



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

April 10, 2019

Re: Animal Welfare Assurance
A3007-01 [OLAW Case 1Z]

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 March 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 September 13, 2018. According to the information provided, OLAW understands that on August 30, 2018 while a baboon was undergoing a laparotomy under an approved protocol, a veterinarian gave permission to the surgical team to also perform an oophorectomy citing veterinary discretion and long-term benefits to the animal. There was no emergency situation or any problematic clinical condition with the animal associated with the presence of the animal's ovaries at the time. Subsequent to an IACUC investigation it was determined that the exercise of veterinary discretion was not appropriate in this instance. This activity was funded by the PHS (1R01DK105503).

Corrective actions included the AV reviewing proper procedures for use of veterinary discretion with his veterinary staff to assure compliance. The AV also worked with his staff to assure proper and enhanced communication with researchers before and during surgical procedures. The IACUC has also approved a modification to the approved protocol allowing oophorectomies in female baboons.

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 with the IACUC's interpretation of the exercise of veterinary discretion and 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
Bob Pike, Chief Grants Management Officer, NIDDK

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

March 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 September 19, 2018, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident concerning conduct of a surgical procedure while a protocol modification to add the procedure was still under review by the Institutional Animal Care and Use Committee ("IACUC" or the "Committee"). The research under the associated protocol (AAAT9462) was supported by the Public Health Service under a subaward to the University under NIH grant # 1R01 DK105503.

This letter reports the results of a review of the incident and the corrective actions approved by the IACUC.

Background and Investigation

On August 30, 2018, a baboon was undergoing laparotomy under an approved protocol while a modification to add oophorectomies in female baboons to the protocol was still under review by the IACUC. A member of the surgical team on the protocol asked a veterinarian from the Institute of Comparative Medicine ("ICM") whether they could conduct an oophorectomy on the animal in addition to the approved procedure, and the veterinarian allowed them to do so, basing the decision on the exercise of veterinary discretion. The veterinarian cited resultant long term benefits to the animal, even though there was no emergency situation nor any problematic clinical condition with the animal associated with the presence of the animal's ovaries.

The Executive Director of the IACUC, Dr. Mary Jo 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 and the other member of the surgical team, as well as with the Attending Veterinarian (AV), Dr. Brian Karolewski, and each of the three veterinarians who were either involved in or aware that the oophorectomy was performed on the baboon.

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 October 11, 2018. The report included the investigative team's conclusion that, while the exercise of veterinary discretion was not appropriate in this instance, the oophorectomy would benefit the animal in the long run. Following review of the facts and discussion, the Committee accepted the following corrective measures implemented by the ICM following the incident:

1. The AV reviewed proper procedures for use of veterinary discretion with his veterinary staff to assure compliance.
2. The AV worked with his staff to assure proper and enhanced communication with researchers before and during surgical procedures.

Since this incident occurred, the IACUC has approved the proposed modification allowing oophorectomies in female baboons to the approved protocol.

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.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 29, 2019 6:52 AM
To: Shepherd, Mary J.
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Columbia University Compliance Reports

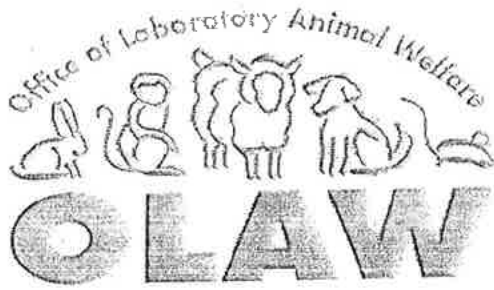
Thanks for these 3 reports, MJ. We will send responses soon.
Axel Wolff

From: Shepherd, Mary J. <ms4387@cumc.columbia.edu>
Sent: Thursday, March 28, 2019 2:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Columbia University Compliance Reports

Attached are three compliance reports from Columbia University. 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: EMDate: 9/13/18Time: 3:00Name of Person reporting: M. J. Shepherd, DVMTelephone #: (b)(6)

Fax #:

Email:

Name of Institution: Columbia Univ.Assurance number: A3007Did incident involve PHS funded activity? Yes?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Transplant surgery. Also did ovariectomy which had not yet been IACUC approved. Animal recovered fine.

Species involved: BaboonPersonnel involved: Researcher

Dates and times:

Animal 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 # _____