



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) 402-7065

July 8, 2019

Re: Animal Welfare Assurance  
#A3045-01 (OLAW Case 1V)

Sheila L. 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 17033-0850

Dear Dr. Vrana,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated June 13, 2019 that was provided in response to our May 29, 2019 correspondence requesting additional corrective actions to address the repeat nature of the reported laboratory's noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

Additional corrective measures described in your letter included the following:

1. IACUC designees will increase laboratory contact for post-approval monitoring to reiterate adherence to the IACUC-approved protocol and to build rapport over the next year.
2. Laboratory members will complete the CITI Program online training module "Working with the IACUC."
3. The principle investigator will meet with laboratory personnel and an IACUC representative to review the content of the laboratory's IACUC-approved protocols.

We appreciate the provided response and the IACUC review and discussion of this incident and of effective methods to address and prevent repeat noncompliance. OLAW is satisfied that the described additional actions are appropriate. Please contact our office if the corrective actions are not carried out as described. Thank you for your organization's commitment to compliance with the PHS Policy and the humane care and use of animals. We find no cause for further action at this time.

Sincerely,

(b) (6)

Jane Na, DVM, CPIA  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare

cc: IACUC contact

Sheila L. Vrana, Ph.D.  
Associate Dean for Research

June 13, 2019

Jane Na, D.V.M.  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare  
Division of Compliance Oversight  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892-6910

Re: OLAW Case 1V (Conduct of animal-related activities without appropriate IACUC review and approval; Animal Welfare Assurance D16-00024 (A3045-01); not PHS funded)

Dear Dr. Na,

The Pennsylvania State University College of Medicine, Assurance D16-00024 (A3045-01), provides this follow-up information, as requested in your letter dated May 29, 2019 in regards to a report of a repeat noncompliance incident reported May 10, 2019 in which lab personnel toe clipped animals.

The following additional corrective action will be implemented to reiterate the importance of being knowledgeable of federal regulations and IACUC-approved protocols, and to prevent repeat noncompliance:

1. IACUC designees will conduct spot-checks over the next year by returning to the laboratory and engaging different lab members in conversation by asking what types of animal use procedures they conduct and what their laboratory is approved for, including asking for details on IACUC-approved procedure. This post-approval monitoring plan, more frequent contact with the lab, will determine if lab personnel have a clear understanding of their IACUC protocols and encourage them to reference their protocols prior to conducting procedures with animals. Furthermore, a goal of increased contact with the lab is to foster rapport so that lab members are comfortable reaching out to the IACUC program whenever questions arise.
2. Laboratory staff will be required to take the CITI Program online training course "Working with the IACUC", which includes modules reviewing IACUCs, federal regulations governing IACUCs and animal research, and outlines sections included on IACUC protocols, as well as making changes to protocols. This must be completed within one month of communication from the IACUC.
3. The principal investigator will be asked to meet with laboratory personnel, and an IACUC representative, to review with the lab members what is approved on the laboratory's IACUC protocols. It will be requested that this meeting take place within three months of communication from the IACUC.

The IACUC discussed this incident of repeat noncompliance and effective methods to not only impress the gravity of repeat noncompliance, as well as encourage familiarity with regulations and IACUC protocols, at a convened meeting of the IACUC on June 12, 2019.

Please feel free to contact me if you require additional information.

Sincerely,

(b) (6)

Sheila Vrana, PhD  
Institutional Official  
Institutional Animal Care and Use Committee



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) 402-7065

May 29, 2019

Re: Animal Welfare Assurance  
#A3045-01 (OLAW Case 1V)

Sheila L. 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 17033-0850

Dear Dr. Vrana:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 10, 2019 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals which was preceded by a preliminary report submitted by phone on April 30, 2019. According to the information supplied, OLAW understands that lab personnel performed toe clipping on mice greater than 7 days old which was not approved on the protocol. The associated animal activity was reported to not be PHS funded.

Corrective actions that were reviewed by the IACUC included a reminder that laboratory personnel are to review their IACUC-approved protocols and procedures including the ages for toe clipping prior to performing procedures and that an amendment should be submitted if a procedure is not on the protocol. The investigator and the laboratory were informed that toe clipping of mice older than 7 days would not be approved.

Your letter indicated that this laboratory previously toe clipped animals without IACUC approval which was addressed by subsequent submission of an amendment and IACUC approval to permit toe clipping in mice up to 7 days old. From our records, we note that an incident matching this description was reported to OLAW, and case A3045-1N was closed on November 19, 2018. Repeat noncompliance of a similar nature may indicate that previous corrective actions did not adequately address the initial incident. OLAW concurs with the described corrective measures but are concerned by the absence of additional corrective actions given this lab's previous protocol noncompliance. We request that the IACUC revisit these incidents to evaluate additional actions for implementation that would help prevent additional repeat occurrences. The OLAW portion of the article OLAW and APHIS: Commons Areas of Noncompliance in Lab Animal, 2000; 29(5) <https://olaw.nih.gov/sites/default/files/LabAnimal.pdf> is suggested for review, especially the paragraphs under the headings Lack of IACUC Approval and Education and Communication Channels.

