PI) providing a comprehensive corrective action plan that included retraining all animal handlers listed in the protocol on the IACUC euthanasia policy. The responsible handler was required to receive hands-on training for confirmation of death procedures. The PI also standardized the procedure for conducting a bilateral thoracotomy in rats by visualizing and severing the diaphragm. The Director of the Office of Animal Welfare retrained the responsible individual on the IACUC euthanasia policy and methods for assuring death in both rats and mice and bilateral thoracotomy was demonstrated on a previously euthanized animal.

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: 2023.10.31 12:15:36 -04'00'
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]

A3245-5C

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 24, 2023 11:02 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-H (A3245-5C)

Hi (b) (6)

Thank you for providing this final report. 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

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From: (b) (6)
Sent: Tuesday, October 24, 2023 10:48 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-H (A3245-5C)

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 on a compliance matter, UVA 2023-H (see attached) which was assigned OLAW case number A3245-5C.

Appropriate corrective action has been taken and the IACUC has determined that this matter is now resolved to their satisfaction.

I have received copies of their final reports 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-H
OLAW Case #: A3245-5C

Nature of Incident(s):	Failure to ensure death of animal after euthanasia procedures (rat)
Summary of Incident:	The veterinary staff reported euthanizing an animal that was discovered due to an animal handler's failure to ensure death after euthanasia procedures were performed. Upon further investigation, the source of the animal and the animal handler responsible for the failed euthanasia were identified. The animal handler had intended to euthanize three animals (>200gms) using an overdose of CO ₂ and two of the three animals had incisions indicating that a bilateral thoracotomy had been performed as the method to confirm death. The animal handler was unsure why the third animal (found alive) had not been confirmed following euthanasia procedures. It appeared that the animal handler understood the requirement for performing confirmation of death following euthanasia as demonstrated by the two properly euthanized animals.
Action taken by IACUC:	The IACUC discussed the incident at the next convened meeting and determined that the incident was a significant deficiency because of the impact on animal welfare. The IACUC sent a letter to the PI describing the deficiency and required a written corrective action plan to prevent reoccurrence.
Action taken by PI:	The PI responded to the IACUC concerns and provided a detailed corrective action plan. All animal handlers on the protocol were immediately retrained with respect to the expectations of the IACUC policy on euthanasia. The PI required that the animal handler involved in the incident receive hands-on retraining for performing confirmation of death procedures. The PI standardized the method for confirming death for all rats on the protocol – performing a bilateral thoracotomy by visualizing and severing the diaphragm. The director of the Office of Animal Welfare retrained the animal handler on the IACUC policy on euthanasia and methods for confirming death for both rats and mice. Bilateral thoracotomy was demonstrated on a previously euthanized animal.
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:	R01 AG071676
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]

A3245-5C

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-H)

Good morning (b) (6)

Thank you for sending us this preliminary report, assigned OLAW case number **A3245-5C**. 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

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From: (b) (6)
Sent: Thursday, September 28, 2023 9:49 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-H)

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 a rat. The UVA tracking number is 2023-H.

The issue is currently under review by the IACUC. We are working towards resolution with the researcher and their animal handlers, and the IO will send a separate compliance report once resolved. It appears that an animal handler failed to ensure the death of an animal after performing euthanasia procedures (CO₂).

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

Sincerely,

