



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

October 31, 2023

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

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

Dear Dr. Vrana,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 27, 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 – Hershey Medical Center. Your letter supplements the information in the prompt telephone preliminary report made on August 24, 2023. According to the information provided, OLAW understands that on August 18, 2023, two cages of mice were transported in a personal vehicle to a laboratory by a research technician without IACUC review and approval. The associated activity was PHS funded.

In addition to immediate counseling of the technician by the ARP manager and the Attending Veterinarian regarding the requirement for IACUC approval of the transportation of animals and the use of animals in a space outside of the animal facilities, additional corrective and preventive actions were recommended by the IACUC:

1. The PI must submit amendments to any protocols which require animals be brought to a laboratory outside the animal facilities. If the laboratory is not already under the IACUC's purview, an inspection would be scheduled.

*An amendment to add the lab space was reviewed and approved by the IACUC.*

2. Use of personal vehicles to transport animals was discouraged, but, if necessary, vehicles should also be included in the protocol amendments. Additionally, inspection of vehicles would be required for approval, and semiannual inspection thereafter.

*The PI determined transport in a personal vehicle was not necessary.*

3. The PI and laboratory personnel were reminded that they must review and follow their IACUC-approved protocols prior to conducting procedures and/or use of animals in locations outside of the central animal facilities.

The consideration of this matter by the Pennsylvania State University – Hershey Medical Center 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.

Sincerely,

**Brent C. Morse -S**

Digitally signed by Brent C.  
Morse -S  
Date: 2023.10.31 09:25:37 -04'00'

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

cc: IACUC contact

**Ware, Teagan (NIH/OD) [E]**

A3045-3P

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, October 30, 2023 7:09 AM  
**To:** 'Vrana, Sheila'  
**Cc:** IACUC; IACUCChair; (b) (6) accredit@aaalac.org (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Communication from Penn State College of Medicine

Good morning,

Thank you for providing us with this report and we will send an official response soon.

Best,  
Teagan

Teagan Ware, MS, PMP  
Animal Welfare Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [teagan.ware@nih.gov](mailto:teagan.ware@nih.gov)

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**From:** Vrana, Sheila <[svrana@pennstatehealth.psu.edu](mailto:svrana@pennstatehealth.psu.edu)>  
**Sent:** Friday, October 27, 2023 4:52 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)>; (b) (6) accredit@aaalac.org; (b) (6) Vrana, Sheila <[svrana@pennstatehealth.psu.edu](mailto:svrana@pennstatehealth.psu.edu)>  
**Subject:** [EXTERNAL] RE: 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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**PennState**  
College of Medicine

Sheila L. Vrana, Ph.D.  
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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  
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October 27, 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: Implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7; Animal Welfare Assurance D16-00024 (A3045-01); R01HL44712

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 August 18, 2023, in which two cages of mice were transported in a personal vehicle to a laboratory by a research technician without IACUC review and approval. This incident was first reported to you on August 24, 2023, by a voicemail from (b) (6).

On August 18, animal resource program (ARP) staff observed a research technician exiting the animal facility to the parking lot with two cages of mice. Shortly after, the ARP manager spoke with the research technician who confirmed the animals were transported in a personal vehicle and brought to the laboratory for a terminal collection of tissues. The ARP manager informed the technician that transport in a personal vehicle is not allowed unless approved by the IACUC and requires semiannual inspection of the vehicle. The technician conveyed they were not aware of this requirement, and this was the first time they had used their vehicle for transport. The ARP manager additionally reviewed the walking route that could be taken between the animal facilities and laboratory location.

The Attending Veterinarian also spoke with the technician to reiterate that use of animals in a space outside of the animal facilities requires IACUC approval and semiannual inspection. As no lab spaces were approved on the protocol the animals were under, the technician was instructed not to conduct animal work in the lab space until the protocol had been amended. A review of protocols under the lab determined that a separate protocol was approved for use of animals in the lab space.

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

1. The PI must submit amendments to any protocols which require animals be brought to a laboratory outside the animal facilities. If the laboratory is not already under the IACUC's purview, an inspection would be scheduled.

*An amendment to add the lab space was reviewed and approved by the IACUC.*

2. Use of personal vehicles to transport animals was discouraged, but, if necessary, vehicles should also be included in the protocol amendments. Additionally, inspection of vehicles would be required for approval, and semiannual inspection thereafter.

*The PI determined transport in a personal vehicle was not necessary.*

3. The PI and laboratory personnel were reminded that they must review and follow their IACUC-approved protocols prior to conducting procedures and/or use of animals in locations outside of the central animal facilities.

The findings of the investigation and actions taken were reviewed at convened meetings of the IACUC on August 28, 2023, and September 25, 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

A3045-3P



## Initial Report of Noncompliance

By: BCM

Date: 8/24/2023

Time: voicemail

Name of Person reporting: (b) (6)  
Telephone #: (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? yes  
Funding component:  
Was funding component contacted (if necessary):

What happened: Two cages of mice transported in personal vehicle to cancer center lab. Neither actions were approved.

Species involved: Mus  
Personnel involved: researcher  
Dates and times: until 8/18/2023  
Animal deaths: used in terminal procedure

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

Lab counseled. Will not use personal vehicle. Protocol amended to allow use of animals in lab.

Projected submission to OLAW of final report from Institutional Official:

<60 days

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Case #