



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

September 12, 2023

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

Debra Thurley
Associate Vice President for Research,
Director of the Office for Research Protections
Pennsylvania State University – University Park
101 Technology Center, Innovation Park
University Park, PA 16802

Dear Ms. Thurley,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 5, 2023, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Pennsylvania State University (PSU). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this office understands that the PSU Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to conditions that jeopardize the health or well-being of animals, resulting in actual harm or death to animals. The final report states on July 12, 2023, a Principal Investigator (PI) reported the death of 9 mice that occurred during transfer between gnotobiotic isolators. It is stated that these mice were being transferred via three 1L glass containers by an animal caretaker with assistance from a post-doc from the PI's lab. Per the report, the caretaker stepped away during the last few steps of the transfer, and the post-doc was alone to monitor animals. It is understood that the transfer vessels did not have sufficient oxygen and 9 animals died.

Per the final report, multiple factors have been identified that may have contributed to the animals' deaths. In response to the incident, the following corrective actions were implemented:

- The transfer SOP was revised to more clearly outline the following: 1) the transfer vessel size and maximum number of animals in sealed vessels; 2) two people are required to be present at all times when there are multiple transfers occurring; and 3) if respiratory distress is noted, then the animals must be immediately removed from the isolator port.

The IACUC determine the incident to be reportable and requested a corrective action plan from the PI. OLAW recommends retraining of the staff involved in animal transfers between gnotobiotic isolators, including but not limited to PI staff and animal care staff.

It is noted that this study is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the IACUC has implemented appropriate measures (as outlined below) 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.

Sincerely,

**Angelina M.
Williams -S**

Digitally signed by Angelina M.
Williams -S
Date: 2023.09.12 10:33:20 -04'00'

Angelina Williams, DVM, MPH, DACLAM
Animal Welfare Program Specialist
Animal Welfare Policy
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3141-3K



PennState

Debra Thurley
Associate Vice President for Research
Director of Research Protections
The Pennsylvania State University
101 Technology Center
University Park, PA 16802

(b) (6)
djd116@psu.edu
research.psu.edu/orp

September 5, 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 (#R00AI147165 and #R35GM151045). This incident was first reviewed by the IACUC on July 18, 2023.

On July 12, 2023, the PI reported the death of 9 mice during transfer between gnotobiotic isolators. Per the report, 24 mice were being transferred via three 1L glass vessels by an animal caretaker with assistance from a post doc in the PI's lab. The caretaker and post doc were using a new type of vessel as they are easier to see inside. The caretaker was present for most of the transfer but stepped away for the last few steps, leaving the post doc alone to monitor the animals. Ultimately, the transfer vessels had insufficient oxygen and 9 mice died.

Through follow up conversation, the deaths are believed to be caused by several factors: the transfer SOP lacking adequate details for observing animals during the transfer, inadequate training of the post-doc to conduct gnotobiotic procedures he did not typically oversee, and a larger number of animals combined with the new transfer vessels resulting in a time delay in moving all the mice. In response to the incident, the transfer SOP was revised to more clearly outline 1) the vessel size to be used and maximum time animals should be in the sealed vessels, 2) that if transfers are being conducted into multiple isolators at once, two people are required to be present at all times, and 3) that if respiratory distress is noted, the animals must immediately be removed from the isolator port.

The IACUC reviewed this incident and determined it to be a reportable event that resulted in death of an animal. The IACUC reviewed the corrective action plan and determined all 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)

Debra Thurley, Institutional Official

cc: Dr. Gary L. Borkowski, AAALAC International Global Director

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, September 5, 2023 4:02 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: PSU Final Report 9.5.2023M

Good afternoon (b) (6)

Thank you for sending us this report, assigned OLAW case number A3141-3K, 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: Tuesday, September 5, 2023 3:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@aaalac.org>; Thurley, Debra <djd116@psu.edu>
Subject: [EXTERNAL] PSU Final Report 9.5.2023M

Good afternoon,

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

Thank you,

(b) (6)