



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

May 8, 2017

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

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 May 4, 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 31, 2017. According to the information provided, OLAW understands that one laboratory was found to have incomplete mouse surgical records, one mouse which exceeded approved humane endpoints, and one mouse which was not monitored as required following surgery. This laboratory had been involved in prior noncompliance.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) suspending all of the laboratory's animal use privileges and activities, prohibiting the addition of new study animals, and requiring retraining of all laboratory staff. All new staff will take online training and be trained by the Principal Investigator (PI)/group leader on the protocol requirements and this will be documented. New staff will also receive hands-on surgical training and will be monitored until proficient. Group leaders will monitor surgical records and problems will be addressed, copies of protocols and surgical standard operating procedures will be maintained in the laboratory, staff will certify understanding of and compliance with the protocol, protocols will be discussed in laboratory meetings, humane endpoints will be kept with the protocols, protocol expiration dates will be monitored, and any animal health or protocol concerns will be directed to the appropriate authority. A senior staff member will be hired to oversee laboratory compliance, the PI was placed on a two year probation, and the laboratory was placed under enhanced IACUC oversight. The funding component was notified about the suspension and the grant was not charged for any unauthorized animal activities.

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

*Page 2 – Ms. Yekel  
May 8, 2017  
OLAW Case A3141-1X*

cc: IACUC Contact

secondary individual Executive Director of Research Compliance



**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

May 4, 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 suspension of activity by the IACUC. The activities were associated with protocols that are supported by PHS funds. This incident was discussed by the IACUC on March 30, 2017, and was reported to you via telephone call by the Penn State IACUC Compliance Director on March 31, 2017.

On March 29, the laboratory animal Attending Veterinarian (Lab AV) reported concerns related to a records review of the laboratory's surgical records. Specifically, the lab AV uncovered instances of incomplete mouse surgical records, one instance of a mouse exceeding an IACUC approved endpoint, and one instance of the lab's failure to follow mouse post-surgical monitoring requirements. Because of these findings, and a past history of noncompliance from this lab, the IACUC determined this lab unable to comply with the requirements for animal use.

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

1. All animal use privileges/ activities were suspended from March 30 until April 5 2017.
2. From April 5 to May 1, 2017 no new animals were permitted to be added to active study.
3. All sponsors funding this work have been informed of this suspension.
4. All lab personnel who worked with animals were required to retake training for "working with the IACUC", "working with mice in research", and "rodent surgery training".
5. The PI developed and presented to the IACUC a comprehensive corrective action plan (CAP) for approval. Key points to this plan include:
  - a. All new personnel will be trained by the PI and group leaders to be proficient for all the experimental procedures, record keeping requirements, post-surgical monitoring and on the identification of clear humane endpoints after surgery (or disease). The training will include the required online courses, including the CITI working with the IACUC and mouse module and Animal

Resource Program online rodent surgery tutorial, and hands-on courses or personal training directly related to working with animals. The certificates for each courses passed from each new personnel will be collected by the group leaders and put into file for auditing. The group leaders (or the liaison, once hired) will be responsible for keeping and updating the certificates. The PI will review the training documentation for all lab members on a quarterly basis to ensure that all lab members are properly trained.

