

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

EOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 480-3387

August 25, 2021

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

Dr. Jeremy Paul Assistant Dean, Basic Science Research Operations New York University School of Medicine 550 First Avenue, Room 256, Medical Science Building New York, NY 10016

Dear Dr. Paul,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 12, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the New York University Langone Medical Center. Your letter supplemented the information contained in an initial telephone report to this office on March 29, 2021. According to the information provided, OLAW understands that on January 4, 2021, your institution received an anonymous report that on December 28, 2020, a research technician was observed placing three male mice in a cage filled with water and leaving them there to swim. The tech indicated that the mice were fighting, and she thought that placing them in water would stop them from fighting. This was not an IACUC- approved method. The PI was contacted and instructed the technician to never use swimming as a method to stop mice from fighting again. Animal access for the research tech was revoked and an IACUC investigation was initiated. The animal activity involved is funded by the PHS.

Corrective and preventive actions included the PI indicating that all members of the lab were advised to remove and when necessary, single house male mice in the event of aggressive behavior. If the behavior was observed to continue, lab members were further instructed to contact a veterinarian.

In addition, the IACUC determined that the PI and all laboratory staff:

- Meet with the IACUC Assistant Director for additional training on:
  - a. Regulations requiring adherence to activities described in IACUC-approved protocols,
  - b. Researcher responsibilities for monitoring animals,
  - c. Interventions that should be taken when mice are fighting
  - d. Adhering to humane endpoints
  - e. Understanding the roles of the IACUC, veterinarians and researcher in an animal care and use program
  - f. IACUC reporting requirements to appropriate regulatory agencies
  - g. Adverse event reporting to veterinarians
  - h. Consequences of non-compliances and not reporting animal illness or incidents
  - i. Ethics of using animals in research
  - j. How to minimize pain and distress in lab animals
  - k. Species-specific criteria of mice -normal behavior, aggressive behavior, effects of water stress, euthanasia

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- Meet with an institutional veterinarian for additional training on:
  - a. Mouse behavior and general health
  - b. Appropriate breeding techniques including management and housing male offspring
  - c. Ways to minimize mice aggression and how to respond to fighting
  - d. What/when to report unusual events to veterinary staff

The PI was further informed that after completing the additional training, the IACUC would increase announced and unannounced monitoring of the laboratory to assess the outcome of the training.

OLAW appreciates the prompt consideration of this matter by the New York University Langone Medical Center, 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 and correct this issue and to prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S Morse -S

-S Digitally signed by Brent C. Morse -S Date: 2021.08.25 15:42:09 -04'00'

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact



Jeremy Paul, PhD Associate Dean, Basic Science Research Operations and Regulatory Affairs Research Associate Professor, Cell Biology

August 12, 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 incident at NYU Grossman School of Medicine (NYUSoM), Assurance #D16-00274

Dear Dr. Morse,

This letter describes an incident of non-compliance with PHS Policy involving research personnel in the laboratory of an NYU Grossman School of Medicine faculty member approved to conduct federally funded research involving animal subjects.

Notification of the incident was initially reported to you by Natalie L. Mays, Director of the NYUSoM's Division of IACUC and IBC Administration in a phone conversation on March 29, 2021. We apologize for sending the written notification with details on the resolution at this late date. What follows is the chronology of this incident.

**January 4, 2021** - IACUC received an anonymous report of an animal welfare concern that occurred in an animal facility housing room on 12/28/2020. The substance of that anonymous report is provided below:

A research technician was observed placing an empty mouse cage in the sink, filling the cage with water and placing 3 male mice in the cage leaving them there to swim. The forced swimming exercise was not approved by the IACUC. The incident was reported to an animal facility supervisor. The supervisor went to the room and the research tech and the water filled cage of mice were gone. The supervisor then contacted a veterinarian. The veterinarian was unable to reach the research technician so the Principal Investigator was called. The PI noted that the swimming procedure was not described in his IACUC protocol and expressed displeasure that the incident occurred. The PI contacted the research technician to determine why the procedure was conducted. The tech indicated that the mice were fighting and she thought that placing them in water would stop them from fighting. The PI instructed the technician to never use swimming as a method to stop mice from fighting again.

**January 5, 2021** - Animal access for the research tech was revoked and an IACUC investigation was initiated. The PI was notified in writing by the IACUC Director that the research tech's access to the facility was revoked and that she would not be allowed to work with animals until the IACUC investigation had been completed. The written notification also included questions for the PI pertaining to the incident for which a written response was required.



