



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 19, 2024

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

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 5, 2024, letter reporting as series 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 March 25, 2024. According to the information provided, OLAW understands that a researcher failed to administer post-operative analgesia, as approved in the protocol, to a rat identified by veterinary personnel in clinical decline. The animal on the PHS-supported study was euthanized upon discovery. The experienced surgeon did not monitor the animal post-procedurally and failed to maintain documentation on the surgery cage cards and clinical scoring log.

The corrective actions consisted of the IACUC voting to suspend the surgeon's animal use privileges for a minimum of thirty days. Reinstatement of these privileges was contingent on the surgeon's review of the protocol and IACUC surgical policy and the development of a surgery and post-operative Standard Operating Procedure (SOP). The SOP, which was reviewed by the Principal Investigator (PI), must include the following from the IACUC surgery policy and protocol:

1. surgical preparation and approaches,
2. anesthesia and dosage,
3. analgesia administration and dosages,
4. perioperative monitoring,
5. frequency of post-operative monitoring,
6. supportive care measures,
7. clinical scoring parameters,
8. veterinary interventions, and
9. euthanasia.

The IACUC voted to reinstate the surgeon's animal use privileges after the thirty-day suspension and completion of policy and protocol review. The detailed SOP submitted by the surgeon was reviewed by the IACUC for congruence with the protocol and IACUC policies. Following the reinstatement of the surgeon's animal use privileges, the IACUC mandated that for a minimum of two months, the PI perform weekly reviews and initial the clinical scoring records from respective post-surgical animals and submit these records to the Office of Animal Welfare (OAW). The PI immediately met with all the animal handlers, the Director of OAW, and the clinical veterinarian and retrained the animal handlers on the importance of monitoring humane endpoints, documenting observations, and familiarity with the details in the approved protocol. Following consultation with the clinical veterinarian, the monitoring sheet was revised. The animal handlers were subsequently retrained on the approved sheet, including identification of clinical signs of pain/distress, methodology for completing clinical scoring records, and methods of providing palliative care. As a group, several related IACUC policies were also reviewed

by the PI and animal handlers. Measures implemented by the PI for enhanced oversight included scheduling weekly meetings with animal handlers and additional reviews of surgical and scoring documentation. In addition, an internal policy was established that required having at least two animal handlers with responsibility for post-operative monitoring of the animals.

In an effort to prevent future similar incidents of noncompliance, this Office recommends that the IACUC implement appropriate measure(s) to ensure that all personnel involved in comparable animal activities are appropriately trained and cognizant of applicable IACUC policies. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V.

Gopee -S

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

Digitally signed by Neera V.

Gopee -S

Date: 2024.04.19 15:58:15

-04'00'

cc: IACUC Chair

[illegible]

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. Teagan Ware, 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 #: 2024-B

OLAW Case #: A3245-51

Nature of Incident(s):	Failure to adhere to IACUC-approved protocol; failure to monitor animals post-procedurally as necessary to ensure well-being; failure to maintain appropriate animal-related records.
Summary of Incident:	The veterinary staff reported to the Office of Animal Welfare (OAW) finding a post-operative animal (rat) in clinical decline. Upon further investigation the following were noted: failure to administer post-operative analgesia as described in the approved protocol; failure to monitor animals as described in the approved protocol; and failure to maintain monitoring documentation on the surgery cage card and on the clinical scoring log. The surgeon was an experienced surgeon and was familiar with the IACUC surgical policy and aspects of animal-related records.
Action taken by IACUC:	<p>The IACUC discussed the incident at a convened meeting and determined that the incident involved several significant deficiencies including deviations from the approved protocol (failure to administer specific analgesic, failure to complete clinical scoring), failure to monitor animals post-procedurally as necessary to ensure well-being; and failure to maintain appropriate animal-related records. The IACUC voted to suspend the animal handling privileges of the surgeon for a minimum of 30 days. Prior to reinstatement, the surgeon was required to review the animal use protocol and IACUC surgical policy and create a standard operating procedure describing the surgery and post-operative care (SOP). The SOP must include aspects of the IACUC surgery policy and animal use protocol describing surgical preparation and approaches, anesthesia and dosage, analgesia administration and dosages, peri-operative monitoring, frequency of post-operative monitoring, supportive care measures, clinical scoring parameters, veterinary interventions, and euthanasia. The intent was for the document to be used as a training tool for surgeons performing the surgery as described in the protocol and include aspects of the IACUC surgery policy. The SOP was reviewed by the PI for accuracy prior to submission to the IACUC.</p> <p>In order to enhance oversight, the IACUC required the PI to review and initial the clinical scoring documentation associated with the specific post-surgical animals on a weekly basis and submit the reviewed</p>

