



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 B 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

January 31, 2018

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

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

Dear Ms. Yekel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 25, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The Pennsylvania State University. According to the information provided, OLAW understands that on December 29, 2017 the Animal Resource Program Veterinarian reported five mouse deaths in two cages. It was subsequently determined that a student, not listed as personnel, anesthetized these animals and returned them to the housing cage and room before they had recovered. The animals were not properly monitored or provided thermal support as required by the protocol. In addition the cages were not properly labeled. This activity was PHS funded.

Corrective actions included counseling of the PI by the IACUC. The PI voluntarily halted new work until issues are resolved. These include adding the student to the protocol and retraining the student. The veterinarian will be consulted as to using isoflurane for anesthesia. If so, a protocol modification will be submitted for IACUC review. The PI will assure that all lab personnel have access to up to date protocols and will discuss the requirements for proper cage labeling. The PI has re-read the SOP for infecting mice with lentiviruses and adenoviruses and required that all lab members do too.

Additional actions required by the IACUC include the PI attending the next IACUC meeting and developing SOPs for training new lab members and for making sure cage cards are accurate. In addition, the lab will serve a probationary period of one year during which the lab will be subject to unannounced visits and records review. The PI, his Department Head and Research Dean have been notified that no unallowable costs may be charged to the NIH grant.

OLAW appreciates the prompt consideration of this matter by The Pennsylvania State University, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Signature

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



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
Fax: 814-863-8699
cay3@psu.edu
research.psu.edu/orp

A3141-17

January 25, 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 20892-7982

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 follow Institutional policies and off-protocol work. The activities were associated with a protocol that is supported by PHS funds. This incident was reviewed by the IACUC on January 17th, 2017 and was reported to OLAW via telephone message on January 22, 2017.

On December 29th, an Animal Resource Program (ARP) veterinarian reported 5 mouse deaths in 2 adjacent cages to the investigator and inquired about their history. The investigator's lab group reported back that a student had anesthetized these animals with Avertin to perform an intranasal infection, as described in the approved protocol, and had returned the mice to their normal housing cage and room before they regained sternal recumbency. When the student returned 3 hours later to check on them, they had already been found dead and removed. According to the protocol, the student who conducted the procedure was not listed as personnel and any animal that underwent this procedure and anesthesia was to be monitored and supplied with additional warmth (via heating mat or lamp) until the animal regained sternal recumbency. In addition, it was discovered that the PI's mouse cages were not properly labeled with associated hazards and protocol numbers.

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 will voluntarily halt new work until issues are resolved, including:
 - a. Adding the student to the protocol and retraining them on the importance in monitoring animals and providing for homeostasis during anesthesia recovery.
 - b. Consultation with the AV to determine if isoflurane can be used instead of Avertin for anesthesia in this procedure. If so, a modification will be made to the protocol for IACUC review and approval.

- c. PI will assure that all lab personnel have access to up to date protocols and will review with them the specific requirements of each. He has also discussed the requirement that everyone be approved on a protocol before beginning work on the protocol and he will personally ensure any new lab members who join will be added to the appropriate protocols before beginning work.
- d. PI has discussed with lab members the requirements for proper cage card labeling and posted a list of IACUC protocols, and which main lines of experiments are associated with each, in the housing room to facilitate proper labeling.
- e. PI has reread the SOP for infecting mice with lentiviruses and adenoviruses and required that all lab member do too. PI has discussed with the lab members the appropriate procedures for working with these biohazards and the need for placement of labels on cages with infected mice to ensure safety for the lab and animal resource personnel.

After review of this plan, the IACUC required additional actions, including:

- 1. The PI will attend the next IACUC meeting to personally address the Committee on these issues.
- 2. The PI must develop and post SOPs for training new lab members to include documentation for what each member was trained on, who they were trained by (must be senior lab personnel) and when the training took place. Current lab members must complete this process as well.
- 3. The PI will develop an SOP for making sure cage cards are accurate and remain accurate.
- 4. The lab will serve a probationary period of one year (January 17th, 2018 to January 17th, 2019). During this time, the lab will be subject to unannounced lab visits and records reviews.

The PI, his Department Head and Research Dean 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 [REDACTED] IACUC Member [REDACTED] IACUC Compliance Director.

Sincerely,

[REDACTED]
Signature

Candice A. Yekel
Institutional Official

cc: [REDACTED] Secondary Individual AAALAC International Global Director

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 25, 2018 4:00 PM
To: IACUC Member; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Yekel, Candice; Secondary Individual
Subject: RE: Final report to OLAW

Thank you for submitting this report. We will send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting 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: IACUC Member [mailto:UC Mem@psu.edu]
Sent: Thursday, January 25, 2018 11:01 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Yekel, Candice <cay3@psu.edu>; Secondary Individual @psu.edu; condary Individu @aaalac.org'
<condary Individu @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
205 The 330 Building
University Park, PA 16802
Direct Line: Phone Number / Fax: Phone Number
www.research.psu.edu/orp

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