- b. All new personnel will take the hands-on surgery course offered by the Animal Resource Program. The group leaders will be responsible to train and supervise the personnel in their initial surgery, and the following 5 surgeries to ensure that all personnel can work independently. An IACUC representative or Lab AV will be notified and invited to monitor one of these supervised surgeries. The surgery performed by the new personnel will be randomly checked once a month by the group leader. A checklist has been generated for this purpose. The training and monitoring will be recorded, signed and dated by the group leaders (or liaison). If a new surgeon has much higher mortality rate than average level, depending on the type of surgery performed, of more than 20% after 10 times training, the surgeon will be re-trained or disqualified. The PI will review the training documentation for all lab members on a quarterly basis to ensure that all lab members are properly trained.
- c. Group leaders (or liaison when hired) will check the surgery records twice a month. The PI will review the surgical records on a quarterly basis to ensure that any on-going problems are resolved. Problems arising from these audits will be promptly noted on the record and resolved by discussion between the group leaders and the surgeon, and immediately brought to the Lab AV and self-reported to the IACUC. Should there be unsolvable problems or unclear issues, the Lab AV will be notified immediately regarding animal health issues, and the group leader and the surgeon will contact the IACUC for clarity.
- d. Updated protocols will be printed and inserted in the front page of the surgery record books. Every protocol in the lab will include an SOP describing the step by step procedures for surgery in more detail than the IACUC protocol. The PI will review the protocols and SOPs on a semi-annual basis to ensure that they are up-to-date and consistent with IACUC rules and regulations. All members involved in the specified work will be required to read this and provide signature assurance that they understand and agree to follow the approved protocol. Non-compliance with this process may result in termination of that lab member's animal use.
- e. The PI will install a regular discussion about IACUC protocols in the first lab meeting of every month, to be presented by the group leader (or liaison when hired). Attendance at these meetings will be recorded; if a member

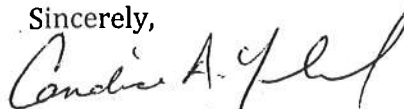
misses the lab meeting, their review of the material will be confirmed and documented afterwards.

- f. The lab will discuss and generate common humane endpoints among different groups and have approved points printed out with each protocol.
  - g. The appointed liaison will monitor the expiration of individual protocols and remind the group leaders and PI to timely renew the protocols before they expire and ensure the continuity of the animal research.
  - h. The lab will communicate with the Lab AV if there is any question in mind regarding animal health concerns. If a question is protocol related, the lab will contact Office for Research Protections. The PI will also communicate with all lab members to emphasize again the importance of following the animal protocols strictly. In addition, the PI will invite IACUC members to come to lab meetings once every semester to educate the lab members and answer any questions the lab members might have.
6. The PI and College are required to hire a senior level staff member who will be responsible for compliance and management of the lab's IACUC protocols. This person will report directly to the College (either the Dean or Associate Dean for Research) and have dotted line reporting to the PI and Lab AV.
7. The PI will be on probation for a period of 2 years (May 1, 2017 to May 1, 2019). During this probationary period, the lab will be subjected to increased IACUC oversight, including announced and unannounced visits by the IACUC or their designee to conduct compliance audits.

The PI acknowledged receipt of the IACUC determination and corrective actions on March 30, 2017. On April 18, the PI presented his CAP. After responding to IACUC comments, the PI submitted a revised CAP on April 27, which was accepted and approved by the IACUC on May 1, 2017. As of May 1, 2017, all required training has been completed.

The activities suspended were in part supported by NIA Grant No. 4 R01 AG045656-04. NIA has been notified. The University certifies that 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:** Thursday, May 04, 2017 1:51 PM  
**To:** Secondary individual  
**Subject:** RE: Final report to OLAW

Thank you for this report. Secondary individual We will respond soon.

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

**From:** Secondary individual [mailto:Secondary individual@psu.edu]  
**Sent:** Thursday, May 04, 2017 1:24 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@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

Secondary individual  
ABI Program Director  
Office for Research Protections  
The Pennsylvania State University  
Room #The 330 Building  
University Park, PA 16802  
Direct Line: telephone # Fax: telephone #  
[www.research.psu.edu/orp](http://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: *3/31/17*Time: *12:00*

Name of Person reporting:

Secondary individual

Telephone #:

telephone #

Fax #:

Email:

Name of Institution:

*Penn State U*

Assurance number:

*A3141*Did incident involve PHS funded activity? *Yes*

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

*Suspension. Exceeding endpoints, no records, no monitoring.*Species involved: *Mice*

Personnel involved: \_\_\_\_\_

Dates and times: \_\_\_\_\_

Animal deaths: \_\_\_\_\_

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

*Retrain, PI meets w/ IACUC to present plan*

Projected submission to OLAW of final report from Institutional Official: \_\_\_\_\_

OFFICE USE ONLY

Case # \_\_\_\_\_