



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

May 5, 2022

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

Deborah Stiles
Vice President for Research Operations and Policy
Columbia University Medical Center
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 April 25, 2022 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 March 11, 2022. According to the information provided, OLAW understands that on March 3, 2022, your institution was notified that four mice had been housed in a laboratory for four days without IACUC approval. The associated activity was PHS-funded.

Corrective and preventive measures included counseling of lab members regarding adherence to the IACUC approved protocol and instructing them on the importance of contacting the IACUC or Institute of Comparative Medicine offices if they have any questions regarding post-procedure housing, or any other concerns. The IACUC Office Director met with the laboratory members to discuss regulatory requirements regarding care and use of laboratory animals, as well as compliance expectations.

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 -

Digitally signed by Brent C.
Morse -S

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Date: 2022.05.05 12:29:45 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

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

April 25, 2022

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 March 11, 2022, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of a reportable situation involving noncompliance observed during an Institutional Animal Care and Use Committee ("IACUC" or the "Committee") compliance monitoring visit to a lab. The animals involved were being used in research supported by the Public Health Service under NIH grant number 5P01HL087123-14.

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

Background and Investigation

On March 3, 2022, an IACUC Compliance and Training Coordinator notified Dr. Mary Jo Shepherd, Executive Director of the Office of the IACUC, that four mice had been housed in a laboratory for 4 days without approval.

Dr. Shepherd notified the IACUC Chair when she learned of the compliance monitor's findings and an investigation was initiated. The IACUC investigative team (Dr. Shepherd 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 who discovered and reported the noncompliance.

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Corrective Actions

A report from the investigative team was provided to the IACUC and a convened meeting of the Committee, at which a quorum was present, was held on April 14, 2022. 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 counseling of lab members regarding adherence to the IACUC approved protocol, and instructing them on the importance of contacting the IACUC or Institute of Comparative Medicine offices if they have any questions regarding post-procedure housing, or any other concerns. The investigator also arranged for Dr. Shepherd to meet with his laboratory members via Zoom to discuss regulatory requirements regarding care and use of laboratory animals, as well as compliance expectations.

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.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 27, 2022 7:28 AM
To: Shepherd, Mary Jo
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Report

Thank you for this report, MJ. We'll send a response soon.
Axel Wolff

From: Shepherd, Mary Jo <ms4387@cumc.columbia.edu>
Sent: Monday, April 25, 2022 4:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: 'MJ Shepherd <ms4387@columbia.edu>
Subject: [EXTERNAL] Compliance Report

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.

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



Initial Report of Noncompliance

By: BCM

Date: 3/11/2022

Time: 2:00

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? no

Funding component:

Was funding component contacted (if necessary):

What happened?

Four cages of mice found housed in lab for at least 3 days. Only approved for 8-10 hours.

Species involved: mus musculus

Personnel involved: Researcher

Dates and times:

Animal deaths:

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

In investigation

Projected submission to OLAW of final report from Institutional Official:

< 60 days. After 14 April.

OFFICE USE ONLY

Case #