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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

June 6, 2019

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Eacsimile</u>: (301) 402-7065

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,

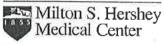
(b) (6)

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

cc: IACUC Chair

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PENNSTATE HERSHEY



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

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

> Penn State Milton S. Hershey Medical Center • Penn State College of Medicine Office of Research Affairs, Mail Code H138, 500 University Drive, P.O. Box 850, Hershey, PA 17033-0850 Tel: 717-531-8495 • Fax: 717-531-0040 • syrana@psu.edu



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PENNSTATE HERSHEY

College of Medicine

Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Tuesday, June 04, 2019 8:34 AM
То:	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 Un 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

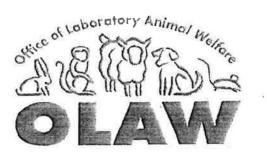
Dear Dr. Morse, Please see attached communication, and let me know if you have additional questions. Thank you Sheila Vrana

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

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A 3045-10



Initial Report of Noncompliance

By: Neera Gopee

Date: 11-28-18

Time: 3.37 pm

College of medicine

Name of Person reporting: Rowald wilson Telephone #: Fax #: Email:

Name of Institution: Cona State Assurance number: A3045-01

Did incident involve PHS funded activity? Funding component: 2001 gas Was funding component contacted (if necessary):

What happened?

Dui Semanner Facility inspiten it was identified that specified a specified is an administer and several an specified is appeared for a facility is appeared for survival Species involved: Rodert Personnel involved: Queandrons

Dates and times: Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #

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