



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

January 14, 2022

Re: Animal Welfare Assurance
A3261-01 [OLAW Case 2P]

Dr. Peter Mohler
Interim Vice President of Research
The Ohio State University
(b) (4) Bricker Hall
190 North Oval Mall
Columbia, OH 43210

Dear Dr. Mohler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 20, 2021 letter reporting a series of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The Ohio State University. According to the information provided, OLAW understands that two cages with three mice were housed at an unapproved satellite location and surgical records were not maintained. The study team member also failed to identify one mouse with poor body condition. Subsequently, all mice involved in the noncompliance were inappropriately euthanized using a defective CO₂ flow meter and at a timeline not approved in the protocol by the IACUC. The associated animal activities were PHS funded.

The corrective actions consisted of the IACUC reviewing and approving a management plan submitted by the PI which details measures to prevent future noncompliance, including how the study team members will be instructed to ensure they understand their responsibilities. Experienced laboratory personnel are required to review the protocol with study team members, focusing on appropriate timelines and procedures when conducting IACUC-approved activities. Performance of surgical procedures by the responsible study team member has been halted pending completion of retraining and will require veterinary observation when conducting the next surgery. All study team members will be retrained by veterinary personnel on the performance of rodent surgical procedures and CO₂ euthanasia, with an emphasis on regulation of the CO₂ flow meter. The Quality Improvement Specialist will review IACUC policies with all study team members conducting surgery and conduct unannounced visits to the laboratory.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee

Digitally signed by Neera V.
Gopee -S
Date: 2022.01.14 13:56:27
-05'00'

-S

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Director, Division of Policy and Education
Office of Laboratory Animal Welfare
National Institutes of Health

cc: IACUC Chair

**THE OHIO STATE UNIVERSITY**

Office of Research

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CONFIDENTIAL

December 20, 2021

Brent Morse, D.V.M. Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Janet M. Weisenberger
Senior Associate
Vice President for Research
614-247-4764 Phone

RE: Animal Welfare Assurance #A3261-01, D16-00168

Dear Dr. Morse:

This letter reports an incident of noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at The Ohio State University. The incident involved mice being housed in an unapproved location. Two cages of mice with three mice were found in a lab area that had not been approved by the IACUC to house animals. It had been determined that the cages were in the room from November 15, 2021, to November 23, 2021.

At the time of the discovery of the incident, the lab manager and study team member were informed that satellite housing was an activity not reviewed and approved by the IACUC. Also, it was noted on the cage card that the mice had an approved survival surgery performed on October 19, 2021. It was determined that the timeline for euthanizing the mice was not being followed as described in the protocol and no surgical records were maintained. One mouse showed signs of decreased body condition (ascites) which was not recognized by the study team member. All mice involved in this incident were euthanized by the study team member immediately. Euthanasia was performed improperly due to a defective CO₂ flow meter in the lab's approved animal use location that was delivering gas at a high pressure. The Attending Veterinarian, Principal Investigator (PI) and Co-Principal Investigator (Co-PI) were notified of this incident.

The study team members were responsive to the concerns when the issue was brought to their attention by halting further surgeries being performed by the study team member involved, posting signage on the CO₂ chamber to not use until the flow meter is replaced, ordering a new flow meter to be installed, meeting with the IACUC compliance subcommittee to gather more information, submitting a management plan and correction plan for the study team member involved. This is the first incident involving this lab and the work is funded by The National Institute of General Medical Sciences (R01GM137203).

The Institutional Animal Care and Use Committee (IACUC) discussed this incident at its convened meeting on December 17, 2021 and requested the following corrective actions from the PI.

1. A management plan needs to be approved by the IACUC. It must clearly state how the lab will prevent further non-compliance and how all study team members will be instructed to ensure that they understand their responsibilities.
2. Study team members should review the protocol with an experienced lab member, PI or Co-PI, to understand the proper timeline and procedures for conducting approved IACUC activities.
3. No further surgical activities may be performed by the study team member involved until completion of retraining and a veterinary observation is performed at the time of the next surgery.
4. All study team members conducting surgery should be retrained by the veterinary training staff on conducting rodent survival surgery and performing euthanasia, in particular how to regulate the CO₂ flow meter.
5. All study team members involved in conducting surgery should meet with the IACUC Quality Improvement Specialist (QIS) to review the IACUC policies.
6. Study team members should review their assigned activities in the protocol and update.
7. IACUC QIS will conduct unannounced visits to the lab to ensure no further compliance items are identified.

The Ohio State University remains committed to ensuring the proper care and use of animals used in research and teaching at the institution. Please contact me at (b) (6) or Mohler.94@osu.edu if you require any further information.

Sincerely,

(b) (6)

Peter Mohler, Ph.D.
Interim Vice President of Research

Cc: Valerie Bergdall, OSU Attending Veterinarian
Peter Reiser, OSU IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 22, 2021 7:48 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reporting Noncompliance #A3261-01, D16-00168

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Monday, December 20, 2021 3:08 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Mohler, Peter J. <mohler.94@osu.edu>; Reiser, Peter <reiser.17@osu.edu>; Bergdall, Valerie <bergdall.1@osu.edu>; (b) (6)
Subject: [EXTERNAL] Reporting Noncompliance #A3261-01, D16-00168

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Attached is a letter from the IO at D16-00168 reporting a noncompliance incident.

Sincerely,



(b) (6)