



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

May 21, 2018

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

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

Dear Dr. Paul:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 18, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals and two deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals* at New York University School of Medicine, following up on an initial telephone report on May 8, 2018. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Two mice were subjected to an orbital blood collection although this procedure was not listed on the approved protocol.

Corrective action: The Principal Investigator involved was counseled to follow the protocol or amend it, and undertook retraining.

- 2) The lights in a mouse housing room remained on continually for one month because the automatic system was overridden during maintenance. No adverse effects were reported in the animals.

Corrective action: The light timer was fixed, a reporting procedure was established for facility concerns and alarms, future facility maintenance will trigger a check to ensure that light timers are working, staff will periodically conduct after hours checks of the light cycles, investigators working after hours will check if lights are off, and the relevant standard operating procedure will include these changes.

- 3) Construction took place in a building with an animal facility and lead was discovered in the dust. No work occurred within the animal area.

Corrective action: The rodents were moved to a new facility. Testing of sentinels did not detect lead.

Based on its assessment of this explanation, OLAW understands that measures have been implemented in all three situations to correct and prevent recurrence of the problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

*Page 2 – Dr. Paul*  
*May 21, 2018*  
*OLAW Case A3435-S*

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Director, Office of the IACUC and IBC



May 18, 2018

Axel V. Wolff, M.S., DVM  
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 incidents at New York University School of Medicine (NYUSoM), Assurance #D16-00274

Dear Dr. Wolff,

This letter describes three separate incidents - one incident of non-compliance with PHS Policy by a faculty member of the NYU School of Medicine, and two separate deviations from *the Guide*. Notification of these incidents were first reported to you by Natalie L. Mays, Director of the NYU Langone School of Medicine IACUC and IBC in a phone conversation on May 8, 2018.

#### **Protocol non-compliance**

On February 1, 2018, the IACUC was informed that an experienced faculty member conducted a blood collection procedure not described in the IACUC-approved protocol on two mice. An IACUC investigative subcommittee was convened and the IACUC determined the following:

1. The PI was requested to confirm that he would remain compliant with any IACUC-approved protocol in which his name appears.
2. The PI must seek IACUC approval for any new blood collection procedures via a protocol amendment.
3. The PI must attend a regulatory lecture focusing on protocol compliance and reporting of animal welfare concerns.
4. The PI must attend euthanasia and blood collection training conducted by an institutional veterinarian.

#### **Deviation from the Guide**

At the March 14, 2018 IACUC meeting, a scientist member responsible for management of a satellite housing room containing approximately 40 mouse cages, reported that the light cycle in the room had malfunctioned. The IACUC member was told by two researchers that lights were found to be on in the evening after times when they were supposed to be off. There is limited traffic in the room which is not visible from the external hallway. The IACUC member immediately launched an investigation and notified personnel from the veterinary staff, Real Estate Development & Facilities, and Environmental Health and Safety.

It was discovered that the during routine equipment maintenance, the light cycle and its history was accidentally overwritten. Based on the timing of the maintenance, it was presumed that mice experienced constant light for approximately one month. After making sure that the light timer was corrected, the IACUC member developed the following plans to prevent future incidents pertaining to the light timer:

1. A clear line of reporting facility concerns and alarms has been established.
2. Any intervention to the facility or equipment will now initiate a check to ensure the light timer is working properly.
3. A data logger and/or a staff member will conduct periodic checks, at least once every six months after-hours to ensure that the timer is working properly.

4. All research staff will be trained to check for the presence of the "off cycle" if they will be working in the area after-hours.
5. All mitigation methods will be incorporated into the written SOPs for the location.

All researchers were informed and were asked to report any health issues to the veterinarians. One researcher noted minor hair loss in one group (4-6 mice). Prior to this incident, mild hair loss was reported in some animals purchased from the same vendor. A veterinarian performed an animal welfare audit on all mice in the room and they were found to be healthy. There has been no increase in morbidity or mortality of mice housed in the room.

#### **Deviation from the Guide**

On April 19, 2018, the IACUC was informed that a test of the dust of a building undergoing construction indicated the presence of lead on those floors undergoing construction. The building also housed an animal facility. At no time were there any construction activities taking place in the animal housing facility. Prior to the discovery of the lead in the dust from the construction zones, this animal housing facility was scheduled to be closed at the end of April and the animals moved to a facility in a new research building on campus. After discovery of the lead, all animals were moved to the new facility on April 23<sup>rd</sup>. Sentinels previously housed in the facility were tested for elevated lead levels and the results were found to be negative.

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  
Assistant Dean, Basic Science Research Operations  
Research Associate Professor, Cell Biology

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, May 18, 2018 10:52 AM  
**To:** Mays, Natalie  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reportable incidents D16-00274

Thank you for this report, Natalie. I'll send a response soon.  
Axel Wolff

**From:** Mays, Natalie [mailto:Natalie.Mays@nyumc.org]  
**Sent:** Friday, May 18, 2018 10:10 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Institutional Animal Care and use Committee <iacuc@nyumc.org>; (b) (6)@med.nyu.edu>  
**Subject:** Reportable incidents D16-00274

Dear Dr. Wolff,

Please see the attached document from Dr. Jeremy Paul, the Institutional Official from the NYU School of Medicine. If you have any questions, do not hesitate to contact either me, or Dr. Paul.

Thank you!

Best regards,  
Natalie

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

**NYU Langone Health**  
**NYU School of Medicine**

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

T (b) (6)  
[natalie.mays@nyumc.org](mailto:natalie.mays@nyumc.org)

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## Initial Report of Noncompliance

By: *aw*

Date: *5/8/18*

Time: *10:30*

Name of Person reporting: *Natalie Mays*

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: *NYU School of Medicine*

Assurance number: *A3435*

Did incident involve PHS funded activity? ☐

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

- 4 incidents*
- 1) Lead in construction dust.*
  - 2) Eye bleed in mouse not covered on protocol.*
  - 3) Mice in satellite facility had light on constantly for 1 month. Light spill over mids.*

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

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

- 1) Move animals to new facility, Rodents. Did blood tests + negative for animals + people.*
- 2) Retain*
- 3) Contact building manager if light problems.*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_