



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 6, 2019

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

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 3, 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, following up on an initial report on November 28, 2018. According to the information provided, OLAW understands that a demonstration rat surgery was conducted at an inadequate level of anesthesia and without local analgesia. During the stereotaxic procedure the rat responded to painful stimuli.

The corrective actions consisted of applying local analgesia when the rat responded, but no additional injectable anesthetic was given. The Institutional Animal Care and Use Committee (IACUC) stated that the experience of instructors must be considered when conducting demonstrations with live animals and that anesthetics are to be correctly used for painful procedures. Animal carcasses rather than live animals are to be used wherever possible in teaching situations.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrences of this problem. While OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy, note that during protocol review the IACUC is to evaluate training and proficiency of investigators, to assess the appropriateness of anesthetics/analgesics, and to determine the appropriateness of the animal used. The assessments are to be made before the animal activity begins so that this type of incident can be assessed in advance and potentially prevented. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair

June 3, 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 adhere to IACUC-approved protocols, conduct of painful procedure without adequate anesthesia; 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 a surgical procedure was conducted at an inadequate level of anesthesia, and local anesthetic was not used when appropriate and as described on the protocol.

It was brought to the attention of the IACUC that on October 3, 2018, an investigator demonstrated a stereotaxic surgery to students. During the conduct of the procedure, the rat undergoing the procedure responded to the manipulation, at which point local anesthetic was applied, however the animal was not provided additional injectable anesthetic.

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

1. Instructors demonstrating procedures under the teaching protocol, and associated course, should be carefully considered regarding their experience and preferred anesthetics (e.g., inhaled vs injected, etc.).
2. Use of an animal carcass in place of a live animal should be considered.

The findings of the investigation were reviewed at a convened meeting of the IACUC on December 17, 2018 and again on January 28, 2019. The IACUC recommended to the me 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 04, 2019 8:34 AM
To: Vrana, Sheila; OLAW Division of Compliance Oversight (NIH/OD)
Cc: IACUC; IACUCChair; Wilson, Ronald; Sheila Vrana
Subject: RE: Commuication from Penn State College of Medicine

Follow Up Flag: Follow up
Flag Status: Flagged

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

Best regards, Brent Morse

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

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

From: Vrana, Sheila <svrana@pennstatehealth.psu.edu>
Sent: Monday, June 03, 2019 2:41 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <IACUC@pennstatehealth.psu.edu>; IACUCChair <IACUCChair@pennstatehealth.psu.edu>; Wilson, Ronald <rwilson2@pennstatehealth.psu.edu>; Sheila Vrana <svrana@psu.edu>
Subject: Commuication from Penn State College of Medicine

Dear Dr. Morse,
Please see attached communication, and let me know if you have additional questions.
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



Initial Report of Noncompliance

By: Nena G. Lee

Date: 11-28-18

Time: 3:37 pm

Name of Person reporting: Ronald Wilson

Telephone #: (b)(6)

Fax #:

Email:

Name of Institution: Penn State College of Medicine

Assurance number: A3045-01

Did incident involve PHS funded activity? Yes

Funding component: 2 R01 grant

Was funding component contacted (if necessary): _____

What happened?

During semiannual facility inspection, it was identified that researchers failed to administer analgesics in rodents as specified in approved protocol for survival surgery.

Species involved: rodents

Personnel involved: researchers

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

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Case # _____