



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

July 19, 2017

Re: Animal Welfare Assurance
A3141-01 [OLAW Case 1W]

Ms. Candice Yekel
Associate Vice President for Research
Director, Office for Research Protection
Pennsylvania State University
330 Building, Suite 205
University Park, PA 16802

Dear Ms. Yekel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 19, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Pennsylvania State University, following up on an initial telephone report on March 29, 2017. According to the information provided, OLAW understands that several live newborn mice were found in the carcass freezer due to a failure to use the required secondary physical method of euthanasia to ensure death following exposure to CO2.

The corrective actions consisted of retraining the Principal Investigator and staff, ensuring that new laboratory staff is appropriately trained on euthanasia, and having new staff work with experienced staff when conducting euthanasia and ensuring death.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

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

cc: IACUC Contact

Secondary individual ABI Program Director



PennState

Candice A. Yekel
Associate Vice President for Research
Director of Research Protections
The Pennsylvania State University
205 The 330 Building
University Park, PA 16802

814-865-1775
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July 19, 2017

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 20892-7982

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 ensure death of animals after euthanasia procedures. The activities were associated with a protocol that is supported by PHS funds. This incident was reported to the IACUC on March 27, 2017 and was reported to you via telephone call on March 29, 2017.

On March 27, an Animal Resource Program (ARP) technician reported concerns related to failure to ensure death of animals after euthanasia procedures. Specifically, the technician uncovered a small bag of "pinkies" found alive in a facilities freezer. After investigation, it was determined a researcher in the PI's lab did not follow the required secondary method of decapitation following CO₂ exposure, as required in the protocol.

To address the situation, the IACUC took corrective actions, which included:

1. The PI and the research team will retake CITI training, working with mice in research.
2. The PI must present to the IACUC a Corrective Action Plan (CAP) for ensuring future lab members are appropriately trained on approved methods of euthanasia and on the difference between euthanasia and anesthesia.

The PI and lab personnel completed their training as required and submitted their CAP plan by June 1, 2017. This plan included:

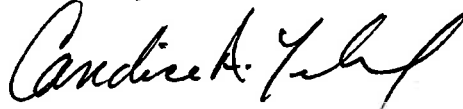
1. All new lab members will be required to read through and understand approved methods of euthanasia on the investigators protocols.
2. All new lab members will work with senior members of the lab to perform the euthanasia process according to the approved methods of the investigators protocols.

Axel Wolff
July 19, 2017
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3. New lab members will be made aware that since the purpose of euthanization is to put animals to death while anesthesia is not, confirmation of the death with a required secondary method will be needed for any euthanization process.

As this non-compliance occurred prior to assignment of animals to a research protocol, no unallowable 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 Secondary individual IACUC Compliance Director.

Sincerely,



Candice A. Yekel
Institutional Official

cc: Dr. James Swearengen, AAALAC International Global Director

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, July 19, 2017 1:12 PM
To: Secondary individual
Subject: RE: Final report to OLAW

Thank you for this report, Secondary individual. We'll send a response soon.

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

From: Secondary individual [mailto:Secondary individual@psu.edu]
Sent: Wednesday, July 19, 2017 12:08 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Yekel, Candice <cay3@psu.edu>; Secondary individual @psu.edu <Secondary individual@psu.edu>; Secondary individual @aaalac.org
Subject: Final report to OLAW

Dear Division of Compliance Oversight,

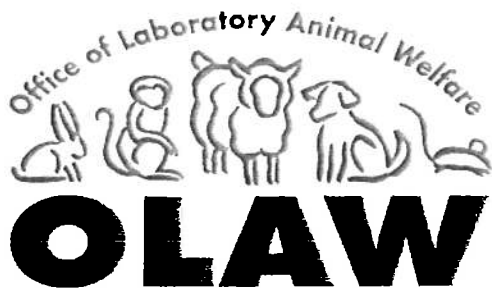
Please find attached a Final Report from The Pennsylvania State University Institutional Official. If you have any questions or concerns, please let me know.

Thank you,

Secondary individual

ABI Program Director
Office for Research Protections
The Pennsylvania State University
Room 330 The 330 Building
University Park, PA 16802
Direct Line: telephone # / Fax: telephone #
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: *3/29/17*

Time: *9:00*

Name of Person reporting: *Secondary individual*

Telephone #: *telephone #*

Fax #:

Email:

Name of Institution: *Pennsylvania State U*

Assurance number: *A3141*

Did incident involve PHS funded activity? *Yes*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

5 pups euthanasia failure, in CO2 chamber & no secondary physical method of euthanasia, remained

Species involved: *Mice*

Personnel involved:

Dates and times:

Animal deaths:

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

Retraining by AV

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____