



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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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 3J)

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 April 21, 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 28, 2023. According to the information provided, OLAW understands that on March 23, 2023, it was determined that mice continued to be bred while a protocol was expired and on holding. Laboratory technicians also requested euthanasia of remaining animals, although they had not reached humane endpoint. Additionally, the lab did not follow the standard process for documenting and resolving veterinary observation/clinical care for two mice. Lab personnel removed cage cards indicating observation prematurely, preventing documentation of resolution of the clinical cases. The associated activity is PHS funded.

Corrective and preventive actions:

1. The PI and laboratory personnel were reminded that no animal work, including breeding and euthanasia for any reason other than animal welfare or humane endpoint, may be conducted while a protocol is expired, and animals are on holding.
2. The IACUC office should update the standard protocol expiration communication to PIs to explicitly clarify that no animal work may be conducted includes breeding and euthanasia for any reason other than animal welfare or humane endpoint.
3. The PI and laboratory personnel must follow the process for animals under veterinary observation, including not removing "observation" cage cards until the clinical case has been resolved/animal euthanized (the IACUC-approved SOP should be provided).

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
May 1, 2023
OLAW Case A3045-3J

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2023.05.01 12:12:00 -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)

A3045-35
500 University Drive
P.O. Box 850
Hershey, PA 17033-0850
(b) (6)
svrana@psu.edu

April 21, 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: Conduct of animal-related activities beyond the expiration date established by the IACUC; 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 March 23, 2023, in which mice continued to be bred while a protocol was expired and on holding. Laboratory technicians also requested euthanasia of remaining animals, although they had not reached humane endpoint. Additionally, the lab did not follow the standard process for documenting and resolving veterinary observation/clinical care for two mice. Lab personnel removed cage cards indicating observation prematurely, preventing documentation of resolution of the clinical cases. This incident was first reported to you on March 28, 2023 by a voicemail from Dr. Jenelle Izer.

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

1. The PI and laboratory personnel were reminded that no animal work, including breeding and euthanasia for any reason other than animal welfare or humane endpoint, may be conducted while a protocol is expired and animals are on holding.

This information was provided to the PI upon determining that euthanasia had been requested by laboratory personnel and was reiterated again after IACUC review of the concern, to ensure the PI transfers any remaining animals to an active protocol and/or the expired protocol renewed.

2. The IACUC office should update the standard protocol expiration communication to PIs to explicitly clarify that no animal work may be conducted includes breeding and euthanasia for any reason other than animal welfare or humane endpoint.
3. The PI and laboratory personnel must follow the process for animals under veterinary observation, including not removing "observation" cage cards until the clinical case has been resolved/animal euthanized (the IACUC-approved SOP should be provided).

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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 24, 2023 7:00 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 A3045-3I 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: Friday, April 21, 2023 3:46 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>; accredit@aaalac.org; Izer, Jenelle <jizer@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
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A3045-3J

Initial Report of Noncompliance

By: BCM

Date: 3/29/2023

Time: 1:13 voicemail

Name of Person reporting: Janell Iser, DVM

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: Protocol expired on February 20, 2023, and mice transferred to holding protocol. Breeding continued and requests for euthanasia.

Species involved: Mus

Personnel involved: PI

Dates and times: until 3/27/2023

Animal deaths:

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

Mice have been transferred to another research protocol and IACUC is updating protocol expiration notification to include "no breeding or euthanasia" on holding protocol.

Projected submission to OLAW of final report from Institutional Official:

<60 days

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Case #