



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

May 1, 2023

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

Sheila Vrana, Ph.D.  
Associate Dean for Research  
Penn State University – Hershey Medical Center  
Office of Research Affairs, H138  
500 University Drive, PO Box 850  
Hershey, PA 17033

Dear Dr. Vrana,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 30, 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 prompt telephone preliminary report made on March 2, 2023. According to the information provided, OLAW understands that on February 27, 2023, it was found that eight of eleven rats who underwent a survival surgery on February 21 and 22 had open incisions. Laboratory personnel repaired the incisions and provided antibiotics, as recommended by veterinary staff, however five rats reopened their repaired incisions and an additional rat exhibited signs of infection. Lab personnel did not record any post-operative monitoring, though did report to veterinarians that the animals were monitored daily. Veterinary staff also recommended additional doses of carprofen analgesia. It was determined that the research associate responsible for these surgical animals did not use an appropriate suturing technique for skin closure, allowing the incisions to open and/or become infected. The activity is PHS funded.

Corrective and preventive actions:

1. The research associate is not permitted to conduct any surgeries or be involved in post-surgical care until the PI provides retraining on the appropriate technique and communicates the date of training to the IACUC.
2. The PI must submit an amendment to the protocol adding Buprenorphine-SR as an additional post-operative analgesic option.
3. The PI and laboratory personnel must document post-operative monitoring in accordance with their IACUC-approved protocol and 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. OLAW encourages the Pennsylvania State University – College of Medicine to maintain a high level of monitoring on this study to minimize negative welfare outcomes. We appreciate being informed of this matter and find no cause for further action by this office, at this time.

Page 2 – Dr. Vrana  
May 1, 2023  
OLAW Case A3045-3H

Sincerely,

**Brent C. Morse -S**

Digitally signed by Brent C. Morse

-S  
Date: 2023.05.01 12:18:35 -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, (b) (4)

A3045-3H  
500 University Drive  
P.O. Box 850  
Hershey, PA 17033-0850  
(b) (6)  
svrana@psu.edu

March 30, 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-approved protocol; failure to maintain appropriate animal-related records.; Animal Welfare Assurance D16-00024 (A3045-01); 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 February 27, 2023, in which eight of eleven rats who underwent a survival surgery on February 21 and 22 had open incisions. Laboratory personnel repaired the incisions and provided antibiotics, as recommended by veterinary staff, however five rats reopened their repaired incisions and an additional rat exhibited signs of infection. Lab personnel did not record any post-operative monitoring, though did report to veterinarians that the animals were monitored daily. Veterinary staff also recommended additional doses of carprofen analgesia.

The PI indicated to veterinary staff that the research associate responsible for these surgical animals did not use an appropriate suturing technique for skin closure, allowing the incisions to open and/or become infected. The PI and veterinary staff agreed the research associate would not be involved with post-operative care and monitoring until review by the IACUC. The PI also indicated that the protocol would be amended to add Buprenorphine-SR as an alternate post-operative analgesic option, as repeat doses of carprofen is contraindicated for the research model. This incident was first reported to you on March 2, 2023 by a voicemail from Dr. Jenelle Izer.

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

1. The research associate is not permitted to conduct any surgeries or be involved in post-surgical care until the PI provides retraining on the appropriate technique and communicates the date of training to the IACUC.
2. The PI must submit an amendment to the protocol adding Buprenorphine-SR as an additional post-operative analgesic option.
3. The PI and laboratory personnel must document post-operative monitoring in accordance with their IACUC-approved protocol and IACUC policy.

The findings of the investigation and actions taken were reviewed at a convened meeting of the IACUC on March 27, 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]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, April 24, 2023 6:58 AM  
**To:** Vrana, Sheila  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Communication from Penn State College of Medicine

Good morning Dr. Vrana,

Thank you for sending us this final report for case A3045-3H 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](mailto:devora.mccoy@nih.gov)

**From:** Vrana, Sheila <[svrana@pennstatehealth.psu.edu](mailto:svrana@pennstatehealth.psu.edu)>  
**Sent:** Friday, April 21, 2023 3:43 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Cc:** IACUC <[IACUC@pennstatehealth.psu.edu](mailto:IACUC@pennstatehealth.psu.edu)>; IACUCChair <[IACUCChair@pennstatehealth.psu.edu](mailto:IACUCChair@pennstatehealth.psu.edu)>; Wilson, Ronald <[rwilson2@pennstatehealth.psu.edu](mailto:rwilson2@pennstatehealth.psu.edu)>; [accredit@aaalac.org](mailto:accredit@aaalac.org); Izer, Jenelle <[jizer@pennstatehealth.psu.edu](mailto:jizer@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  
 (b) (6) |  [svrana@psu.edu](mailto:svrana@psu.edu)

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A3045-3H



## Initial Report of Noncompliance

By: BCM

Date: 3/2/2023

Time: voicemail (12:04 pm)

Name of Person reporting: Janell Eiser, DVM, AV

Telephone #: (b) (6)

Fax #:

Email:

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

Assurance number: A3045

Did incident involve PHS funded activity? yes

Funding component:

Was funding component contacted (if necessary):

What happened: Lab member who had been barred from conducting survival surgery in 2011, performed survival surgery on 11 rats. Did not provide all doses of analgesic, did not record post-op obs on cage cards, and there were questions regarding suturing and aseptic technique. Incisions dehiscd in eight rats. Lab re-sutured and started ABOs. Some animals dehiscd again. Rats now cared for by Comparative Medicine.

Species involved: rattus

Personnel involved: researcher

Dates and times: 2/20 - 2/21/2023

Animal deaths: no

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

IACUC investigating this incident. I advised Dr. Eiser to report this incident to the funding component at NIH.

Projected submission to OLAW of final report from Institutional Official:

<60 days

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Case #