



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

March 30, 2018

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

Dr. Paul Horn
Senior Vice Provost for Research
New York University
70 South Washington Square South
New York, NY 10012

Dear Dr. Horn,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 28, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at New York University Washington Square Campus. According to the information provided, OLAW understands that a nonhuman primate was transferred from one protocol to another without appropriate review and approval by the Institutional Animal Care and Use Committee (IACUC). The initial protocol involved awake brain recording while the second one involves use of paralytics under anesthesia for one week for brain recording followed by euthanasia. The acute study is closely monitored by research and veterinary staff and the Principal Investigator (PI) is required to notify the IACUC and Office of Veterinary Resources prior to scheduling the procedure. The transfer request did not specify that animals may be used on the acute study and did not list the number of the originating protocol.

The corrective action consisted of requiring the PI to provide the IACUC and veterinary staff with the protocol numbers of the originating protocols to ensure that the animals have been approved to participate in the study. The protocol was amended to account for animals that had been previously transferred.

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
Robert Gibbens, D.V.M., USDA-APHIS-AC



PAUL HORN
Distinguished Scientist in Residence
Senior Vice Provost for Research
Office of the Provost

Office of the Provost
Elmer Holmes Bobst Library
70 Washington Square South, Room 1228
New York, New York 10012-1091

P: 212 998 3228
F: 212 995 4300
paul.horn@nyu.edu

March 28, 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 transfer of an animal from IACUC approved protocol 07-1290 titled *Quantitative Studies of Visual Pathways* to IACUC approved protocol 08-1306/00-1051 titled *Neurophysiology of the Central Visual System* without appropriate IACUC review and approval. Both studies are headed by the same principal investigator and are NIH funded by grant(s) # EY22428, EY24914, Simons Foundation 328059 and 543019SP1. This incident was first reported to your attention on March 16, 2018 via a telephone call by Mark Klinger, DVM, DACLAM, Attending Veterinarian and Director, Office of Veterinary Resources (OVR).

On December 7, 2017 a request to the UAWC and OVR was sent for transfer of a Macaque primate from protocol 07-1290 involving awake brain recording to protocol 08-1306/00-1051. Protocol 00-1051 involves brain recording under continuous IV general anesthesia utilizing an opioid along with use of a paralytic for approximately one week (acute study). At the end of the recording period, animals are then overdosed with a Na pentobarbital-based euthanasia solution under general anesthesia and the brain is perfused for further study.

OVR veterinary staff routinely assist in induction and initial set up of animals undergoing the acute study. Maintenance and monitoring of adequate anesthesia is provided by research staff present in shifts over 24 hour periods throughout the course of the study. Physiologic parameters and anesthetic depth along with experimental recording of brain function is documented continuously at regular intervals. Veterinarians make unannounced visits at various time points, at least once daily, and upon request, monitor and assist in anesthetic maintenance and note findings.

Due to the nature of the acute study, the PI is required to notify both the IACUC and OVR at least three days prior to scheduling the procedure. When the request to transfer was sent on December 7th, protocol 07-1290 did not specify the possibility that animals may be transferred to the prolonged acute study and it listed anesthetic overdose and perfusion as its

scientific endpoint. Furthermore, the email notification of the transfer sent to the UAWC did not stipulate the protocol number the animal originated from.

The IACUC and Principal Investigator discovered the oversight upon request for a similar transfer on March 15, 2018. An evaluation of animal transfers into the acute study was initiated during the 3 year review of protocol 00-1051 [December 15, 2017] when it was noted that the study had expanded to include transfer of animals from other protocols. Therefore, the UAWC determined that the PI must provide the UAWC and Veterinary staff with the approved protocol numbers from which animals would be transferred to ensure that those animals were approved to participate in the study and assure compliance. Evaluation of the most recent transfer request (March 15) determined that protocol 07-1290 had not been granted approval for the transfer of animals to the acute study. Therefore, amendments were generated, reviewed and approved for each of two animal transferred into the acute study that occurred subsequent to the Dec 7 2017 noncompliant incident.

At their meeting on March 22, 2018, the NYU WSC UAWC (IACUC) reviewed this incident, the corrective action included in the new protocol covering the acute study, 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)

Paul Horn, PhD,
Senior Vice Provost for Research
Institutional Official
New York University.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, March 29, 2018 7:13 AM
To: (b) (6)@nyu.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Non-compliance Report_NYU_A3317-01

Thank you for this report. We will respond soon.
Axel Wolff

From: (b) (6)@nyu.edu
Sent: Wednesday, March 28, 2018 3:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
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.

Thank you very much,

(b) (6)

