



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

February 21, 2018

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

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 February 15, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at New York University School of Medicine. According to the information provided, OLAW understands that a student was conducting activities with mice without having undertaken the required training and without being listed on the protocol. The student had anesthetized mice with inhalant gas but had not used the fume hood which is a violation of the protocol and institutional policy. The mice were monitored and experienced no problems. The Principal Investigator (PI) was aware that the student had not been trained or been added to the protocol.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) counseling the PI to ensure that all individuals have completed the required training and have been included on the protocol before working with animals and to follow the protocol. The PI confirmed agreement with the IACUC's directive. The PI and laboratory staff were retrained and the IACUC will also help ensure that all students receive the appropriate training.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC 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



A3435-R
Obtained by Rise for Animals. Uploaded 07/08/2020

February 15, 2018

Brent Morse, DVM
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Reportable non-compliance
NIH-funded study on Genetic Functional Dissection of Brain Circuitry underlying social behaviors in mice.

New York University School of Medicine (NYUSoM), Assurance #D16-00274 formerly A3435-01

Dear Dr. Morse,

This letter is a report of non-compliance with PHS Policy by the principal investigator (PI) for the above noted research project. The PI is an Assistant Professor in the Department of Psychiatry and the Department of Neuroscience and Physiology at NYU School of Medicine. The non-compliance was first reported to you by Natalie L. Mays, Director of the IACUC and IBC in person on January 9, 2018.

The non-compliance involved an MD/PhD student's concerns regarding her activities with mice prior to receiving IACUC-required training and being approved on an IACUC-approved protocol. Conducting experimental procedures on animals without being approved on an IACUC-approved protocol and deviating from the protocol is a violation of PHS Policy and NYUSoM's Animal Welfare Assurance.

I informed the IACUC of this noncompliance in late September after it was reported to me by a senior member of the PI's department. The report was made on behalf of the student who at that time, was unknown to the IACUC. After notifying the IACUC Director, IACUC personnel interviewed the senior member of the department and the student's advisor. The student agreed to be interviewed after being informed of the IACUC's investigation by her advisor. A veterinarian performed an animal welfare audit on this investigator's mice and they were found to be healthy.

An investigative subcommittee of the IACUC was convened to discuss the details of the concern. The relevant facts related to the non-compliance are as follows:

- An inexperienced MD/PhD student was assigned to work with mice during a 6-week rotation during July-August 2017 in the lab of the PI identified above. The student's responsibilities included anesthetizing and monitoring mice. Although training for all new personnel is required prior to being approved on a protocol and working with animals, the student did not receive the training and was not approved on the protocol.
 - On two occasions, the student was left alone in the lab to work with mice. During that time, she administered isoflurane to mice on a lab bench outside of a fume hood. She then monitored recovery of the mice.
 - This is a deviation from the IACUC-approved protocol and a non-compliance with institutional guidelines for administering inhalant anesthesia.
- The PI admitted that the student did not receive training even though the PI was aware that training was required. The PI also admitted that she was aware that the student had not been added to the IACUC-approved protocol.

The PI was notified of the IACUC investigation on October 31, 2017 and was reminded of the requirement to adhere to the IACUC-approved protocol at all times. The PI met with the subcommittee on November 6, 2017 to respond to the concerns of the student and

the IACUC. The subcommittee's findings and the PI's responses were presented to the full IACUC on December 13, 2017. The committee confirmed non-compliance with institutional and PHS Policy and agreed to the following corrective actions:

- The PI must ensure that all personnel are appropriately trained and added to an IACUC-approved protocol prior to exposure to live animals.
- The PI and all personnel listed as Study Staff on the current IACUC-approved protocol are required to attend an IACUC regulatory training lecture conducted by the IACUC Assistant Director. They must also attend training on the safe use of inhalant anesthetics in a laboratory environment conducted by Environmental Health and Safety personnel.
- The PI was also required to submit a written plan describing how this type of noncompliance will be prevented in the future.

In the written plan, the PI agreed with the results of the investigation and confirmed that effective immediately, all lab members, including temporary rotation students will be appropriately trained and approved on an IACUC-approved protocol prior to handling animals. All current lab members will adhere to the IACUC-approved protocol.

Even though it is the PI's responsibility to notify incoming students of the training requirements for working with lab animals, the IACUC Assistant Director has met with management of the graduate student institutes to develop a plan to provide targeted and timely training to rotational students prior to their exposure to animals in the lab.

Finally, we plan to reach out to the student who initially reported this concern, informing her of the resolution.

The NYU 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. Thank you for your time.

Sincerely,

(b) (6)

Jeremy Paul, PhD
Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, February 20, 2018 7:38 AM
To: Institutional Animal Care and use Committee; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: NYU School of Medicine Report of Noncompliance

Thank you for this report. We will send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Institutional Animal Care and use Committee [mailto:iacuc@nyumc.org]
Sent: Friday, February 16, 2018 3:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Institutional Animal Care and use Committee <iacuc@nyumc.org>
Subject: NYU School of Medicine Report of Noncompliance
Importance: High

Dear Dr. Morse,

Attached is a report of non-compliance by an NYU faculty member. Please let either Natalie Mays (Director) or Dr. Paul (IO) know if you have any questions. Thank you!

Best regards,

(b) (6)

On behalf of:
Natalie L. Mays, BA, LATG, CPIA
NYU Langone Health
Director
Institutional Animal Care and Use Committee (IACUC)
Institutional Biosafety Committee (IBC)
1 Park Avenue, 6th Floor
New York, NY 10016
Phone: (b) (6)
Email: natalie.mays@nyumc.org

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