



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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 5L]

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-N), received March 26, 2024. 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 six incomplete surgery cage cards from two surgeons (mice). The analgesia was listed on the surgery cage cards; however, the documentation of administration was incomplete, and the cards were incomplete for the required number of post-operative observations. According to the veterinarian, the animals appeared to be fine at the time of the inspection. One of the surgeons was not listed as an animal handler on the appropriate protocol and had not completed all required training prior to performing the surgery. The surgeon was an approved animal handler on a different protocol belonging to the same PI and was approved to perform similar surgeries. The activity was PHS funded.

The IACUC required the PI to re-evaluate the training program provided to surgeons. In addition to retraining the two surgeons involved, the individual(s) responsible for training them must be retrained.

The PI provided corrective actions including enhanced oversight. Animal handlers must request, in writing, and obtain approval from the PI prior to starting a new procedure/task. The PI will ensure that the individual is approved for the requested task according to the protocol prior to granting approval. This approval mechanism will be reviewed monthly and will be part of the initial training for incoming animal handlers. Graduate students and postdocs will no longer provide surgical training without the presence of senior laboratory staff to ensure the quality of the training. Senior staff will review the surgical log daily to ensure that all information and post-surgical monitoring and analgesia are completed. The laboratory implemented periodic reviews of surgical practices of new surgeons to ensure that proper surgical technique is maintained. The laboratory will review all protocol procedures quarterly to ensure that surgical training and the protocol are in alignment. At the beginning of each semester, the laboratory will conduct a mandatory orientation to review the protocol system and review approved procedures in the protocol. Senior staff will work with the Office of Animal Welfare to ensure the training plan is in accordance with IACUC policies and expectations.

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.

Page 2 – Dr. Epstein
April 3, 2024
OLAW Case A3245-5L

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2024.04.03 15:20:51 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

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. 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-N

OLAW Case #: not assigned

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| Nature of Incident(s): | Failure to monitor animals post-procedurally as necessary to ensure well-being; failure to adhere to approved protocol; failure to maintain appropriate animal-related records |
| Summary of Incident: | During the semi-annual facility inspection, the Institutional Animal Care and Use Committee (IACUC) inspection team found six incomplete surgery cage cards from two surgeons (mice). The analgesia was listed on the surgery cage cards; however, the documentation of administration was incomplete, and the cards were incomplete for the required number of post-operative observations. According to the veterinarian, the animals appeared to be fine at the time of the inspection. One of the surgeons was not listed as an animal handler on the appropriate protocol and had not completed all required training prior to performing the surgery. The surgeon was an approved animal handler on a different protocol belonging to the same PI and was approved to perform similar surgeries. |
| Action taken by IACUC: | <p>Upon discovery, the Director of the Office of Animal Welfare (OAW) met with the laboratory manager. The cards from the two surgeons were incorrect in identical ways thereby indicating that the issue was likely related to insufficient training and oversight of the surgeons. The laboratory manager discussed the issues with the PI and initiated resolution.</p> <p>The IACUC discussed the issues at a convened meeting and determined that there were three significant deficiencies: failure to adhere to approved protocol with respect to post-operative analgesia and monitoring as necessary to ensure well-being; failure to maintain appropriate animal-related records; and, participation of an individual in an animal-related activity who had not been determined by the IACUC to be appropriately trained as required. Based on the repetitive nature of the deficiencies seen on the surgery cage cards, the IACUC required the PI to re-evaluate the training program provided to surgeons. In addition to retraining the two surgeons involved, the individual(s) responsible for training them must be retrained. The IACUC sent a letter to the PI and required a written corrective action plan addressing the deficiencies.</p> |

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| Action taken by PI: | The PI responded to the IACUC concerns and provided corrective actions including enhanced oversight. The PI determined that the failures leading to the deficiencies included a lack of oversight in assigning students to projects, inadequate training, and consistent post-training oversight and review. The PI enhanced each of these areas to avoid recurrence of the issues noted. Animal handlers must request, in writing, and obtain approval from the PI prior to starting the new procedure/task. The PI will ensure that the individual is approved for the requested task according to the protocol prior to granting approval. This approval mechanism will be reviewed monthly and will be part of the initial training for incoming animal handlers. Graduate students and postdocs will no longer provide surgical training without the presence of senior laboratory staff to ensure the quality of the training. Senior staff will review the surgical log daily to ensure that all information and post-surgical monitoring and analgesia are completed. The laboratory implemented periodic reviews of surgical practices of new surgeons to ensure that proper surgical technique is maintained. The laboratory will review all protocol procedures quarterly to ensure that surgical training and the protocol are in alignment. At the beginning of each semester, the laboratory will conduct a mandatory orientation to review the protocol system and review approved procedures in the protocol. Senior staff will work with the Office of Animal Welfare to ensure the training plan is in accordance with IACUC policies and expectations. |
| 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: | 1R01-NS120945 |
| 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 10:59 AM
To: (b) (6)
Cc: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Report UVA 2023-N

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3245-5L**. 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 9:49 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-N

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-N (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)