



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 10, 2018

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

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 June 28, 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 May 7th a PI self-reported the use of 3642 mice in the first two years of his study. This exceeded the number of animals approved for three years by 1142 animals. It was determined that the PI did not understand that he needed to include in his initial request the number of unassigned mice generated to obtain the number of the desired genotype. This activity was PHS funded by grant 1R01CA197942-01A1.

Corrective actions included notifying the PI to halted breeding until a protocol modification could be reviewed and approved to cover the additional animals needed. A protocol modification has been submitted for IACUC review. The PI has been educated regarding the animal numbers to consider when planning and submitting a study for approval.

The PI, his Department Head and Research Dean have been notified in writing regarding the 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. The Chief Grants Management Officer for NCI is copied on this letter for consideration of any charges to the grant during the period of noncompliance. 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

Page 2 – Ms. Yekel
July 10, 2018
OLAW Case A3141-24

cc: IACUC Contact
Crystal Wolfrey, Chief Grants Management Officer, NCI

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 09, 2018 3:09 PM
To: 'DeRicco, Jeremy'
Subject: RE: Final report to OLAW

Thank you for this additional information Mr. DeRicco. I will send an official response soon.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
 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: DeRicco, Jeremy [mailto:jzd237@psu.edu]
Sent: Monday, July 09, 2018 11:31 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Final report to OLAW

Dear Dr. Morse,

Yes, is funded by the national cancer institute; 1R01CA197942-01A1. If you need any additional information, please let me know.

Thank you,
 Jeremy

Animal, Biosafety and Isotope (ABI) Program Director
Office for Research Protections
The Pennsylvania State University
 (b) (4)
 University Park, PA 16802
 Direct Line: (b) (6) / Fax: (b) (6)
www.research.psu.edu/orp

ANNOUNCEMENT: Beginning 1/2/2018, we are implementing a FULL ROLLOUT of the new CATS IACUC protocol management system. All New IACUC applications must be submitted in CATS IACUC (details: <https://www.research.psu.edu/iacuc>).

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
Sent: Thursday, July 5, 2018 3:43 PM
To: DeRicco, Jeremy <jzd237@psu.edu>
Subject: RE: Final report to OLAW

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, July 05, 2018 3:42 PM
To: DeRicco, Jeremy
Subject: RE: Final report to OLAW



Dear Mr. DeRicco,

Please confirm whether or not the involved protocol was PHS or NSF funded and if so, please include the grant number(s). Thank you.

Sincerely, Brent Morse

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

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: DeRicco, Jeremy [mailto:jzd237@psu.edu]
Sent: Thursday, June 28, 2018 2:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Yekel, Candice <cay3@psu.edu>; (b) (6)@psu.edu; 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)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 02, 2018 2:24 PM
To: DeRicco, Jeremy; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Yekel, Candice; (b) (6)
Subject: RE: Final report to OLAW

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

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: DeRicco, Jeremy [mailto:jzd237@psu.edu]
Sent: Thursday, June 28, 2018 2:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Yekel, Candice <cay3@psu.edu>; (b) (6)@psu.edu; 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)
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>).



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

A3141-2A

June 28, 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 (PI) using significantly more animals than they were approved for. This was reviewed by the IACUC on May 16th, 2018 and reported to you by phone on June 20th, 2018.

On May 7th, the PI self-reported during an annual review the use of 3642 mice in the first 2 years of his study. This exceeded the number of animals he was approved for over three years (2500) by 1142, or almost 50%. During investigation it was determined that the PI did not understand that he needed to include in his initial request the number of unassigned mice which would be generated to obtain the needed number with the desired genotype.

To address the situation, the following corrective actions were taken:

1. The PI was immediately notified that he had exceeded his numbers and that breeding would need to stop until a modification to add additional numbers was submitted to the IACUC and approved.
2. The PI was educated on policy that requires all animal numbers need to be considered when planning and submitting a study for approval (Breeders, experimental, those euthanized prior to assignment).
3. The PI submitted a modification to cover those used and the additional numbers he would need for year 3 of the study.
4. A noncompliance letter was send to the PI, his department head and the research dean. This letter will be kept on file with the Penn State Office for Research Protections.

Axel Wolff
June 28, 2018
Page 2

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.

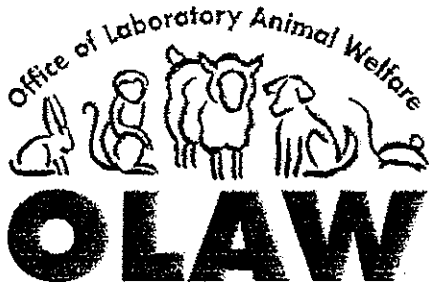
Should you have any questions regarding this report, please contact Jeremy DeRicco, IACUC Compliance Director.

Sincerely,

(b) (6)

Candice A. Yekel
Institutional Official

cc: Dr. James Swearingen, AAALAC International Global Director



Division of Compliance Oversight

Record of Call for Case # A3141-2A

Date & Time	Message	Initials
7/25/18 10:30	Conference call between OLAW, Penn. St and NCI Prog. Official. Penn St will provide NCI date when excess animals were started to be used, # of mice and cost breakdown.	(b) (6)