



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

June 27, 2023

Re: Animal Welfare Assurance
A3045-01 (OLAW Case 3K)

Sheila 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

Dear Dr. Vrana,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 13, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the Pennsylvania State University – College of Medicine. Your letter supplements the information in the telephone preliminary report made on May 25, 2023. According to the information provided, OLAW understands that on April 10, 2023, a surgical procedure was conducted on twenty mice that involved an inguinal incision to make an injection into a mammary fat pad, utilizing isoflurane anesthesia and Buprenorphine-SR analgesia. Several mice on another protocol previously underwent the procedure. The two protocols describe a subcutaneous approach and are not approved for a surgical opening for the injection. Moreover, the protocols describe ketamine/xylazine anesthesia and Buprenorphine HCl analgesia. Additionally, the mice that underwent the procedure on April 10, 2023, were returned to their housing room while still under anesthesia without a heat source. The veterinarian on-call treated the sedated mice with supplemental heat, and all recovered well. The activities were not PHS supported.

Corrective and preventive actions included:

1. The PI must submit amendments to the protocols adding the surgical procedure to make an inguinal incision for mammary fat pad injection; and add additional methods of anesthesia and/or analgesia.
2. The PI and laboratory personnel were reminded that they must review and follow the IACUC-approved protocols prior to conducting procedures. They were reminded they must follow the anesthesia and analgesia described in the IACUC-approved protocols, until amendments have been approved.
3. Animals must be provided supplemental heat, e.g., by an incubator (as described in the protocols) or another source.
4. The PI and laboratory personnel must document anesthesia and post-procedural monitoring in accordance with IACUC policy.

The consideration of this matter by the Pennsylvania State University – College of Medicine was consistent with the philosophy of institutional self-regulation. Similarly, reporting the issue to OLAW was appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Page 2 – Dr. Vrana
June 27, 2023
OLAW Case A3045-3K

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2023.06.27 07:30:54 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact



PennState
College of Medicine

Sheila L. Vrana, Ph.D.
Associate Dean for Research
Associate Professor, Dept. of Pharmacology
Institutional Official, Animal Care and Use Committee
Penn State College of Medicine
Mail Code H138, Room C1614

500 University Drive
P.O. Box 850
Hershey, PA 17033-0850
(b) (6)
svrana@psu.edu

A3045-3K

June 13, 2023

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

Re: Failure to adhere to IACUC protocols, implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7, 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 noncompliance that occurred on April 10, 2023, in which a postdoctoral scholar conducted a surgical procedure on twenty mice that involved an inguinal incision to make an injection into a mammary fat pad, utilizing isoflurane anesthesia and Buprenorphine-SR analgesia. Several mice on another protocol previously underwent the procedure. Although the two protocols are approved for a mammary fat pad injection, the protocols describe a subcutaneous approach and are not approved for a surgical opening for the injection. Moreover, the protocols describe ketamine/xylazine anesthesia and Buprenorphine HCl analgesia.

Additionally, the mice that underwent the procedure on April 10, 2023 were returned to their housing room while still under anesthesia without a heat source. The veterinarian on-call treated the sedated mice with supplemental heat and all recovered well. This incident was first reported to you on May 25, 2023 by a voicemail from Dr. Jenelle Izer.

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

1. The PI must submit amendments to the protocols adding the surgical procedure to make an inguinal incision for mammary fat pad injection; and add additional methods of anesthesia and/or analgesia.
2. The PI and laboratory personnel were reminded that they must review and follow the IACUC-approved protocols prior to conducting procedures. They were reminded they must follow the anesthesia and analgesia described in the IACUC-approved protocols, until amendments have been approved. (b) (6)
3. Animals must be provided supplemental heat, e.g., by an incubator (as described in the protocols) or another source.
4. The PI and laboratory personnel must document anesthesia and post-procedural monitoring in accordance with IACUC policy.

The findings of the investigation and actions taken were reviewed at a convened meeting of the IACUC on May 22, 2023. 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

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 14, 2023 4:13 PM
To: Vrana, Sheila
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Communication from Penn State College of Medicine

Good afternoon Dr. Vrana,

Thank you for sending us this final report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: Vrana, Sheila <svrana@pennstatehealth.psu.edu>
Sent: Wednesday, June 14, 2023 2:25 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) accredit@aaalac.org; Izer, Jenelle <jizer@pennstatehealth.psu.edu>; Vrana, Sheila <svrana@pennstatehealth.psu.edu>
Subject: [EXTERNAL] Communication from Penn State College of Medicine

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

Sheila L. Vrana, Ph.D. (*she, her, hers*)
Associate Dean for Research and Associate Professor of Pharmacology
Penn State College of Medicine
500 University Drive Box 850, Mail Code H138 | Hershey, PA 17033 | USA
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A3045-3K

Initial Report of Noncompliance

By: BCM

Date: 5/25/2023

Time: 1:15 voicemail

Name of Person reporting: Jenelle Izer, DVM

Telephone #: [REDACTED] (b) (6)

Fax #:

Email:

Name of Institution: Penn St. Univ. Hershey Med. Cen., Coll. of Med.

Assurance number: A3045

Did incident involve PHS funded activity? no

Funding component:

Was funding component contacted (if necessary):

What happened: Lab staff made inguinal incision for mammary fat pad injection in 20 mice. No incision was approved on protocol. Some incisions dehiscd. Vet repaired. Also incorrect anesthesia and analgesia and improper monitoring during anesthetic recovery. Cage found flooded. Mice responded to Vet treatment.

Species involved: Mus

Personnel involved: Researchers

Dates and times: until 4/10/2023

Animal deaths: no

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

Projected submission to OLAW of final report from Institutional Official:

<60 days

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Case #