



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 10, 2019

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

G. Michael Purdy, Ph.D.
Executive Vice President for Research
Columbia University Medical Center
535 West 116th St. — (b) (4) Low Library MC 4310
New York, NY 10027

Dear Dr. Purdy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 5, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Columbia University. Your letter supplements the information in the initial prompt telephone report made by Dr. Shepherd on July 31, 2019. According to the information provided, OLAW understands that on April 24, 2019 the Executive Director of the IACUC was notified of a concern that two nonhuman primates were being water restricted as behavioral motivation for approximately 40 days although they were not actively being studied during that period. During this period the animals did receive daily fruit. The principal investigator self-reported the issue later that same day. The animals were immediately put on ad lib water and assessed by a veterinarian and determined to be in good health. The associated activity was funded by the PHS.

The IACUC imposed the following corrective measures: the PI will conduct a group meeting of laboratory members to discuss the incident and emphasize the critical importance of adhering to fluid regulation procedures. A second meeting will be held with the two responsible individuals to review those procedures again. Warning letters will be placed in those two individuals' files and they will undergo sensitivity training by a veterinarian. A post-doctoral fellow will be appointed to review the water logs for all animals in the laboratory on a regular basis.

OLAW appreciates the consideration of this matter by Columbia University, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, correct the noncompliance, and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact
Mary Jo Shepherd, DVM, IACUC Office Director
Dr. Robert M. Gibbens, USDA, APHIS, AC

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK
EXECUTIVE VICE PRESIDENT FOR RESEARCH

December 6, 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. Wolff,

On July 31, 2019, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident in which two nonhuman primates ("NHP") were inadvertently kept on restricted fluid intake although they were not actively being studied at the time. The research under the associated protocol was supported by the Public Health Service under NIH grant #5R01MH082017-12.

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

Background and Investigation

On April 24, 2019, Dr. Mary Jo Shepherd, Executive Director of the IACUC, received a phone call regarding a concern about two nonhuman primates in a study using water regulation for behavioral motivation. The reported concern was that the animals' fluid intake had been restricted for a period of approximately 40 days although they were not actively being studied during that period. Later that same day, the principal investigator on the study protocol independently contacted Dr. Shepherd to report the same issue. The principal investigator also notified a veterinarian from the Institute of Comparative Medicine (ICM), who examined the animals and determined that they were in good health. The animals had received fruit every day during the period when fluid intake was restricted. They were immediately put on ad lib water when the inappropriate fluid restriction was discovered.

Dr. Shepherd notified the IACUC Chair when she learned of the incident and an investigation was initiated. The IACUC investigative team (Dr. Shepherd and another IACUC member) met with the

principal investigator, the individual who initially reported the concern to Dr. Shepherd, and the two individuals determined to be responsible for the oversight.

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 August 8, 2019. Following review of the facts and discussion, the Committee voted to impose the following corrective measures:

1. The investigator was required to fully implement and continue to adhere to his plan for correction, which included a group meeting of laboratory members to discuss the incident and to emphasize the critical importance of adhering to fluid regulation procedures in the approved protocol; a separate meeting with the two individuals responsible to review those procedures again; placement of warning letters in the Human Resources files of the individuals responsible; appointment of a postdoctoral fellow in the laboratory to review the water logs for all animals in the laboratory on a regular basis; and sensitivity training for the two individuals responsible by a veterinarian from the ICM.

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)

Brian Karolewski, D.V.M.
MJ Shepherd, D.V.M.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, December 10, 2019 8:54 AM
To: Shepherd, Mary J.; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Mary J. Shepherd
Subject: RE: Compliance Report From Columbia University

Thank you for providing this final report Dr. Shepherd. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Shepherd, Mary J. [mailto:ms4387@cumc.columbia.edu]
Sent: Tuesday, December 10, 2019 5:08 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Mary J. Shepherd <ms4387@columbia.edu>
Subject: Compliance Report From Columbia University

Please let me know if there are any question of concerns. Thank you. MJ

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



Initial Report of Noncompliance

By: BJMDate: 7/31/19Time: 12:50Name of Person reporting: M. J. Shepherd, DVMTelephone #: (b) (6)

Fax #:

Email:

Name of Institution: Columbia UnivAssurance number: A3007Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? NHPs in lab, water restricted 30+ days w/o relief days. Animals O.K. per vet.Species involved: NHPsPersonnel involved: ResearchDates and times: April 2019Animal deaths: No

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____