



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 13, 2021

Re: Animal Welfare Assurance
#A3435-01 (OLAW Case U)

Dr. Jeremy Paul
Assistant Dean, Basic Science Research Operations
New York University School of Medicine
430 East 29th Street, (b) (4)
New York, NY 10016

Dear Dr. Paul:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 8, 2021 letter reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at New York University Grossman School of Medicine, following up on an initial telephone report on August 25, 2021. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Mice were left unattended in a CO2 chamber, which is contrary to institutional policy. The incident constitutes a repeat noncompliance for the research technician responsible.

Corrective actions: The technician's animal use privileges were suspended, the technician was retrained on CO2 euthanasia procedures, the Principle Investigator will monitor the technician's activities, the protocol was amended to include a statement that laboratory staff will follow the CO2 euthanasia standard operating procedure, and it was confirmed that laboratory staff has access to the protocol and has certified understanding of the content. The technician will now perform all animal activities during regular work hours, she was retrained, and animal use privileges were restored.

- 2) Mice were housed in a laboratory that had not been approved as a satellite facility.

Corrective actions: The mice were checked by the veterinarian, found to be in good condition, and moved to an appropriate housing room. The animal use privileges of staff involved were suspended and the individuals were retrained. It was confirmed that laboratory staff has access to the protocol and has certified understanding of the content, the laboratory was placed under enhanced post-approval monitoring, and the animal use privileges were subsequently restored.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



September 08, 2021

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Re: Reportable incidents at NYU Grossman School of Medicine (NYUSoM), Assurance #D16-00274 (A3435-01)

Dear Dr. Morse,

This letter describes two instances of non-compliance with PHS Policy involving personnel conducting federally funded research involving animal subjects.

Notification of these incidents was initially reported to Dr. Axel Wolff by Natalie L. Mays, Director of the NYUSoM's Division of IACUC and IBC Administration in a phone conversation on **August 25, 2021**. We apologize for sending the written notification with details on the resolutions at this late date. What follows is the chronology of each incident.

Incident #1 – Grant #s R01CA202025, R01CA202027

March 30, 2021 - The IACUC received an anonymous report of an animal welfare concern that occurred in an animal facility euthanasia chamber on **3/24/2021**. The substance of that anonymous report is provided below:

A research technician left 6 cages of mice unattended in a CO₂ euthanasia chamber within a central animal facility. This is non-compliant with the Institution's standard operating procedure for conducting rodent CO₂ euthanasia as well as signage displayed on the euthanasia equipment and throughout the facility. This was also the 2nd instance of non-compliance involving this research technician. The first instance was reported to OLAW on **8/13/2021** (OLAW Case T).

An institutional veterinarian emailed the PI and the research technician concerning the non-compliance indicating that the research technician's animal facility access would be immediately revoked. The research technician was instructed to repeat the institution's online CO₂ euthanasia training module as well as meet with the veterinarian to review the euthanasia SOP. The research technician completed the online training and met with the veterinarian. The PI's Laboratory Manager accompanied the research technician to the meeting with the veterinarian.

March 31, 2021 – The IACUC Director notified the PI via email of the non-compliance and indicated that an investigative subcommittee of the IACUC would be convened.

The subcommittee was convened and met to discuss the non-compliance and draft recommendations to be presented to the full IACUC at its next regularly scheduled meeting.

April 14, 2021 - The full IACUC received notification of the investigation at its regularly scheduled meeting. After discussion of the subcommittee's recommendations, the full committee voted to require that the following actions be put in place to secure the welfare of animals involved in this PI's laboratory:

1. PI must provide a written plan on how this research technician's activities would be monitored by the PI to prevent future non-compliances.
2. PI must amend all procedures in his protocol to include a statement that all lab personnel will follow the SOP for rodent CO₂ euthanasia. The updates specifically state that anyone performing CO₂ euthanasia will remain with the animals until death has been confirmed and that everyone will adhere to the IACUC-approved protocol.

3. PI will verify that all lab members are able to access the IACUC-approved protocol. They must also sign a statement indicating that they have read and understood the content of the protocol. The signed “statement of understanding” document will be signed by the PI as verification and submitted to the IACUC.

April 16, 2021 – The IACUC Chair notified the PI of the IACUC’s decisions regarding the non-compliance.

April 30, 2021 – The IACUC received the “statement of understanding” signed by lab members available at that time. Additional lab members were on a leave of absence and would sign the statement when they returned to work.

May 4, 2021 – The IACUC received a written response from the PI dated **4/29/2021**. In addition to the items required by the IACUC, the following actions were taken by the PI:

- The research technician was instructed to complete all animal-related activities during regular lab operation hours to ensure maximum laboratory staffing availability for monitoring and assistance when needed.
- The research technician completed in-house re-training from other laboratory members on the procedures to which she was assigned in order to ensure understanding of expectations and compliance with regulations and institutional guidelines.
- The protocol amendment required by the IACUC was submitted.

May 10, 2021 – The research technician’s access was restored.

June 9, 2021 – The amendment to clarify all procedures in the protocol was approved by the IACUC. All laboratory members, including those who were previously on leave and the PI signed the “statement of understanding” which was forwarded to the IACUC on **July 2, 2021**.

Incident #2 – Grant #R01 NS047325

March 31, 2021 – The IACUC received an email from an external email box indicating that there was suspected housing of mice for longer than 24 hours in a location not approved by the IACUC. The details of the report and investigation are below:

The email via the IACUC email box indicated that there were mouse cages “hidden” in a laboratory of a faculty member who had unexpectedly left the institution. An IACUC staff member immediately went to the location and found 5 unlabeled cages being housed in an area of the lab behind a curtain that was used for microscopy. Four cages housed 2 mice and one cage housed one mouse. In addition to the cages of mice, rodent chow and water bottles were also found in the laboratory.

