



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

April 3, 2024

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

Frederick H. Epstein, Ph.D.
Professor and Interim Vice President for Research
University of Virginia - Charlottesville
P.O. Box 400301
Charlottesville, VA 22904-4301

Dear Dr. Epstein,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your 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-M), received March 26, 2024. According to the information provided it is understood that during the IACUC semi-annual facility inspection, four post-operative mice were found with an incomplete surgery cage card. The card was incomplete for the required number of post-operative observations, and analgesia was not documented appropriately. Upon further review, adequate and appropriate analgesia was not administered by the surgeon. According to the veterinarian, the animals appeared to be okay at the time of the inspection. The activity was PHS funded.

The OAW Director reviewed the post-operative monitoring and recordkeeping requirements with the PI and surgeon. Understanding was confirmed. The PI provided the IACUC corrective actions including enhanced oversight. The PI purchased the appropriate analgesic in accordance with the approved protocol. The PI immediately reviewed the differences in analgesia with all animal handlers and verified understanding. The PI will review this information annually as a refresher, and future animal handlers will be tested on this information during the on-boarding process. The PI will require surgeons to perform post-operative monitoring beyond the required time points outlined in the IACUC surgery policy. Each surgeon will be required to create a standard operating procedure for each surgery they are interested in performing, and the document must include the number of post-operative observations and a description of adequate recordkeeping. New surgeons will be required to complete a comprehension quiz before being allowed to perform surgeries, and they will be required to report to the laboratory trainer for a minimum of one week after the surgery regarding post-operative monitoring.

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. Please be sure that any surgery SOP created by a surgeon is in congruence with the IACUC-approved protocol. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S Digitally signed by Brent C. Morse -S
Date: 2024.04.03 14:10:16 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3245-5K

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-M

OLAW Case #: not assigned

Nature of Incident(s):	Failure to monitor animals post-procedurally as necessary to ensure well-being; failure to adhere to approved protocol resulting in inadequate post-operative analgesic
Summary of Incident:	During the semi-annual facility inspection, the Institutional Animal Care and Use Committee (IACUC) inspection team found four post-operative mice with an incomplete surgery cage card. The card was incomplete for the required number of post-operative observations. Analgesia was not documented appropriately on the surgery cage card. Upon further review, adequate and appropriate analgesia was not administered by the surgeon. According to the veterinarian, the animals appeared to be okay at the time of the inspection.
Action taken by IACUC:	<p>Upon discovery, the Director of the Office of Animal Welfare (OAW) met with the PI and surgeon to discuss the issue. The surgeon and PI did not realize the difference between a local and systemic analgesic with similar names; therefore, a single dose of local analgesia was administered to the animals following surgery instead of the systemic opioid as described in the approved protocol. The PI indicated that no additional surgeries would be performed until the correct analgesic was obtained. The OAW Director reviewed the post-operative monitoring and recordkeeping requirements with the PI and surgeon. Understanding was confirmed.</p> <p>The IACUC discussed the incident at a convened meeting and determined that the incident was a significant deficiency for failure to adhere to the approved protocol and for conditions that jeopardized the health or well-being of animals resulting in actual harm. The failure to adequately monitor post-operative animals was considered a second significant deficiency. The IACUC sent a letter to the PI and required a written corrective action plan addressing the deficiencies.</p>

Action taken by PI:	The PI responded to the IACUC concerns and provided corrective actions including enhanced oversight. The PI purchased the appropriate analgesic in accordance with the approved protocol. The PI immediately reviewed the differences in analgesia with all animal handlers and verified understanding. The PI will review this information annually as a refresher, and future animal handlers will be tested on this information during the on-boarding process. The PI will require surgeons to perform post-operative monitoring beyond the required time points outlined in the IACUC surgery policy. Each surgeon will be required to create a standard operating procedure for each surgery they are interested in performing, and the document must include the number of post-operative observations and a description of adequate recordkeeping. New surgeons will be required to complete a comprehension quiz before being allowed to perform surgeries, and they will be required to report to the laboratory trainer for a minimum of one week after the surgery regarding post-operative monitoring.
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 NS097271
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Frederick H. Epstein	Date: (b) (6)

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, March 26, 2024 10:58 AM
To: (b) (6)
Cc: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Report UVA 2023-M

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3245-5K**. 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, March 26, 2024 9:48 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] Compliance Report UVA 2023-M

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 M (see attached).

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)