



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

July 10, 2019

Re: Animal Welfare Assurance  
A3007-01 [OLAW Case 2D]

G. Michael Purdy,, Ph.D.  
Executive Vice President for Research  
Columbia University Medical Center  
535 West 116<sup>th</sup> St. – 313 Low Library MC 4310  
New York, NY 10027

Dear Dr. Purdy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 9, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Columbia University, following up on an initial telephone report on March 19, 2019. According to the information provided, OLAW understands that an associate research scientist failed to administer medication to a nonhuman primate over two days but had checked off in the record that the drugs had been given. Animal room access records and security camera footage verified that the individual had not entered the animal room. The same issue occurred over another weekend. There was no harm to the monkey from not receiving the medication.

The corrective actions consisted of revoking the individual's animal use privileges for one year. After that time, animal use privileges will only be restored following training on animal health records and on humane care and use of animals.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Executive Director, IACUC

COLUMBIA UNIVERSITY  
IN THE CITY OF NEW YORK

EXECUTIVE VICE PRESIDENT FOR RESEARCH

July 9, 2019

Brent Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6705 Rockledge Drive  
Suite 360, MSC 7982  
Bethesda, MD 20892-7982

Re: Columbia University  
Animal Welfare Assurance # D16-00003 (A3007-01)

Dear Dr. Morse,

Columbia University (the "University") previously notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an allegation concerning falsification of animal health records. The research under the associated protocol (AAAX1455) was supported by the Public Health Service under NIH grant # 5U19 AI131474-02.

This letter reports the results of a review of the incident and the corrective actions taken by the Institutional Animal Care Use Committee ("IACUC" or the "Committee").

**Background and Investigation**

On February 22, 2019, Dr. Mary Jo Shepherd, Executive Director of the IACUC, received a phone call from a veterinarian in the University's Institute of Comparative Medicine ("ICM") informing her that a veterinary postdoctoral research scientist in ICM had reported an instance of possible falsification of animal health records. The allegation was that an associate research scientist who was responsible for administering medication to a nonhuman primate during the holiday weekend of February 16-18, 2019 had pre-checked off boxes in the animal's health record indicating that the drugs had been administered. The Attending Veterinarian ("AV") was informed of the allegation by his staff.

Dr. Shepherd notified the IACUC Chair of the allegation and Dr. Shepherd and the Chair investigated further. The investigative team subsequently met with the principal investigator on the protocol and the associate research scientist alleged to have falsified the records, the veterinary postdoctoral research scientist who submitted the allegation and the AV. The investigative team was also provided with identification card animal room access records and was informed of the results of an analysis of security camera footage, which demonstrated that

the associate research scientist did not enter the animal room where the nonhuman primate was housed during two of the three days of the long weekend. The associate research scientist stated that he had programmed pumps on Friday to deliver the drugs on Saturday, but admitted that he did not check on the animal on Saturday and that the animal did not receive the prescribed drugs on Sunday.

During the investigation, the investigative team learned that the same individual was also responsible for administering drugs to the same animal on the previous weekend, February 9-10, 2019. After review of animal room access records for that weekend, the investigative team determined that he also had not entered the room where the animal was housed on February 9 or 10, and that medications were apparently not given as prescribed to the animal over that weekend as well.

The ICM reported that the animal in question had previously undergone total body irradiation, which causes immunosuppression, but that there was no clinical evidence that the animal was harmed from any lack of administration of the prescribed medications.

### **Corrective Actions**

A report from the investigative team was provided to the IACUC and a convened meeting of a quorum of the Committee was held on April 3, 2019. Following review of the facts and discussion, the Committee voted to impose the following corrective measures:

1. Animal use privileges of the individual responsible were revoked for 12 months. During this time, he may not participate in any activities involving live animals at this institution.
2. After 12 months, if the individual responsible wishes to regain in vivo privileges, he will be required to complete all routine mandatory training and special ICM training concerning proper maintenance of animal health records. In addition, he will be required to undergo sensitivity training regarding the use of living animals for research.

Columbia University remains committed to achievement and maintenance of the highest standards of laboratory animal care and use. If you have any further questions concerning this report, please contact Dr. Shepherd at (b) (6)

Sincerely,

(b) (6)

G. Michael Purdy, Ph.D.  
Executive Vice President for Research

cc:

(b) (6)

MJ Shepherd, D.V.M.

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

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, July 10, 2019 12:04 PM  
**To:** Shepherd, Mary J.  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Compliance Report from Columbia University

Thanks MJ. We'll send a response soon.  
Axel

---

**From:** Shepherd, Mary J. <ms4387@cumc.columbia.edu>  
**Sent:** Tuesday, July 9, 2019 10:30 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Compliance Report from Columbia University

Please see the attached report. Let me know if you have any questions or concerns. Thank you. MJ

Mary Jo (MJ) Shepherd, DVM, CPIA  
Executive Director of the Office of the IACUC  
Columbia University

(b) (6)



## Initial Report of Noncompliance

By: *[Signature]*Date: *3/19/19*Time: *2:50*Name of Person reporting: *MJ Shenker*Telephone #: *(b) (6)*

Fax #:

Email:

Name of Institution: *Columbia University*Assurance number: *A3007*Did incident involve PHS funded activity? *Yes*

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

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

What happened? *Falsification of animal observation/IX records by post-doc fellow. Pre-dating + post-dating entries*Species involved: *NHP*Personnel involved: *Post-doc MD*Dates and times: *Weekend of 2/16/19*Animal deaths: *No. No observable harm to animal.*

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

*Removed post-doc from all in vivo work.*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

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