



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) 480-3387

July 5, 2023

Re: Animal Welfare Assurance
A3141-01 [OLAW Case 3H]

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 May 19, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Pennsylvania State University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this office understands that the Pennsylvania State University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to animal handling by unauthorized personnel. The final report states on March 1, 2023, a Principal Investigator (PI) reported that an undergraduate student that was not listed on the protocol, handled, and was bitten by a mouse. The individual was supervised by a graduate student during the incident, and neither individual was cognizant that handling animals is not permitted without prior IACUC review and approval.

Per the report, the PI consulted with the undergraduate student regarding risks associated with a mouse bite and recommended follow up with the university or personal physician. The PI also met with all lab members to discuss the importance of adhering to institutional policies and provided retraining to personnel. Per email correspondence, it is understood the undergraduate student did not work with animals after the incident. If the individual returns to work in the lab this fall, they will complete all required training and be added to an approved protocol prior to conducting any animal activities.

The matter was reviewed by the IACUC, and the corrective actions were determined to be acceptable. It is noted that this research project is supported by PHS funding.

Based on its assessment of this explanation, OLAW understands that the Pennsylvania State University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Ms. Yekel
July 5, 2023
OLAW Case A3141-3H

Sincerely,

Jacquelyn T.

Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2023.07.05 14:53:23
-04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3141-3H

McCoy, Devora (NIH/OD) [E]

From: (b) (6)
Sent: Thursday, June 29, 2023 5:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Tubbs, Jai (NIH/OD) [E]
Subject: [EXTERNAL] RE: PSU Final Report 5.22.2023S

Follow Up Flag: Follow up
Flag Status: Flagged

Good afternoon,

Thank you for bringing this to my attention and I apologize for the oversight in the final report.

The undergraduate student did not work with animals after this incident (this was an initial introduction to the lab). If he returns to work in the lab this fall, he will take all required training and be added to an approved protocol before he conducts any animal related activities. Let me know if you have any other questions.

Thank you,

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Sent: Wednesday, June 28, 2023 12:03 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; (b) (6)

Cc: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>

Subject: RE: PSU Final Report 5.22.2023S

Hello,

I'm reviewing the final report and I have a couple of questions for clarification. Did the undergraduate student complete IACUC training? Was the undergraduate student added to the protocol after submission of an amendment? It is understood that the PI counseled the undergraduate student and met with lab members, but corrective actions regarding unauthorized personnel handling animals is not mentioned in the report. Please clarify.

Kind Regards,

J. Tubbs

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Sent: Monday, May 22, 2023 12:51 PM

To: (b) (6)

Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: RE: PSU Final Report 5.22.2023S

Good afternoon (b) (6)

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: [REDACTED] (b) (6)

Sent: Monday, May 22, 2023 10:50 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: AAALAC International <accredit@aaalac.org>; Yekel, Candice <cay3@psu.edu>; [REDACTED] (b) (6)

Subject: [EXTERNAL] PSU Final Report 5.22.2023S

Good morning,

Please see the attached final report. Let me know if you have any questions or concerns.

Thank you,

(b) (6)



PennState

Candice A. Yekel
Associate Vice President for Research
Director of Research Protections
The Pennsylvania State University
110 Technology Center
University Park, PA 16802

(b) (6)
cay3@psu.edu
research.psu.edu/orp

A3141-3H

May 19, 2023

Dr. Brent Morse, DVM
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD 20892-6910

Dear Dr. Morse:

The Pennsylvania State University, in accordance with Assurance A3141-01 and PHS Policy IV.F.3., provides this report regarding non-compliance with the PHS Policy. The activities were associated with a protocol that is supported by PHS funds (#R01AT005378). This issue was first reviewed by the IACUC on March 21, 2023.

On March 1, 2023, a PI reported that an undergraduate student, not listed on the approved protocol, had handled, and been bitten by a mouse. Per the report, a graduate student was supervising the undergraduate student during the incident. Neither student was aware that handling animals is not allowed without prior IACUC training and approval.

In response to the incident, the PI consulted with the undergraduate student about risks associated with a mouse bite and recommended follow up with a university or personal physician. Additionally, the PI met with all lab members to discuss the importance of following institutional policies and she also provided retraining to personnel.

The IACUC reviewed this incident and determined it to be noncompliance for conduct of animal-related activities without appropriate IACUC review and approval and found the corrective actions to be acceptable.

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 (b) (6)

Sincerely,

(b) (6)

Candice A. Yekel
Institutional Official

cc:

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD)
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: PSU Final Report of NCI 5.22.2023C
Date: Monday, May 22, 2023 12:50:18 PM

Good afternoon (b) (6)

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Monday, May 22, 2023 10:48 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@aaalac.org>; Yekel, Candice <cay3@psu.edu>; (b) (6)
(b) (6)
Subject: [EXTERNAL] PSU Final Report of NCI 5.22.2023C

Good morning,

Please see the attached final report of non-compliance. Let me know if you have any questions or concerns.

Thank you,

(b) (6)

(b) (6)