



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

February 20, 2020

Re: Animal Welfare Assurance
#A3045-01 (OLAW Case 2A)

Sheila L. Vrana, Ph.D.
Associate Dean for Research
Penn State University – Hershey Medical Center
Office of Research Affairs, (b) (4)
500 University Drive, PO Box 850
Hershey, PA 17033-0850

Dear Dr. Vrana,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 14, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Pennsylvania State University- Hershey Medical Center. The incident had been identified during the OLAW site visit. According to the information provided, OLAW understands that mice received required post-operative analgesia at a different frequency than described in the protocol and that the administration of saline was not documented in the surgical logs.

The corrective actions consisted of the Principal Investigator and staff reviewing their protocols to ensure that all animal activities are conducted as approved. The Institutional Animal Care and Use Committee (IACUC) will monitor the laboratory's record keeping to ensure all substances are given as required and that the information is recorded. A subsequent post-approval monitoring visit found that procedures were being conducted in accordance with the protocol.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



Sheila L. Vrana, Ph.D.
Associate Dean for Research

February 14, 2020

Brent C. Morse, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare
Division of Compliance Oversight
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

Re: Failure to adhere to IACUC approved protocols; Failure to monitor animals post-procedurally as necessary to ensure well-being; Failure to maintain appropriate animal-related records; Animal Welfare Assurance D16-00024 (A3045-01); R01MH116176

Dear Dr. Morse,

The Pennsylvania State University College of Medicine, in accordance with Assurance D16-00024 (A3045-01) and PHS Policy IV.F.3., provides this report of a noncompliance regarding an incident in which the post-surgical analgesic was not provided to mice after a surgical procedure as described in the protocol, and administration of saline was not being recorded in the lab's surgical logs. This incident was discovered during the OLAW site visit on November 21, 2019 when the researcher's lab was visited by the site visit team.

When asked about post-surgical analgesia and administration of subcutaneous fluids, a team member stated that carprofen is delivered once post-procedurally and as needed after that, and that fluids were being administered post-procedurally but were not being recorded in the surgical logs. The protocol describes carprofen administration once every 24 hours for a total of 48 hours and as needed thereafter. It also stated warm sterile saline will be given before and after surgery, as often as every 12 hours after surgery.

To address the situation, the IACUC recommended the following corrective action plan:

1. The PI and laboratory staff must review and follow their IACUC-approved protocols, especially regarding analgesic delivery.
2. A subset of the IACUC will reinspect surgical logs to confirm appropriate recordkeeping and analgesic delivery per the lab's IACUC-approved protocols. Records must also include delivery of isotonic fluids, such as saline.

The findings of the investigation were reviewed at a convened meeting of the IACUC on November 25, 2019. A subset of the IACUC reinspected the lab on January 6, 2020 and verified that analgesic administration and isotonic fluid (saline) administration is being documented, and that pain assessment is occurring. The IACUC recommended to the IO that the incident be reported to OLAW.

Please feel free to contact me if you require additional information.

Sincerely,

 (b) (6)

Sheila Vrana, PhD
Institutional Official

Penn State Milton S. Hershey Medical Center • Penn State College of Medicine
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Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, February 18, 2020 10:53 AM
To: Vrana, Sheila; OLAW Division of Compliance Oversight (NIH/OD)
Cc: IACUC; IACUCChair; (b) (6)
Subject: RE: Communication from Penn State College of Medicine

Thank you for providing these reports Dr. Vrana. We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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-----Original Message-----

From: Vrana, Sheila <svrana@pennstatehealth.psu.edu>
Sent: Monday, February 17, 2020 1:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <IACUC@pennstatehealth.psu.edu>; IACUCChair <IACUCChair@pennstatehealth.psu.edu>; (b) (6)
(b) (6)
Subject: Communication from Penn State College of Medicine

Dear Dr. Morse,
Please see attached communications, and let me know if you have additional questions.
Thank you
Sheila Vrana

Sheila L. Vrana, Ph.D.
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Associate Professor of Pharmacology
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