



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

October 31, 2018

Re: Animal Welfare Assurance
A3141-01 [OLAW Case 2C]

Ms. Debra Thurley
Executive Director of Research Compliance
Pennsylvania State University
330 Building, (b) (4)
University Park, PA 16802

Dear Ms. Thurley,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 29, 2018 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Pennsylvania State University, following up on an initial telephone report on October 25, 2019.

According to the information provided, OLAW understands that two mice died due to a lack of food. The mice had been weaned into a new cage in which there was no food.

The corrective actions consisted of counseling the laboratory staff responsible and having two individuals involved in the weaning procedure to allow for cross checking. The weaning standard operating procedure was updated to reflect the change. A notice of noncompliance was issued to the Principal Investigator.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Contact

(b) (6)



PennState

Office for Research Protections
Vice President for Research
The Pennsylvania State University
205 The 330 Building
University Park, PA 16802

814-865-1775
Fax: 814-865-8699
orp@psu.edu
research.psu.edu/orp

October 29, 2018

Axel Wolff, M.S., D.V.M.
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-

Dear Dr. Wolff:

The Pennsylvania State University, in accordance with Assurance A3141-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding the Principle Investigator's (PI) failure to provide adequate food to two research animals (mice). The activities were associated with a protocol that is supported by PHS funds. This incident was reviewed by the IACUC on October 17th, 2018 and was reported to OLAW via telephone message on October 25, 2018.

On September 4th, an Animal Resource Program (ARP) technician reported two mouse deaths to the investigator and the IACUC and inquired about their history. It was reported the cage did not have food. The investigator's lab group reported back that a lab member had weaned these animals on August 29th, 2018. The mice were necropsied and no food was found in the stomach. All evidence indicated that the mice were mistakenly left without food after weaning.

To address the situation, the IACUC took corrective actions, which included requiring submission of a plan by the PI to address reoccurrence. This plan included:

1. The PI took immediate action including:
 - a. Conducting an internal investigation of the incident.
 - b. Provided information on who weaned the animals and when to the IACUC and informed those responsible of the concern.
 - c. Spoke with laboratory members and caretakers to identify critical points where errors such as these can best be eliminated. To immediately address the situation, they determined that two sets of eyes on a situation are better than one. To that end, they made effective immediately, that weaning procedure will take place in teams of two, providing a cross check system of two persons that can verify that the cage is in proper order.

2. Additional action included:

- a. The group will update the lab weaning SOP to reflect the new requirement of having 2 people involved in weaning for all litters.
- b. The PI was sent a non-compliance notice which will be kept on file with the office for research protections.

After review, the IACUC determined that the corrective actions were appropriate.

The PI, and his Department Head have been notified that no unallowable costs may be 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 Jeremy DeRicco, IACUC Compliance Director.

Sincerely,

(b) (6)

Debra Thurley
Executive Director of Research Compliance

cc: Dr. James Swearingen, AAALAC International Global Director

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 30, 2018 8:57 AM
To: Dericco, Jeremy Saul; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Thurley, Debra Janine Dreibelbis
Subject: RE: Final report to OLAW

Thank you for providing this report. 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.

From: Dericco, Jeremy Saul [mailto:jzd237@psu.edu]
Sent: Tuesday, October 30, 2018 8:43 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Thurley, Debra Janine Dreibelbis <djd116@psu.edu>; accredit@aaalac.org
Subject: Final report to OLAW

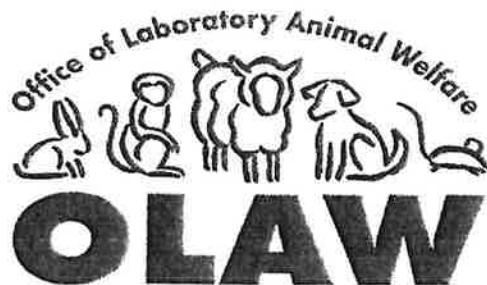
Dear Division of Compliance Oversight,

Please find attached a Final Report from The Pennsylvania State University Institutional Official. If you have any questions or concerns, please let me know.

Thank you,
Jeremy

Jeremy DeRicco, MBA, CPIA
ABI Program Director
Office for Research Protections
The Pennsylvania State University
(b) (4) *The 330 Building*
University Park, PA 16802
Direct Line: (b) (6) / *Fax:* (b) (6)
www.research.psu.edu/orp

The pilot release of CATS IACUC, replacing PRAMS, is underway (details: <https://www.research.psu.edu/iacuc>).



Initial Report of Noncompliance

By: AW

Date: 10/25/18

Time: 10:30

Name of Person reporting: Jeremy Derrecho

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Pennsylvania State U

Assurance number: A3141

Did incident involve PHS funded activity? Yes

Funding component: Aging

Was funding component contacted (if necessary): _____

What happened?

Mice died due to no food. Were given at evening

Species involved: mice

Personnel involved:

Dates and times:

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____