After interviewing individuals working in the lab, it was determined that a post-doc listed as personnel on the previous faculty member’s protocol as well as another active faculty member’s protocol, brought the animals to the lab from the central animal facility on **3/24/2021**. The post-doc attempted to return the cages on **3/30** but his access was turned off due to the unexpected departure of the PI who he previously worked with. Since the post-doc could not return the animals, he checked the animals in the lab daily and provided food and water as necessary. The previous PI’s protocols were in process of being transferred to new PIs who collaborated with the previous PI. The post-doc indicted that the animals were housed under the protocol of one of the new PIs.

A veterinarian came to the lab to assess the health of the animals and determined that they were healthy and could be moved to a housing room designated for animals that had been removed from the central animal barrier facility. Animal facility staff moved all animals into clean cages inside of the designated housing room that same day.

An investigative subcommittee of the IACUC was convened and met to discuss the non-compliance. Animal facility access for all members of the laboratory was immediately revoked even though some post-docs were listed on active faculty members’ protocols.

April 5, 2021 – The new PIs responsible for assuming the research previously conducted by the former PI were notified of the non-compliance involving personnel who were newly assigned to work in their labs. The subcommittee determined that since the individual who illicitly housed the animals as well as others who observed the animals being illicitly housed in the laboratory were being assigned to work with new PI’s, those faculty members needed to be aware of the non-compliance.

April 13, 2021 – The investigative subcommittee met with the lab members involved in the non-compliance. After the meeting, the subcommittee met to discuss the non-compliance and draft recommendations to be presented to the full IACUC.

April 14, 2021 – The full IACUC was initially informed of the non-compliance at its regularly scheduled meeting.

May 12, 2021 - The full IACUC discussed the investigation and recommendations from the investigative subcommittee at its regularly scheduled meeting. After discussion of the investigative subcommittee's recommendations, the full committee required the following:

1. All individuals who were aware of mice being housed in the lab along with their new PI were required to attend regulatory lecture to discuss researcher responsibilities including protocol adherence and adherence to federal regulations and institutional guidelines pertaining to the use of animals in research. This training was presented by IACUC staff.
2. Each PI was required to verify that all lab members were able to access the IACUC-approved protocol. They were then required to sign a statement indicating that they read and understood the content of the protocol. The signed document was signed by the PI as verification and submitted to the IACUC.

Each PI was informed that the IACUC would implement an enhanced monitoring plan to include the following:

- Unannounced and scheduled inspections;
- Presentation of procedure related documents (i.e. surgical records) to the IACUC upon request.

May 13, 2021 – PIs submitted "statements of understanding" signed by all involved individuals and their new PIs.

May 20, 2021 – Regulatory training for all individuals involved was completed and animal facility access was restored.

May 28, 2021 – IACUC staff returned to the lab location. No animals were being housed.

The NYU Grossman School of Medicine takes the welfare of animals used in research seriously. Should you have any questions regarding this notification or our actions as described above, please do not hesitate to contact me.

Sincerely,

(b) (6)

Jeremy Paul, PhD
Institutional Official
Associate Dean, Basic Science Research Operations
Research Associate Professor, Cell Biology

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 10, 2021 7:12 AM
To: Mays, Natalie
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: notification of noncompliance - Assurance #D16-00274 (A3435-01)

Thank you for these reports, Natalie. I also received your message about the funding and will cross off the other items on the preliminary report. We will send a response soon.

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

From: Mays, Natalie <Natalie.Mays@nyulangone.org>
Sent: Wednesday, September 8, 2021 4:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Paul, Jeremy <Jeremy.Paul@nyulangone.org>
Subject: notification of noncompliance - Assurance #D16-00274 (A3435-01)
Importance: High

Dear Dr. Morse,

Attached is a letter from our Institutional Official, Dr. Jeremy Paul that contains details of two events noncompliant with PHS Policy that occurred at the NYU Grossman School of Medicine. Please contact Dr. Paul if there are any questions or if additional information is required.

Best regards,
Natalie

Natalie L. Mays, BA, LATG, CPIA
Director,
Division of IACUC and IBC Administration
Institutional Contact Dual Use Research (ICDUR)

NYU Langone Health
NYU Grossman School of Medicine

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Initial Report of Noncompliance

By: (b) (6)

Date: 8/25/21

Time: 11:00

Name of Person reporting: Natalie Mays

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: New York University

Assurance number: A3435

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary):

What happened?
 ✓ 1) 6 mouse cages left unattended in CO2 chamber
 X 2) 5 anesthetized mice unattended by post-doc
 X 3) overcrowded mice in cage in CO2 chamber.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

X 4) Mouse ear tag too close to head, post-doc took off entire ear

✓ 5) 5 cages housed in lab not approved as satellite mice etc

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

✓ 1) Counsel research tech responsible, retrain, increase monitoring. All lab certify understanding of euthanasia procedures.

X 2) Called vet tech to monitor mice. Modify census info on monitoring. Retrain post-doc.

X 3) Reverse faulty access, take off protocol, retrain lab

Projected submission to OLAW of final report from Institutional Official:

X 4) Vet tech treated mouse, analgesia, Retrain postdoc

OFFICE USE ONLY

Case #

✓ 5) Put mice back in approved holding room, retrain all lab staff, increase PAM

Note: Reports 2, 3, 4 retracted because not PHS funded