

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

March 9, 2022

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

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 March 7, 2022 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, following up on an initial telephone report on January 25, 2022. According to the information provided, OLAW understands that following a mouse bite of a faculty staff member at the New York University College of Dentistry, it was discovered that the Health Services at that location no longer provided treatment. The Institutional Animal Care and Use Committee (IACUC) had not been informed of this potential change in the occupational health and safety program.

The corrective actions consisted of the individual receiving care at the student health center at a different campus location. The matter was investigated and it was determined that the occupational health program procedures had not changed and that a misunderstanding had occurred. The IACUC received a copy of the current procedures in place for handling laboratory staff injuries and a copy of the Occupational Exposure Protocol. This protocol was distributed to all applicable individuals and was posted in the Dental College vivarium.

Based on its assessment of this explanation, OLAW understands that the matter was resolved and that the description of the occupational health program outlined in the Assurance continues to represent the procedures in place. 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



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

March 07, 2022

Axel Wolff, MS, DVM
Deputy Director
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

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

Dear Dr. Wolff,

This letter describes a programmatic non-compliance with PHS Policy involving the Occupational Health program for a subset of researchers and students from the New York University College of Dentistry/NYU Washington Square who conduct federally funded research involving animal subjects at the NYUSoM campus. The College of Dentistry is a component of our Assurance.

non-compliance to you, in a phone conversation on **January 25, 2022**. What follows are details of the non-compliance.

January 11, 2022

The NYU Director of Research Safety notified (b) (6) and the Director of the Division of Comparative Medicine that on January 11, a mouse bit a member of a laboratory of a faculty member from the NYU College of Dentistry. Per institutional policy, the individual reported to the Health Services Unit (HSU) within the Dental College for treatment and was told that laboratory staff could no longer receive treatment at that location. As a result, the individual was treated at the Student Health Center on the NYU downtown campus, approximately 2 miles away. The Director of Research Safety inquired about the correct process laboratory staff should follow in the event of injuries including animal bites. This was the first alert to the IACUC that the process had changed. In the past, at least once every six months, the IACUC Director confirmed the process with the NYU College of Dentistry's Vice Dean for Academic Affairs who retired in September 2021. There was no notification to the IACUC that the process may have changed.

The IACUC Director contacted the NYU Assistant Director for Research Ethics & Governance to inquire about the apparent change in procedures individuals need to follow in case of injury.

Smillow Research Center

522 First Avenue, Room 201B, New York, NY 10016 T 646-501-8715 jeremy.paul@nyulangone.org



January 11 - 25, 2022

NYU Langone Health and NYU Washington Square representatives investigated the incident and conferred with one another on numerous occasions via email and virtually.

February 4, 2022

Following the investigation described above, NYU Langone Health and NYU Washington Square representatives jointly determined and agreed that the Occupational health program had not changed and apparently, HSU personnel misunderstood the procedures. The Senior Director of the Health Screening Unit clarified this misunderstanding.

To ensure that everyone understood the process, the IACUC Director requested written documentation from representatives of the NYU College of Dentistry specifically outlining procedures their laboratory personnel should follow in the event of laboratory or animal related injuries.

March 1, 2022

The Administrator/Assistant Chemical Hygiene Officer provided the IACUC Director with an Occupational Exposure Protocol.

The Protocol lists four steps summarized below:

- 1. Administer first aid:
- 2. Notify the PI or Laboratory Supervisor;
- 3. Contact or report to the Health Services Unit during working hours (Monday-Friday 9:00 am 5:00 pm);
- Report to a local hospital emergency room during non-working hours.

The Occupational Exposure Protocol will be distributed to all applicable individuals and posted within the Dental College vivarium.

The NYU Grossman School of Medicine takes the Institutional requirement for an occupational health program and the provisions of our OLAW Assurance 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:

Monday, March 7, 2022 10:05 AM

To:

(b) (6)

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Assurance #D16-00274 (A3435-01) update of noncompliance report

Thank you for this report,

(b) (6) We will send a response soon.

Axel Wolff

From:

(b) (6)

Sent: Monday, March 7, 2022 9:39 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Paul, Jeremy < Jeremy. Paul@nyulangone.org>

Subject: [EXTERNAL] Assurance #D16-00274 (A3435-01) update of noncompliance report

Importance: High

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.

Dear Dr. Wolff,

Attached is a letter from the NYU Grossman School of Medicine's Institutional Official, Dr. Jeremy Paul, detailing updates to a preliminary report of programmatic noncompliance with PHS Policy. Please contact Dr. Paul if there are any questions or if additional information is required.



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A3435-V



Case #_____

Initial Report of Noncompliance

FHAA	Ву: (6) (6)
Date: 1/25/22	Time: 800
Name of Person reporting: Telephone #: Fax #: Email:	(b) (6)
Name of Institution: New York U (Assurance number: A 3435	Trussman School of Medicine
Did incident involve PHS funded activity? Punding component: Was funding component contacted (if necessary):	
What happened? Occupation of Heatel groups animal but not enrolled is	a strong Lat 11.5
Species involved: Personnel involved: Dates and times: Animal deaths:	e responsibility.
Projected plan and schedule for corréction/prevention	
Warring among all do	partiral to get all
Projected submission to OLAW of final report from	Institutional Official:
OFFICE USE ONLY	a