Please provide a response **no later than July 12, 2019** by email to [jane.na@nih.gov](mailto:jane.na@nih.gov) to describe additional corrective measures that have been or that will be instituted as well as a timeline or schedule of implementation. We appreciate being informed of these matters and look forward to your response.

Sincerely,

(b) (6)

A large black rectangular redaction box covers the signature area.

Jane Na, DVM  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare

cc: IACUC Contact

PENNSTATE HERSCHEY



Milton S. Hershey  
Medical Center

Sheila L. Vrana, Ph.D.  
Associate Dean for Research

May 10, 2019

Brent C. Morse, D.V.M.  
Animal Welfare Program Specialist  
Office of Laboratory Animal Welfare  
Division of Compliance Oversight  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892-6910

Re: Conduct of animal-related activities without appropriate IACUC review and approval;  
Animal Welfare Assurance D16-00024 (previously 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 a noncompliance regarding an incident in which lab personnel genotyped adult animals (age greater than postnatal day 7) via toe clipping. This incident was first reported to Dr. Jane Na on April 30, 2019 via a phone call by (b) (6)

The same group previously toe clipped animals without IACUC approval on their protocol, and to correct the prior situation, an amendment was submitted and approved by the IACUC to add toe clipping of mice up to age day P7. In the current event, adult mice were toe clipped, which is not approved on their IACUC protocol.

To address the current situation, the following corrective action plan was implemented:

1. Laboratory personnel were reminded to review their IACUC-approved protocols and procedures, including the ages for toe clipping, *prior* to conducting procedures. If a procedure is not on the protocol and if necessary, an amendment should be submitted to the IACUC to update the protocol.
2. The PI and laboratory were informed that adult toe clipping will not be approved by the IACUC. Their protocol is approved for tail snips from mice that are pre-weaning age and toe clips from mice prior to 7 days old. Ear tissue is included on the protocol to be collected from any age of mice for purposes of genotyping.

The findings of the investigation and the actions taken were reviewed at a convened meeting of the IACUC on April 22, 2019. 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  
Institutional Animal Care and Use Committee

Penn State Milton S. Hershey Medical Center • Penn State College of Medicine  
Office of Research Affairs, Mail Code H1138, 500 University Drive, P.O. Box 850, Hershey, PA 17033-0850  
Tel: 717-531-8495 • Fax: 717-531-0040 • svrana@psu.edu



An Equal Opportunity University

Obtained by Rise for Animals. Uploaded 08/31/2020  
Retrieved from Animal Research Laboratory Overview (ARLO)



## Morse, Brent (NIH/OD) [E]

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, May 13, 2019 7:23 AM  
**To:** Vrana, Sheila; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** IACUC; IACUCChair; (b) (6) Sheila Vrana  
**Subject:** RE: Communication from Penn State College of Medicine

Thank you for providing this final report Dr. Vrana. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

-----Original Message-----

**From:** Vrana, Sheila [mailto:svrana@pennstatehealth.psu.edu]  
**Sent:** Friday, May 10, 2019 3:28 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) <rwilson2@pennstatehealth.psu.edu>; Sheila Vrana <svrana@psu.edu>  
**Subject:** Communication from Penn State College of Medicine

Dear Dr. Morse,  
Please see attached communication.  
Thank you,  
Sheila Vrana

Sheila L. Vrana, Ph.D.  
Associate Dean for Research  
Associate Professor of Pharmacology  
Penn State College of Medicine  
500 University Drive, Box 850, (b) (4)  
Hershey PA 17033-0850  
(b) (6)  
svrana@psu.edu



## Initial Report of Noncompliance

By: JN

Date: **April 30, 2019**

Time: **Voicemail at noon**

Name of Person reporting: **Dr. Wilson (attending veterinarian)**

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: **Pennsylvania State University - Hershey Medical Center**

Assurance number: **A3045-01**

Did incident involve PHS funded activity? \_\_\_\_\_

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

**Unapproved toe clipping in mice that were outside the acceptable age for this per institutional policies**

Species involved: **Mice**

Personnel involved: **Investigator**

Dates and times:

Animal deaths: **None**

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

**Retraining to occur.**

Projected submission to OLAW of final report from Institutional Official:

**Final to be submitted soon**

OFFICE USE ONLY

Case # \_\_\_\_\_