	documentation to the OAW for a minimum of two months once the surgeon was reinstated and/or surgeries were restarted. The IACUC sent a letter to the PI detailing the requirements and required a written corrective action plan addressing the deficiencies.
Action taken by PI:	<p>The PI responded to the IACUC concerns and provided corrective actions including enhanced oversight. The PI immediately met with all animal handlers, Director of OAW, and the clinical veterinarian. The PI reiterated and retrained animal handlers on: the importance of humane endpoint monitoring, importance of documenting observations, and the importance of being familiar with the details in the approved protocol. The monitoring sheet was updated after consultation with the clinical veterinarian and, upon approval, the animal handlers were retrained with respect to identifying clinical signs of pain/distress, methodology for completing clinical scoring documentation, and methods of providing supportive care. As a group, the PI and animal handlers reviewed several associated IACUC policies.</p> <p>The PI instituted additional reporting and oversight measures including: weekly meetings with animal handlers, and additional reviews of surgical and scoring documentation. The laboratory instituted an internal policy of having at least two animal handlers be responsible for post-operative monitoring.</p> <p>After the 30-day suspension, the surgeon submitted the detailed SOP and indicated completion of policy and protocol review. The IACUC reviewed the SOP for congruence with the protocol and IACUC policies and then voted to reinstate the animal handling privileges of the suspended surgeon.</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:	1R21EB026723-01A1
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Frederick H. Epstein	<div style="background-color: #cccccc; padding: 5px;">(b) (6)</div> <div>Date: April 5, 2024</div>

From: OLAW Division of Compliance Oversight (NIH/OD)
To: (b) (6)
Cc: (b) (6); Epstein, Frederick H (fhe6b); (b) (6) OLAW
Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Case #A3245-5I
Date: Friday, April 5, 2024 1:52:00 PM

Good afternoon,

Thank you for providing this final report for OLAW case **A3245-5I**. 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 1:49 PM

To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: (b) (6) Epstein, Frederick H (fhe6b)
<fhe6b@virginia.edu> (b) (6)

(b) (6)

Subject: [EXTERNAL] OLAW Case #A3245-5I

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:

Please find attached a copy of the UVA Compliance report 2024-B. A preliminary email notification was submitted to OLAW and receipt acknowledged 25 March 2024 as OLAW A3245-5I.

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)

A3245-SI

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 25, 2024 10:51 AM
To: (b) (6)
Cc: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Notification of Non-Compliance: UVA - #A3245-01 (Case #2024-B)

Good morning,

Thank you for providing this preliminary report, which has been assigned as OLAW case **A3245-SI**. Please reference this case number when providing any updates or the final report for this incident.

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: Monday, March 25, 2024 10:44 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
(b) (6) Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: [EXTERNAL] Preliminary Notification of Non-Compliance: UVA - #A3245-01 (Case #2024-B)

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. The UVA tracking number is listed below. The issue is under review by the IACUC, and they are working towards resolution, and the IO will send a compliance report once adequately resolved.

- 2024-B: Researcher failed to monitor animal post-procedurally, failed to provide appropriate analgesia, and failed to adhere to humane endpoints (rat).

Contact me with any questions or concerns prior to receiving our final report.

Sincerely,

(b) (6)

(b) (6)