



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

April 9, 2024

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

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

Dear Dr. Epstein,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 4, 2024 report of an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Virginia (UVA Compliance Case #: 2023-O). According to the information provided it is understood that during the semi-annual facility inspection, the Institutional Animal Care and Use Committee (IACUC) inspection team found notes on cage cards referencing seizure activity in two voles. The animals were not reported to the veterinary team for consultation or evaluation, and the veterinarians were unaware of the findings. The animals had been euthanized. The animals were part of a PHS-supported activity.

Corrective and preventive measures: The laboratory and husbandry staff will use the established veterinary notification system for reporting animal health concerns. All laboratory staff were trained on the reporting practices. Laboratory staff will be informed of veterinary issues by husbandry personnel. However, all health issues will be reported to the veterinary staff for consultation, possible treatment, and ongoing evaluation. Animals with seizure-like behavior will be monitored by the laboratory and veterinary staff until euthanized.

OLAW believes that the corrective and preventive measures put in place by the University of Virginia are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C.

Morse -S

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

Digitally signed by Brent C.
Morse -S

Date: 2024.04.09 15:06:28
-04'00'

cc: IACUC Contact

(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. Due to the timing of the discovery, investigation, and resolution, a preliminary email notification to OLAW was not feasible. This document is a summary of the incident, actions taken, and final resolution.

UVA Case #: 2023-O (PI and husbandry staff)

OLAW Case #: not assigned

Nature of Incident(s):	Failure to provide adequate veterinary care resulting in a condition that <i>potentially</i> jeopardized the health of an animal
Summary of Incident:	During the semi-annual facility inspection, the Institutional Animal Care and Use Committee (IACUC) inspection team found notes on cage cards referencing seizure activity in two voles. The animals were not reported to the veterinary team for consultation or evaluation, and the veterinarians were unaware of the findings; however, the laboratory staff and husbandry staff had communicated about the finding.
Action taken by IACUC:	<p>Upon discovery, the Director of the Office of Animal Welfare (OAW) communicated with the PI and colony manager. The PI failed to report the seizure-like activity because the occurrence was rare and once observed, the animals were removed from the experimental colony as soon as feasible and euthanized. The established methods for reporting veterinary concerns was reviewed in detail with the colony manager and PI.</p> <p>The IACUC discussed the issues at a convened meeting and determined that the incident was a significant deficiency because the animals should have been reported immediately for veterinary consultation using established practices. The IACUC considered this a failure to provide adequate veterinary care resulting in a condition that <i>potentially</i> could have jeopardized the health of the animal. The IACUC held both the research and husbandry staff responsible for the failure to report the health issue. It was not possible to characterize the activity observed as specifically a seizure; therefore, it was referenced as seizure-like. The IACUC sent a letter to both the PI and Attending Veterinarian (AV) notifying them of the deficiency. Both the PI and AV were required to respond independently in writing with a corrective action plan to prevent reoccurrence with staff members (researchers and animal husbandry staff).</p>

Action taken by PI:	The PI responded to the IACUC concerns and provided corrective actions. The laboratory staff will use the established veterinary notification system for reporting animal health concerns. All animal health concerns will be reported at the cage level, room level, and with email notification to the veterinary staff. Animals with seizure-like behavior will be monitored by the laboratory and veterinary staff until euthanized. The PI and colony manager met with the AV and Clinical Veterinarian to discuss the issue and reporting measures. All laboratory staff were trained on the reporting practices.
Action taken by AV:	The AV responded with a corrective action plan. The veterinary staff was immediately contacted upon discovery and discussed the issue with the researchers, vivarium supervisor, and husbandry staff. The husbandry management team reviewed the issue with the husbandry staff and will ensure that they report animal health issues using the established mechanisms for veterinary consultation. They stressed the need to include the clinical veterinarian in all emails with the research staff when related to animal health issues. Laboratory staff will be informed of veterinary issues; however, all health issues will be reported to the veterinary staff for consultation, possible treatment, and ongoing evaluation.
Action taken by IACUC:	The IACUC felt that the PI and AV responded appropriately, and no further action was deemed necessary.
Decision/Resolution:	The IACUC accepted the corrective action plans as submitted by the PI and AV and considered the incident resolved.
Federal Funding:	R01-HD098117
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Frederick H. Epstein	(b) (6) Date: April 4, 2024

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 5, 2024 9:28 AM
To: (b) (6)
Cc: (b) (6); Epstein, Frederick H (fhe6b) (b) (6)
(b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UVA Compliance Report 2023-O

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3245-5M**. 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

***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: Friday, April 5, 2024 8:22 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdcn@od.nih.gov>
Cc: (b) (6); Epstein, Frederick H (fhe6b) <fhe6b@virginia.edu>; (b) (6)
(b) (6)
Subject: [EXTERNAL] UVA Compliance Report 2023-O

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 attach a copy of the UVA Compliance report 2023-Q. Due to the timing of the discovery, investigation, and resolution, a preliminary email notification to OLAW was not feasible.

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

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

(b) (6)