



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

June 3, 2019

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

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 May 30, 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 February 13, 2019. According to the information provided, OLAW understands that an investigator was conducting surgery inappropriately on a mouse. Specifically, aseptic technique was not used, there was no thermal support, the surgical approach was different from what was described in the protocol, and there were no surgical/anesthesia records.

The corrective actions consisted of counseling the Principal Investigator and laboratory member responsible. The procedure involved was terminated, all staff took online and hands on veterinary retraining, and all staff was retrained on regulatory requirements.

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 institution to comply with the PHS Policy. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Mary Jo Shepherd, D.V.M., IACUC Office Director

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

May 30, 2019

Axel Wolff, M.S., D.V.M.  
Deputy Director  
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 February 13, 2019, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident in which an individual was conducting mouse survival surgery not in compliance with the applicable protocol. The research under the associated protocol (AAAU2465) was supported by the Public Health Service under NIH grant # 1R01 AI142428-01.

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 February 7, 2019, an Institute of Comparative Medicine ("ICM") veterinarian notified Dr. Mary Jo Shepherd, Executive Director of the IACUC, that an individual was conducting mouse survival surgery out of compliance with the applicable protocol. The violations observed included lack of aseptic technique, failure to use a heating pad; use of a surgical approach other than the one described in the protocol; and lack of surgical/anesthesia records.

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 and the researcher who had conducted the surgery in question, and the ICM veterinarian who made the observations.

### **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. The investigator was required to fully implement and continue to adhere to his plan for correction, which included termination of the experiment observed by the ICM veterinarian, extensive online and hands on veterinary retraining, and in person regulatory retraining for all individuals listed on the 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)  
MJ Shepherd, D.V.M.

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, May 31, 2019 6:49 AM  
**To:** Shepherd, Mary J.  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Columbia University Compliance Report

Thank you for this report, MJ. We'll respond soon.  
Axel

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**From:** Shepherd, Mary J. <ms4387@cumc.columbia.edu>  
**Sent:** Thursday, May 30, 2019 12:33 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Columbia University Compliance Report

Please see the attached report and let me know if you have any questions. 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: *aw*Date: *2/13/19*Time: *10:00*Name of Person reporting: *MS Shepherd*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?

*Survival surgery in 6 mice, all anesthetized at same time,  
incisions open, not following protocol, not aseptic*

Species involved: *mice*

Personnel involved:

Dates and times:

Animal deaths: *no*

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

*Retrain, work under vet monitoring  
Lab taking more training*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

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