



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

September 4, 2019

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

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

Dear Dr. Purdy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 27, 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 April 16, 2019. According to the information provided, OLAW understands that on April 8, 2019 the Executive Director of the IACUC was notified by a principal investigator that a nonhuman primate on a study using water regulation for behavior motivation was inadvertently not provided drinking water for three days. During this period the animal did receive peanuts and fruit. The animal was immediately offered water and assessed by a veterinarian. The animal appeared normal at that time. There had been miscommunication between members of the laboratory concerning responsibility for providing water over the weekend and in addition, the ICM husbandry technician failed to provide backup water as required. This activity was funded by the PHS.

The IACUC imposed the following corrective measures: a single laboratory technician will be responsible for providing water for the animals for the weekend each Friday with a second laboratory member assigned to double-check; all ICM personnel were retrained regarding water regulation in nonhuman primates and in their backup role for assuring water provision, and; the ICM has instituted an enhanced response by immediately providing water to any nonhuman primate where there is incomplete or missing documentation for that animal.

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

August 27, 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,

On April 19, 2019, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident concerning inadvertent lack of provision of drinking water to a nonhuman primate for 3 days. The research under the associated protocol was supported by the Public Health Service under NIH grants # 5R01EY017039-10, 5P30EY019007-08 and 5R21EY028749-02.

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" or the "Committee").

Background and Investigation

On April 8, 2019, a principal investigator telephoned the Executive Director of the IACUC, Dr. Mary Jo Shepherd, and informed her that a nonhuman primate in a study using water regulation for behavioral motivation was inadvertently not provided drinking water for 3 days. When the oversight was discovered, a veterinarian from the Institute of Comparative Medicine ("ICM") immediately assessed the animal for well-being and the animal was immediately offered approximately 500 ml of water. At that time, the animal appeared normal. The animal did receive peanuts and fruit during the time it was without water.

Dr. Shepherd notified the IACUC Chair when she learned of the incident, and an investigation was initiated. The investigative team subsequently met with the principal investigator, the two members of his laboratory responsible for the oversight, as well as with the animal husbandry technician assigned to the care of the animal over the weekend, and the ICM veterinarian who assessed the animal for well-being after the oversight was identified. The investigative team

determined that the incident was due to a miscommunication between members of the laboratory concerning responsibility for providing water bottles for the animal for that weekend and that, in addition, the ICM husbandry technician incorrectly assumed that water had been provided despite the lack of appropriate documentation, and so failed to provide backup water as required.

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 June 13, 2019. Following review of the facts and discussion, the Committee accepted the following corrective measures:

1. The investigator was required to fully implement and continue to adhere to his plan for correction, which included assigning a single technician in the laboratory the task of filling animals' water bottles for the weekend each Friday, with a second laboratory member assigned to check that the bottles are filled appropriately.
2. The ICM veterinary staff retrained all ICM personnel in all aspects of water regulation in nonhuman primates and in their backup role for assuring water provision.

In addition, following this incident, the ICM instituted an enhanced response to deficiencies in documentation concerning the provision of water to nonhuman primates on studies involving water regulation, and began immediately providing water to any nonhuman primate in the event the documentation for that animal for the previous day is missing or incomplete.

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.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, September 03, 2019 12:47 PM
To: Shepherd, Mary J.; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Report from Columbia University

Thank you MJ. We'll 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, September 03, 2019 11:46 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Compliance Report from Columbia University

See attached letter. Please 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: BMDate: 4/16/19Time: 3:05Name of Person reporting: M.J. Shepherd, DVMTelephone #: (b) (6)

Fax #:

Email:

Name of Institution: Columbia Univ.Assurance number: A3007Did incident involve PHS funded activity? _____Funding component: _____Was funding component contacted (if necessary): _____

What happened? Animal on water restriction for behavior study, but no water given for 3 days. Missed by researchers + care staff. Animal O.K., given fruit.

Species involved: Macaque

Personnel involved: Researcher + care staff

Dates and times: March 5, 6 + 7

Animal deaths: No

Projected plan and schedule for correction/prevention (if known): _____One staff member fired.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____