



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 11, 2018

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

Ms. Candice Yekel
Associate Vice President for Research
Director, Office for Research Protection
Pennsylvania State University
330 Building, (b) (4)
University Park, PA 16802

Dear Ms. Yekel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 26, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The Pennsylvania State University. Your letter supplements the information contained in a prompt telephone report to this office on September 24, 2018. According to the information provided, OLAW understands that on September 6, 2018 it was determined that post-op records were incomplete for some rats that had undergone surgeries. There was no indication that any complications had arose from the surgeries. This activity was PHS funded.

Corrective actions included The PI retraining the responsible student stressing the importance of regular post-op care, monitoring and record keeping. The PI will audit the post-op notes of all animals.

The PI, his Department Head and Research Dean have been notified that no unallowable costs may be charged to the NIH grant during the period of noncompliance.

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,

(b) (6)

Brent C. Morse, DVM
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

September 26, 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. The activities were associated with a protocol that is supported by PHS funds. This incident was reviewed by the IACUC on September 19, 2018 and was reported to OLAW via telephone message on September 24, 2018.

On September 6th, an investigator reported incomplete records on a rat that had undergone surgery on August 30th. According to the report, only four of the seven required post-op checks had been recorded. The IACUC investigated the additional post-op records of the lab group and discovered four other instances where one or more post-op check was not recorded. While there is no indication that any complications had arose from the surgeries, this lack of record keeping was inconsistent with policy and the protocol.

To address the situation, the PI took corrective actions. This plan included:

1. The PI retrained the student responsible for not recording the checks. This training included:
 - a. Stressing the importance of regular post-op care and monitoring.
 - b. The various elements of record keeping, including the need for sufficient notes to guide proper care and track potential problems.
 - c. That from a compliance and oversight standpoint, lack of notes is equivalent to the work not having been done
2. The PI will audit the post-op notes of all animals.

After review of this plan, the IACUC deemed this action acceptable.

Axel Wolff
September 26, 2018
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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 Jeremy DeRicco, IACUC Compliance Director.

Sincerely,

(b) (6)

Candice A. Yekel
Institutional Official

cc: Dr. James Swearengen, AAALAC International Global Director

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 26, 2018 11:22 AM
To: Dericco, Jeremy Saul
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final report to OLAW

Thank you Jeremy for the final report. Dr. Wolff or Dr. Morse will respond soon.

Regards,
Joan

From: Dericco, Jeremy Saul <jzd237@psu.edu>
Sent: Wednesday, September 26, 2018 10:05 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Yekel, Candice <cay3@psu.edu>; (b) (6) <accredit@aaalac.org>
Subject: Final report to OLAW

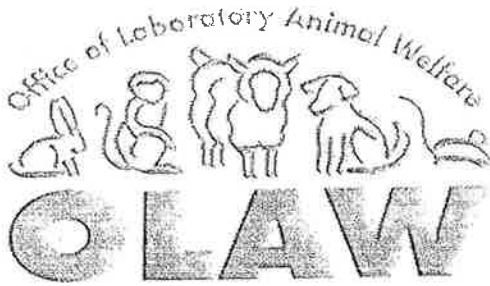
Dear Division of Compliance Oversight,

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: *JDM*Date: *9/24/18*Time: *Voicemail*

Name of Person reporting: *Jeremy DiRicco*
 Telephone #: *[REDACTED]* (b) (6)
 Fax #: *[REDACTED]*
 Email: *[REDACTED]*

Name of Institution: *Penn. St. U.*
 Assurance number: *A3141*

Did incident involve PHS funded activity? *?*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? *No post-op checks done for some dates*

Species involved: *Rats*
 Personnel involved: *Researchers*
 Dates and times: _____
 Animal deaths: _____

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

Projected submission to OLAW of final report from Institutional Official:

Soon

OFFICE USE ONLY

Case # _____