



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

September 6, 2023

Re: Animal Welfare Assurance  
A3141-01 [OLAW Case 3I]

Debra Thurley  
Associate Vice President for Research,  
Director of the Office for Research Protections  
Pennsylvania State University – University Park  
101 Technology Center, Innovation Park  
University Park, PA 16802

Dear Ms. Thurley,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 28, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Pennsylvania State University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this office understands that the Pennsylvania State University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to failure to adhere to the IACUC-approved protocols. The final report states on April 10, 2023, a Principal Investigator (PI) reported the death of a rat under anesthesia during a neural recording session. It is stated surgery was performed on March 30<sup>th</sup> and lasted ~6h. The following day, the animal appeared healthy and was sedated for a neural recording session. However, a software update resulted in a prolonged session to accommodate recalibration following the update. Per the report, the rat recovered and was determined to be in good condition the following morning. The animal was sedated for a neural recording (as per the protocol) and died during the second short recording session.

The report states protocol review revealed the recording sessions are expected to last approximately 5-30 minutes. Some factors the PI noted that may have resulted in the animal's death include the following:

- The anesthetic scavenging system was not turned on during the second recording procedure.
- The rat was not connected to a pulse oximeter during the recording sessions.
- The rat had undergone two long anesthetic sessions the previous two days.

It is stated the PI consulted with research personnel to emphasize the importance of monitoring animals under anesthesia and adhering to what is approved in the protocol. A protocol amendment was submitted to define plans more accurately for neural recording sessions, and the amendment was approved on May 3, 2023.

The IACUC determine the incident to be reportable and requested a corrective action plan from the PI. The plan was submitted and included the following:

- The PI asked all team members working with animals to re-read the protocol and verify current procedures are consistent with procedural descriptions. Some updates were already incorporated into the protocol amendment approved by the IACUC on May 3<sup>rd</sup>.
- The PI posted a checklist on the wall above the surgery table to help personnel remember to take the steps necessary when initiating a surgery or neural recording session. A second sign was posted above the anesthesia machine reminding users to turn on the scavenging system.
- The PI indicated that personnel have been instructed to use a pulse oximeter whenever animals are under anesthesia. This requirement was included in the signage mentioned above. Additionally, the PI has reviewed all anesthesia records since the incident and indicated personnel following prescribed monitoring and record keeping during surgery and recording sessions. The PI will continue to perform spot checks of records to ensure monitoring procedures are not drifting.

The IACUC determined the corrective action plan is acceptable and it is noted that this research is supported by PHS funding.

Based on its assessment of this explanation, OLAW understands that the Pennsylvania State University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,  
Jacquelyn T.  
Tubbs -S

Digitally signed by Jacquelyn T.  
Tubbs -S  
Date: 2023.09.06 12:48:20  
-04'00'

Jacquelyn Tubbs, DVM, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



**PennState**

**Debra Thurley**  
Associate Vice President for Research  
Director of Research Protections  
The Pennsylvania State University  
101 Technology Center  
University Park, PA 16802

(b) (6)  
djcl116@psu.edu  
research.psu.edu/orp

A3141-3I

August 28, 2023

Dr. Brent Morse, DVM  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive  
Suite 2500, MSC 6910  
Bethesda, MD 20892-6910

Dear Dr. Morse:

The Pennsylvania State University, in accordance with Assurance A3141-01 and PHS Policy IV.F.3., provides this report regarding non-compliance with the PHS Policy. The activities were associated with a protocol that is supported by PHS funds (#R44MH131514). This incident was first reviewed by the IACUC on April 18, 2023.

On April 10, 2023, the PI reported the death of a rat under anesthesia during a neural recording session. Surgery was performed by research personnel on March 30<sup>th</sup> per the approved protocol and this procedure lasted for about 6 hours. The next day, the animal looked healthy and was eating so it was sedated for a neural recording session. However, due to a software update issue, the session was prolonged (approximately 3.5-4 hours) to accommodate recalibration following the update. The rat recovered and was judged to be in good condition the next morning. Thus, the rat was again sedated for a neural recording per the protocol. Unfortunately, the animal died during this second short recording session.

Upon review of the protocol, it was noted that the recording sessions are expected to last about 5 to 30 minutes. Additionally, the PI noted the following factors that may have contributed to the rat's death: 1) the anesthetic scavenging system was not turned on during the second recording procedure which likely resulted in high isoflurane and oxygen levels under anesthesia; 2) the rat was not connected to a pulse oximeter during the recording sessions as they were anticipated to be short so personnel did not have readouts to monitor the animal under anesthesia; and 3) the rat had undergone two long anesthetic sessions the previous two days which could have contributed to anesthetic complications. In response to the incident, the PI consulted with research personnel to stress the importance of monitoring animals under anesthesia and adhering to what is approved in the protocol. He also submitted a protocol amendment to more accurately define plans for neural recording sessions. This amendment was approved by the IACUC on May 3, 2023.

The IACUC reviewed this incident and determined it to be noncompliance for not adhering to IACUC approved protocols. The committee requested the PI submit a corrective action plan to indicate how he would 1) ensure personnel know what is listed in the approved protocol, 2) ensure staff turn on the anesthetic scavenging system for procedures under anesthesia, and 3) ensure staff use a pulse oximeter to monitor animals during anesthesia. The PI submitted a plan to the IACUC on May 17, 2023 that outlined the following:

- 1) The PI asked all team members working with animals to re-read the protocol and verify current procedures are consistent with procedure descriptions. Some updates were already incorporated into the protocol amendment approved by the IACUC on May 3<sup>rd</sup>.
- 2) The PI posted a checklist on the wall above the surgery table to help personnel remember to take the steps necessary when initiating a surgery or neural recording session. A second sign was posted above the anesthesia machine reminding users to turn on the scavenge.
- 3) The PI indicated that personnel have been instructed to use a pulse oximeter whenever animals are under anesthesia. This requirement was included in the signage mentioned above. Additionally, the PI has reviewed all anesthesia records since the incident and indicated personnel following prescribed monitoring and record keeping during surgery and recording sessions. The PI will continue to perform spot checks of records to ensure monitoring procedures are not drifting.

The IACUC reviewed the corrective action plan and determined all corrective actions to be acceptable. No (un)allowable costs were charged to the NIH grant at issue in this incident of noncompliance.

The Pennsylvania State University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Melanie Lucas, IACUC Director.

Sincerely,

 (b) (6)

Debra Thurley, Institutional Official

cc: Dr. Gary L. Borkowski, AAALAC International Global Director

## McCoy, Devora (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, August 28, 2023 2:35 PM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: PSU Final Report 8.28.2023D

Good afternoon (b) (6)

Thank you for sending us this report, assigned OLAW case number A3141-3I, 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](mailto:devora.mccoy@nih.gov)

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**From:** (b) (6)  
**Sent:** Monday, August 28, 2023 12:13 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Cc:** AAALAC International <[accredit@aaalac.org](mailto:accredit@aaalac.org)>; Thurley, Debra <[djd116@psu.edu](mailto:djd116@psu.edu)>  
**Subject:** [EXTERNAL] PSU Final Report 8.28.2023D

Good afternoon,

Please see the attached final report. Let me know if you have any questions or concerns.

Thank you,

(b) (6)