



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) 480-3387

October 27, 2021

Re: Animal Welfare Assurance
A3007-01 [OLAW Case 20]

Deborah Stiles
Vice President for Research Operations and Policy
Columbia University
535 West 116th St. - (b) (4) Low Library MC 4310
New York, NY 10027

Dear Ms. Stiles,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 22, 2021 letter reporting several instances 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 August 18, 2021. According to the information provided, OLAW understands that a laboratory conducting non-survival surgery in mice failed to maintain records, used an anesthetic not approved in the protocol, and conducted the activity in a laboratory which had not been approved for this purpose by the Institutional Animal Care and Use Committee (IACUC).

The corrective actions consisted of stopping additional surgeries until the laboratory staff was retrained on anesthesia and record keeping, amending the protocol to include the laboratory as a site for performing non-survival surgery, having a veterinarian counsel the staff on proper anesthetic use, and counseling the laboratory staff on appropriate animal care and use.

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 IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Vice President for Research Operations and Policy
Chief Operating Officer

October 22, 2021

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 August 18, 2021, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of a reportable situation involving multiple forms of noncompliance observed during an Institutional Animal Care and Use Committee ("IACUC" or the "Committee") semiannual inspection. The animals involved were being used in research supported by the Public Health Service under NIH grant number 5R01NS109858-03

This letter reports the results of a review of the matter and the corrective actions taken by the IACUC.

Background and Investigation

On August 11, 2021, an IACUC Compliance and Training Coordinator notified (b) (6) that IACUC members conducting a semiannual inspection found multiple forms of noncompliance when a laboratory was inspected. The noncompliance included lack of records for non-survival surgery in mice, use of an anesthetic for non-survival surgery in mice that was not approved in the protocol, and conduct of non-survival surgery in mice in a laboratory location that was not approved for such use.

(b) (6) notified the IACUC Chair when she learned of the inspection findings and an investigation was initiated. The IACUC investigative team ((b) (6) and another IACUC member) met with the principal investigator and the individual primarily responsible for the noncompliance. They also met separately with the IACUC Compliance and Training Coordinator that participated in the inspection.

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 7, 2021. Following review of the facts and discussion, the Committee imposed the following corrective measures:

The investigator was required to fully implement and continue to adhere to his plan for correction, which included stoppage of conduct of all non-survival surgery in mice until laboratory members were retrained on rodent anesthesia and proper record keeping, submission of a protocol modification to add the laboratory location for non-survival surgery, and consultation with an Institute of Comparative Medicine ("ICM") veterinarian regarding the proper use of anesthesia. The investigator also arranged for (b) (6) to meet with his laboratory members via Zoom to discuss regulatory requirements regarding care and use of laboratory animals, as well as compliance.

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 (b) (6)

Sincerely,

(b) (6)

Deborah F. Stiles, J.D.

Vice President for Research Operations and Policy

Chief Operating Officer, Office of the Executive Vice President for Research

cc:

(b) (6)

Wolff, Axel (NIH/OD) [E]

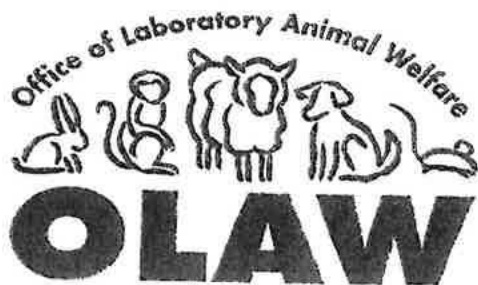
From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, October 27, 2021 7:32 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Columbia University Compliance Report

Thank you for this report, (b) (6) We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Monday, October 25, 2021 1:43 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Columbia University Compliance Report

Please see attached and let me know if there are any questions or concerns. Thank you. (b) (6)

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 8/18/21

Time: 11:20

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

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

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*No records for survival surgery in mice,
used isoflurane rather than TBE drug, lab not approved for surgery*

Species involved: Mouse

Personnel involved:

Dates and times:

Animal deaths: 0

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

Retrain, stop surgery

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____