



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

July 12, 2021

Re: Animal Welfare Assurance
A3317-01 [OLAW Case H]

Dr. Stacey Bloom
Vice Provost for Research
New York University
70 South Washington Square South
New York, NY 10012

Dear Dr. Bloom,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 9, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at New York University, following up on an initial telephone report on June 28, 2021. According to the information provided, OLAW understands that an expired analgesic was given to one mouse. No adverse effects were reported with the mouse due to receipt of the expired drug.

The corrective actions consisted of the Principal Investigator setting calendar reminders of drug expiration dates and having the laboratory manager also set these reminders independently. The institutional program which monitors controlled drugs and expiration dates has resumed its responsibilities after being on hiatus due to the pandemic.

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 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



NEW YORK UNIVERSITY

A private university in the public service

University Animal Welfare Committee
15 Washington Place #1-H
New York, NY 10003
Phone 212-998-4256, Fax 212-995-4029

July 9, 2021

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

New York University, Washington Square Campus, in accordance with Assurance A3317-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident involving the use of an expired analgesic in a mouse procedure on a Principal Investigator's (PI) IACUC approved animal study protocol. The protocol is supported by NIH grant R01DC018802-01.

This incident was first reported to Dr. Axel Wolff, OLAW, on June 28, 2021 via a telephone call by Dr. Mark Klinger, DVM, DACLAM, Director of The Office of Veterinary Resources (OVR).

On May 11, during a semiannual inspection of research laboratories, members of the IACUC found expired Buprenorphine in the drug locker of the PI's lab and records indicate it had been administered to an animal on 3/31/21 which was after the date of expiration. This was discussed with the IACUC at the convened meeting on 6/17/21 and subsequently reported to the Institutional Official (IO).

The animal's health records did not indicate any complications resulting from the use of the expired drug and therefore, the protocol remained active during the IACUC's review of this incident. The PI was informed of the finding shortly after the semiannual inspection and in a formal response to the IACUC, took responsibility and expressed regret for the oversight and assured that it would not recur. To address the situation, the following corrective actions have been implemented by the PI:

To ensure that expired drugs are not administered moving forward, we are incorporating a two-pronged approach. First, I (the PI) will personally set calendar reminders regarding the expiration date of all drugs in the lab for 1 month prior to each drug's expiration date. These reminders will serve as a timely warning that we need to replenish our supply and to ensure that mice never receive expired drugs. As an additional backup, our lab manager will also set calendar reminders independently, acting as a redundant failsafe to ensure that this does not fall through the cracks.

At the June 17, 2021 meeting, the IACUC discussed and accepted the corrective action plan as submitted by the PI. During the meeting, it was noted that there had been a program in place for at least 3 years shared by Research Lab Safety (RLS) and OVR involving monthly scheduled inspections of research labs for appropriate use and documentation of controlled substances and inspection of drugs for expiration and collection, if expired. Unfortunately, that program lapsed due to Covid constraints related to on-site staffing over the past year. The IACUC was assured that the program would be re-instituted immediately, which it has.

New York University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Mark Klinger, DVM, Director, Office of Veterinary Resources.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Stacie Bloom
Vice Provost for Research
New York University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 9, 2021 11:38 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Non-compliance Report_ NYU _A3317-01

Thank you for this report, (b) (6) We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Friday, July 9, 2021 11:18 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Mark M Klinger <mark.klinger@nyu.edu>; Stacie Grossman Bloom <blooms03@nyu.edu>; (b) (6)
Subject: Non-compliance Report_ NYU _A3317-01

Dear Dr. Wolff,

The attached is a report of non-compliance for New York University, Washington Square Campus.

If you need any additional information, please let me know.

Thanks very much.

Best,

(b) (6)





Initial Report of Noncompliance

By: (b) (6)

Date: 6/28/21

Time: 3:45

Name of Person reporting: MARK Klinger
 Telephone #: (b) (6)
 Fax #: (b) (6)
 Email: (b) (6)

Name of Institution: New York U
 Assurance number: A3317

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

What happened?

1 mouse given expired analgesics.
No adverse effects.

Species involved: Mouse

Personnel involved: _____

Dates and times: _____

Animal deaths: _____

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

Projected submission to OLAW of final report from Institutional Official: _____

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Case # _____