



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 3J]

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 institutional policies/procedures. The final report states on June 13, 2023, the IACUC was informed of a mouse breeding protocol that expired on April 14, 2023. The Principal Investigator (PI) was sent multiple reminders from the electronic protocol system and from the IACUC staff prior to expiration. The report states after the protocol expired, the mice were maintained on the Animal Resource Program (ARP) holding protocol. The PI was informed that no animal-related costs could be charged to the NIH grant at issue during the period of protocol expiration.

Per the report, while animals were on the holding protocol, ARP staff determined 3 cages were removed from the animal room and protocol cage cards were left in the room. The PI confirmed his lab staff euthanized the animals due to their old age. However, lab personnel did not consult with veterinary staff prior to euthanasia. In response to this finding the PI was reminded that animals on the holding protocol are under the supervision of the Director of ARP and should only be euthanized for clinical health concerns after consulting with the Director.

The IACUC determined the incident was reportable and requested a corrective action plan from the PI. The plan was submitted to the IACUC on July 13, 2023 and included the following:

- The PI is in the process of consolidating several protocols into one protocol to reduce administrative burden and facilitate improved oversight.
- The PI would plan experiments in advance with enough time to prevent protocol expiration while experiments are ongoing.
- The PI will conduct training of new lab members to ensure they understand and follow institutional policies and procedures.

The report states the IACUC determined the corrective actions to be acceptable and the triennial review of the breeding protocol was approved on June 20, 2023. 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
Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2023.09.06 12:42:28
-04'00'

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)
djd116@psu.edu
research.psu.edu/orp

A3141-3J

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 (#R01AI123521). This incident was first reviewed by the IACUC on May 13, 2023.

On June 13, 2023, the IACUC was presented with a report regarding a mouse breeding protocol that expired on April 14, 2023. Per the report, the protocol expired despite multiple reminders sent to the PI from the electronic protocol system in addition to multiple reminders sent to the PI from IACUC staff. Following expiration, the mice were maintained on the Animal Resource Program (ARP) holding protocol per IACUC approved policies. At the time of expiration, the PI of the breeding protocol was notified that no animal related costs could be charged to the NIH grant at issue during the period of protocol expiration.

While animals were on the holding protocol, ARP staff noted three cages that were removed from the animal room and protocol cage cards were left in the room. In follow up discussions, the PI confirmed his lab personnel euthanized these animals due to old age, but personnel did not consult with veterinary staff prior to euthanasia. The PI was reminded that per the IACUC holding policy, animals on the holding protocol are under the supervision of the Director of ARP and should only be euthanized for clinical health concerns after consulting with the Director.

The IACUC reviewed this incident and determined it to be noncompliance for not adhering to institutional policies and procedures. The committee requested the PI submit a corrective action plan to indicate how he would provide training and oversight to his lab group to address these issues and prevent future occurrences. The PI submitted this plan to the IACUC on July 13, 2023, outlining the following corrective actions:

Dr. Brent Morse
August 28, 2023
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- 1) The PI is in the process of consolidating several protocols into one protocol to reduce administrative burden and facilitate improved oversight.
- 2) The PI would plan experiments in advance with enough time to prevent protocol expiration while experiments are ongoing.
- 3) The PI will conduct training of new lab members to ensure they understand and follow institutional policies and procedures.

The IACUC reviewed the corrective action plan and determined all corrective actions to be acceptable. The triennial review of the breeding protocol was approved by the IACUC on June 20, 2023. 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 (b) (6)
(b) (6)

Sincerely,

(b) (6)

Debra Thurley, Institutional Official

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

McCoy, Devora (NIH/OD) [E]

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 8.28.2023K

Good afternoon (b) (6)

Thank you for sending us this report, assigned OLAW case number A3141-3J, 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: (b) (6)
Sent: Monday, August 28, 2023 12:20 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@aaalac.org>; Thurley, Debra <djd116@psu.edu>
Subject: [EXTERNAL] PSU Final Report 8.28.2023K

Good afternoon,

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

Thank you,

(b) (6)