**January 6, 2021** - The PI response was received. He stated that according to the research tech, 3 large male B6 mice were fighting with two other smaller cage mates. In this written account provided by the PI, they noted that the aggressors were removed and placed in the water in an effort to curb the behavior. The PI again stated that this was not an IACUC- approved method and to his knowledge had not been used by any members of his lab previously. He also indicated that he discussed this issue with the tech and he believed that the message was clearly communicated that the procedure must not be done again. The PI also indicated that all members of the lab were advised to remove and when necessary, single house male mice in the event of aggressive behavior. If the behavior was observed to continue, lab members were further instructed to contact a veterinarian.

January 8, 2021 - An IACUC investigative subcommittee met to review the incident. It was determined at that time that more information was required and a meeting with the research tech was needed.

**January 13, 2021** - The full IACUC received initial notification of the investigation at its regularly scheduled meeting.

**January 22, 2021-** the IACUC investigative subcommittee met with the PI, research tech, lab manager and another post-doctoral fellow from the lab. Prior to the meeting, IACUC members were requested to submit in writing any questions they had for the research tech to the IACUC office. During the meeting, the research tech indicated that mice were in the water for one minute, dried, then placed in a clean cage. She stated that she never left the room. The subcommittee then met to evaluate responses from the meeting with laboratory staff and determined that further clarifications from the research tech were still needed.

**February 1, 2021** - The PI was provided with the additional questions in writing to which he responded on February 3, 2021.

**February 10, 2021** - An update and recommendations from the subcommittee were presented to the full IACUC at its regularly scheduled meeting. After discussion of the subcommittee's recommendations, the full committee voted to require that the PI and all laboratory staff complete the following:

- 1. Meet with the IACUC Assistant Director for additional training on:
  - a. Regulations requiring adherence to activities described in IACUC-approved protocols,
  - b. Researcher responsibilities for monitoring animals,
  - c. Interventions that should be taken when mice are fighting
  - d. Adhering to humane endpoints
  - e. Understanding the roles of the IACUC, veterinarians and researcher in an animal care and use program
  - f. IACUC reporting requirements to appropriate regulatory agencies
  - g. Adverse event reporting to veterinarians
  - h. Consequences of non-compliances and not reporting animal illness or incidents
  - i. Ethics of using animals in research
  - j. How to minimize pain and distress in lab animals
  - k. Species-specific criteria of mice normal behavior, aggressive behavior, effects of water stress, euthanasia



- 2. Meet with an institutional veterinarian for additional training on:
  - a. Mouse behavior and general health
  - b. Appropriate breeding techniques including management and housing male offspring
  - c. Ways to minimize mice aggression and how to respond to fighting
  - d. What/when to report unusual events to veterinary staff

The PI was further informed that after completing the additional training, the IACUC would increase announced and unannounced monitoring of the laboratory to assess the outcome of the training.

March 1, 2021 - The PI and laboratory staff completed the IACUC portion of the training.

March 8, 2021 – The PI and laboratory staff completed the veterinarian portion of the training.

All meetings including the required training took place via webex, zoom or other on-line platforms.

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, August 13, 2021 9:52 AM
То:	Mays, Natalie
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: notification of noncompliance - Assurance #D16-00274

Thank you Natalie. We'll send a response soon. Axel Wolff

From: Mays, Natalie <Natalie.Mays@nyulangone.org> Sent: Friday, August 13, 2021 9:34 AM 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 Importance: High

Dear Dr. Morse,

Attached is a letter from our Institutional Official, Dr. Jeremy Paul that contains details of a noncompliance 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

One Park Avenue, (b) (4) New York, NY 10016

(b) (6)

natalie.mays(a)nyulangone.org

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## **Initial Report of Noncompliance**

By: BCM

Date: 3/29/2021

Time: 4:35

Name of Person reporting: Natalie Mays Telephone #: (b) (6) Fax #: Email:

 Name of Institution:
 \_\_\_\_\_New York Univ. Grossman SOM \_\_\_\_\_\_

 Assurance number:
 \_\_\_\_\_A3435 \_\_\_\_\_\_

Did incident involve PHS funded activity? \_\_?\_\_\_ Funding component: \_\_\_\_\_ Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Anonymous report of research tech placing three mice in cage filled with water "to stop fighting".

Species involved: mus musculus Personnel involved: Research Tech Dates and times: 12/28/2020 Animal deaths: No

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

Animal facility access revoked. PI notified. PI to meet with and train all lab staff. PI and lab staff to meet with vet staff.

Projected submission to OLAW of final report from Institutional Official:

< 60 days.

OFFICE USE ONLY Case #\_\_\_\_\_