



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

April 24, 2019

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

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 April 1, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Pennsylvania State University – Hershey Medical Center. According to the information provided, OLAW understands that on November 28, 2018 four mice had died as a result of not receiving post-operative care and monitoring after undergoing a cecal ligation and puncture (CLP) surgical procedure two days prior. The laboratory staff also did not have facility badge access at the time. It was stated that the animal activity was not PHS funded.

Corrective and preventive actions included recommending that: all laboratory personnel must ensure they have facility access when performing surgical procedures on animals; all laboratory personnel must ensure they have reviewed the use of surgical cage cards, and; animals that undergo the CLP procedure should be monitored more frequently than every 24 hours. In consultation with a clinical veterinarian, the laboratory put together a plan to monitor animals every 6-8 hours, including use of a health scoring system.

The consideration of this matter by the Pennsylvania State University – Hershey Medical Center was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC contact

Obtained by Rise for Animals. Uploaded 08/31/2020

Retrieved from Animal Research Laboratory Overview (ARLO)

A3045-10



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



April 1, 2019

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 monitor animals post-procedurally as necessary to ensure well-being; Animal Welfare Assurance D16-00024 (A3045-01); not PHS-funded

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 lab personnel inadequately monitored animals after a surgical procedure was conducted (cecal ligation and puncture), resulting in the death of several mice.

It was brought to the attention of the IACUC that on November 28, 2018, four mice had died as a result of not receiving post-operative care and monitoring after undergoing a cecal ligation and puncture (CLP) surgical procedure two days prior. Additionally, laboratory staff did not have facility badge access at the time, preventing their access to provide monitoring and care to animals.

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

1. All laboratory personnel must ensure that they have facility access when performing surgical (e.g., CLP) procedures on animals.
2. All laboratory personnel must ensure they have reviewed the use of surgical cage cards, which describe the procedure animals underwent, and post-procedural analgesia, care, and monitoring (e.g., observations of animals' health).
3. Animals that undergo the CLP procedure should be monitored more frequently than every 24 hours. In consultation with a clinical veterinarian, the laboratory put together a plan to monitor animals every 6-8 hours, including use of a health scoring system.

The findings of the investigation were reviewed at a convened meeting of the IACUC on December 17, 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: Wednesday, April 10, 2019 9:12 AM
To: Vrana, Sheila; OLAW Division of Compliance Oversight (NIH/OD)
Cc: IACUC; IACUCChair; (b) (6) svrana@psu.edu
Subject: RE: Communication from Penn State College of Medicine

Thank you for providing 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

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

From: Vrana, Sheila [mailto:svrana@pennstatehealth.psu.edu]
Sent: Monday, April 01, 2019 1:31 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) 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.
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Associate Professor of Pharmacology
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