



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

February 2, 2023

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

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 January 25, 2023 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 on October 19, 2022. According to the information provided, OLAW understands that on October 17, 2022, your institution was notified that an unapproved non-survival surgery had been performed on three mice. Although the research was PHS funded, no funds were used for the conduct of the unapproved activity.

The principal investigator took full responsibility and stated that it was an oversight, and he described measures he had put in place to prevent any recurrence, which included posting in multiple locations, a list of presently approved laboratory protocols and their expiration dates. Additionally, during weekly laboratory meetings, he and his staff will review the list of the group's approved protocols and their expiration dates.

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,

Brent C. Morse -S

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

Digitally signed by Brent C.
Morse -S
Date: 2023.02.02 08:12:10 -05'00'

cc: IACUC contact
Mary Jo Shepherd, DVM, IACUC Office Director

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Vice President for Research Operations and Policy
Chief Operating Officer

January 25, 2023

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 October 19, 2022, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of a reportable situation involving conduct of a non-survival surgical procedure in three mice without Institutional Animal Care and Use Committee ("IACUC") approval. The animals involved were being used in research supported by the Public Health Service under NIH grant numbers 5R01HL144852-03 and 5R35GM140880-02.

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

Background and Investigation

On October 17, 2022, an IACUC compliance monitor notified Dr. Mary Jo Shepherd, Executive Director of the Office of the IACUC, that an unapproved non-survival surgery had been performed on three mice.

Dr. Shepherd notified the IACUC Chair when she learned of the findings and an investigation was initiated. The IACUC investigative team (Dr. Shepherd and another IACUC member) met separately with the responsible principal investigator and the IACUC compliance monitor who brought the incident to Dr. Shepherd's attention. The principal investigator took full responsibility and stated that it was an oversight, and he described measures he had put in place to prevent any recurrence. The compliance monitor noted that the principal investigator's group had a good compliance history.

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Corrective Actions

A report from the investigative team was provided to the IACUC at a convened meeting of the Committee, at which a quorum was present, on December 8, 2022. Following review of the facts and discussion, the Committee imposed the following corrective measures:

1. The investigator was required to fully implement and continue to adhere to his plan for correction, which included posting in multiple locations, a list of presently approved laboratory protocols and their expiration dates.
2. Additionally, during weekly laboratory meetings, he and his staff will review the list of the group's approved protocols and their expiration dates.

Note that no federal funds were used for the conduct of this unapproved activity.

Columbia University remains committed to the 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)

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)

MJ Shepherd, D.V.M.

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 25, 2023 2:57 PM
To: Shepherd, Mary Jo
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Investigation Report

Good afternoon Mary Jo,

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: Shepherd, Mary Jo <ms4387@cumc.columbia.edu>
Sent: Wednesday, January 25, 2023 2:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: MJ Shepherd (ms4387@columbia.edu) <ms4387@columbia.edu>; (b) (6)
Subject: [EXTERNAL] Compliance Investigation Report

Attached is a compliance report from Columbia University. Let me know if there are any questions or concerns. Thank you. MJ

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

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

A3007-28



Initial Report of Noncompliance

By: BCM

Date: 10/19/2022

Time: 4:15

Name of Person reporting: MJ Shepherd, AV

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Columbia Univ

Assurance number: A3007

Did incident involve PHS funded activity? yes

Funding component:

Was funding component contacted (if necessary):

What happened? Protocol expired before the 3-year complete review was approved by the IACUC. During the interim, 3 mice underwent non-survival procedure without an approved protocol.

Species involved: mus musculus

Personnel involved: PI

Dates and times: Institution notified on 10/6/2022 (records review)

Animal deaths:

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

Protocol was eventually approved. PI accepted responsibility.

Projected submission to OLAW of final report from Institutional Official:

< 60 days.

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Case #