



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) 402-7065

December 13, 2018

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

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 December 11, 2018 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 November 15, 2018. According to the information provided, OLAW understands that the veterinary staff was not notified about weight loss in a nonhuman primate on a controlled water access behavioral training study. The protocol called for removal of animals from study when a specified loss of weight had been reached, but this was not done.

The corrective actions consisted of assessing, monitoring, and providing veterinary care to the monkey. The laboratory staff was retrained and monthly meetings will be held between the veterinarians and researchers. A targeted database will be used to track the care and use of the primates on study.

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



STACIE GROSSMAN BLOOM
Vice Provost for Research
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December 11, 2018

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 (NYUWSC), in accordance with Assurance A3317-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding the failure of a research laboratory to adhere to IACUC procedures pertaining to the use of a non-human primate involved in controlled water access behavioral training. This incident was first reported to your attention on November 15th, 2018 via a telephone call by Mark Klinger, DVM, DACLAM, Attending Veterinarian and Director, Office of Veterinary Resources (OVR).

The animal involved (USDA ID#: RQ6843) was used under University Animal Welfare Committee (UAWC) approved protocol number 05-1249 titled "Cortical Mechanisms for Hand-Eye Coordination" which is NEI funded by grant # 5R01EY024067-05.

On October 15th, 2018, OVR veterinary staff were contacted via email by the Principal Investigator's laboratory expressing concern over a primate that had undergone behavioral testing and been returned to its cage. Following assessment, monitoring and veterinary care, an investigation was conducted into the events surrounding this animal's use. The investigation determined that guidelines related to notification of veterinary staff for animal health evaluation and removal of animals from study were not followed in accordance with procedures for controlled water access as detailed in POP-033 *NHP Controlled Water Access* and SOP 400-012-00 *NHP Veterinary care and health monitoring for Macaque Species in Controlled Water Access (CWA) Behavioral Studies*.

The following corrective actions will be implemented in response to these issues: The Attending Veterinarian and Director of Veterinary Clinical Medicine and Associate Director of the Office of Veterinary Resources (OVR) will meet with the Principal Investigator in December of 2018 to put in place corrective actions to assure future compliance. Corrective actions will comprise an initial training session with all lab members to review POP-033 and SOP-400-012-00. This initial training session will be followed by regular scheduled monthly meetings between OVR veterinary staff and lab

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staff to review the status and well-being of their individual primates on study. Aside from the detailed daily hand written health records being maintained in the animal facility, a targeted database listing the care and use of primates on study will be used for review at the scheduled meetings. General comments on each primate on study may be discussed to maintain productive communication between the lab and veterinary staff.

At their meeting on November 15th, 2018, the NYU WSC UAWC (IACUC) reviewed this incident, proposed corrective actions, and recommended that the IO report the incident to OLAW.

New York University is committed to the highest standards of ethical and humane animal care and use in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Chiye Aoki PhD, UAWC Chair.

Thank you for your consideration of this matter.

Sincerely,

 (b) (6)

Stacie Bloom, PhD
Vice Provost for Research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 13, 2018 7:38 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 respond soon.

Axel Wolff

From: (b) (6)
Sent: Wednesday, December 12, 2018 4:55 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Stacie Grossman Bloom <blooms03@nyu.edu>; (b) (6) mark.klinger@nyu.edu; Chiye Aoki <ca3@nyu.edu>
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 have any questions or concerns, please let me know.

Thanks very much,

(b) (6)





Initial Report of Noncompliance

By: aw

Date: 11/15/18

Time: 5:00

Name of Person reporting: Mark Kleiger Attending Vet
 Telephone #: (b)(6)
 Fax #:
 Email:

Name of Institution: New York University - Wash. Square
 Assurance number: A-3317

Did incident involve PHS funded activity? Yes

Funding component: NEI

Was funding component contacted (if necessary): _____

What happened?

Protocol called for 5% weight loss to notify vet. If over 10% loss take off study but it didn't occur. Monday 11/15/18

Species involved: Monkey

Personnel involved:

Dates and times: 10/13-15/18

Animal deaths: NO

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

Retain lab, counsel to call vets

Projected submission to OLAW of final report from Institutional Official: End of Dec

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Case # _____