



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

June 26, 2017

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

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 June 26, 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 June 21, 2017. According to the information provided, OLAW understands that two mice with implanted cancer cells were not monitored and euthanized in accordance with the approved protocol. The cage cards had not been updated with timely information and this contributed to the problem.

The corrective actions consisted of counseling the laboratory staff on details of the protocol procedures, ensuring completeness of cage cards, keeping a notebook outlining the animals used and procedures conducted, and informing laboratory staff about the recorded animal procedures. The Principal Investigator was counseled on promptly reporting animal welfare concerns to the Attending Veterinarian (AV) and the Institutional Animal Care and Use Committee (IACUC), the technician responsible was retrained, and the technician must work with the AV to revise the laboratory standard operating procedures (SOP) covering animal activities. The revised SOP must be presented to the IACUC.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

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

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June 26, 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 PI's failure to monitor animals and remove from the study according to procedures and end-points described and approved in his IACUC protocol. The activities were associated with a protocol that is supported by PHS funds, NIH R01CA212587. This incident was discussed by the IACUC on June 14, 2017, and was reported to you via telephone call on June 21, 2017.

On June 12, 2017, a PI informed the IACUC that a research technician had not updated cage cards after an animal transfer, resulting in failure to move two mice from a breeding room to an experimental room. These two mice were implanted with cancer cells on May 1, 2017 but, due to the technician's oversight, they were not monitored and euthanized as required in the PI's approved IACUC protocol. To prevent future oversights, the PI presented the following corrective action plan.

- Discuss in lab meeting about written procedures that describe in detail how each experiment will be conducted and how animals should be monitored and euthanized at the endpoint of the study.
- Make sure lab members clearly label the cages, clearly record procedures and dates on cage cards, assign ID numbers to animals on a study.
- Keep a separate notebook listing all animals in the study with ID numbers, procedures that have been performed, and the times points that each animal was monitored.
- The written operating procedures will be made available and discussed to all lab members involved in animal studies.

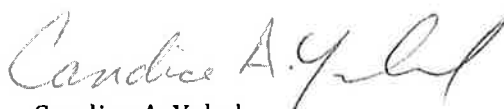
Axel Wolff
June 26, 2017
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The IACUC approved the PI's proposed corrective action plan and reminded the PI of the importance of prompt reporting of animal welfare concerns to both the Attending Veterinarian and the IACUC. In addition, the IACUC included the following corrective actions:

1. The research technician responsible for this oversight must re-take the IACUC CITI mouse training module.
2. The research technician responsible for this oversight must work with the Attending Veterinarian to draft and revise the PI's lab SOP describing the experiments, animal monitoring procedures, and relevant euthanasia procedures. Additionally, the technician must submit this SOP to the IACUC for review at a committee meeting and the technician must attend this meeting to address any committee concerns.

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 [redacted] Secondary individual Director for Institutional Animal Care and Use, Biosafety, and Isotopes.

Sincerely,



Candice A. Yekel
Institutional Official

cc: [redacted] Secondary individual AAALAC International Global Director

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 26, 2017 1:21 PM
To: Secondary individual
Subject: RE: Final report to OLAW

Thank you for this report, Secondary individual. We will 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: Monday, June 26, 2017 12:20 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

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



Initial Report of Noncompliance

By: awDate: 6/21/17Time: 8:30Name of Person reporting: Secondary individual

Telephone #:

telephone #

Fax #:

Email:

Name of Institution: Pennsylvania State UAssurance number: A3141Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

2 mice were found dead, info not on cage cardSpecies involved: mouse

Personnel involved:

Dates and times:

Animal deaths:

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

Better lab documents, label cages, counsel staff
Time points: Retain, develop SOP

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____