



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 31)

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 February 16, 2023, the total approved number of rabbits in pain category D was exceeded on a protocol: a survival surgery procedure was conducted on six rabbits more than the number described in the IACUC-approved protocol. This error occurred in part because the PI has several active IACUC protocols approved for same surgical procedure, and animal numbers were not being appropriately tracked by the PI and laboratory personnel. The associated activity is not PHS funded.

Corrective and preventive actions: The PI must devise their own system to keep track of animals (ordered and surgeries conducted) on each protocol so as not to exceed the approved surgical cases and total approved number of animals.

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. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. 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: 2023.05.01 12:23:13 -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)

A3045-3I
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: Failure to adhere to IACUC-approved protocol; 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); 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 February 16, 2023, in which the total approved number of rabbits in pain category D was exceeded on a protocol: a survival surgery procedure was conducted on six rabbits more than the number described in the IACUC-approved protocol. This error occurred in part because the PI has several active IACUC protocols approved for same surgical procedure, and animal numbers were not being appropriately tracked by the PI and laboratory personnel. This incident was first reported to you on March 28, 2023 by a voicemail from Dr. Ronald Wilson.

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

- The PI must devise their own system to keep track of animals (ordered and surgeries conducted) on each protocol so as not to exceed the approved surgical cases and total approved number of animals.

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 7:03 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 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 3:51 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; (b) (6)
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

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.



A3045-3I

Initial Report of Noncompliance

By: BCM

Date: 3/28/2023

Time: 11:42 voicemail

Name of Person reporting: Ron Wilson, 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? No _____

Funding component: _____

Was funding component contacted (if necessary): _____

What Happened: Researchers used 32 animals on knee surgery protocol in Cat D instead of approved 24 animals.

Species involved: Rabbit

Personnel involved: Researcher

Dates and times: Mid-February, 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

OFFICE USE ONLY

Case # _____