



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) 402-7065

June 24, 2019

Re: Animal Welfare Assurance
#A3045-01 (OLAW Case 1X)

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 June 13, 2019 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. According to the information provided, OLAW understands that analgesia had not been given following surgery. Several analgesics were described in the protocol but none were being used.

The corrective actions consisted of the Institutional Animal Care and use Committee (IACUC) directing the investigator and staff to follow the protocol and give the analgesics as described. Surgical logs documenting peri-operative care and provision of analgesia will be maintained and will be monitored by the IACUC to confirm compliance.

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. Please remember to indicate the species involved.

Sincerely,

(b) (6)

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

cc: IACUC contact

A3045-1X

PENNSTATE HERSEY



Milton S. Hershey
Medical Center

Sheila L. Vrana, Ph.D.
Associate Dean for Research
June 13, 2019

PENNSTATE HERSEY



College of Medicine

Brent C. Morse, D.V.M.
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; Animal Welfare Assurance D16-00024 (A3045-01); P01HL134609

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 post-surgical analgesics were not provided after a surgical procedure as described on the protocol. During semi-annual inspections (October 2018), a lab member stated to the inspection team that they do not give analgesia after surgery. The protocol describes Carprofen and/or Buprenorphine to be administered at the start of surgical procedures. There is an additional statement that "Buprenorphine SR as analgesic will be given once after the surgery."

To address the situation, the IACUC interviewed the investigator and team and recommended the following corrective action plan:

1. That the protocol will be followed hereon, and analgesics will be given pre- and post-surgery as described.
2. That logs of each animal under surgery, including peri- and post-operative care and analgesia be kept for review by the IACUC for compliance.

Implementation of corrective actions were confirmed during spring semi-annual inspections in April 2019, when surgical logs were reviewed by the IACUC inspection team and the laboratory's surgical preparation and process were reviewed.

The findings of the investigation were reviewed at a convened meeting of the IACUC on November 26, 2018. 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
Institutional Animal Care and Use Committee



Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, June 18, 2019 8:07 AM
To: Vrana, Sheila; OLAW Division of Compliance Oversight (NIH/OD)
Cc: IACUC; IACUCChair; (b) (6) Sheila Vrana
Subject: RE: Communication from Penn State College of Medicine

Thank you for this report Dr. Vrana. We will send an official response soon.

Best regards, Brent Morse

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

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.

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

From: Vrana, Sheila [mailto:svrana@pennstatehealth.psu.edu]
Sent: Monday, June 17, 2019 3:09 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) Sheila Vrana <svrana@psu.edu>
Subject: Communication from Penn State College of Medicine

Dear Dr. Morse,
Please see attached communication.
Thank you,
Sheila Vrana

Sheila L. Vrana, Ph.D.
Associate Dean for Research
Associate Professor of Pharmacology
Penn State College of Medicine
500 University Drive, Box 850, (b) (4)
Hershey PA 17033-0850
(b) (6)
svrana@psu.edu