



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

September 30, 2021

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

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 September 15, 2021 letter reporting a repeat instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Columbia University. This case number (-2L) has been re-opened due to the continued noncompliance. According to the information provided, OLAW understands that on June 7, 2021, the Institute of Comparative Medicine (ICM) Associate Director notified the Executive Director of the IACUC, that ICM personnel had once again observed overcrowding of mice in the same laboratory, despite counseling, retraining and an IACUC investigation. The associated activity was PHS-funded.

The matter was discussed at the June 10, 2021, IACUC meeting, where the Committee voted unanimously to suspend the associated protocol for 3 months.

Corrective and preventive measures: on August 31, 2021, the Executive Director of the IACUC and an ICM veterinarian provided the Principal Investigator and the members of his laboratory with a refresher training session regarding animal care and use compliance and proper procedures for mouse breeding/housing.

The Committee strongly recommended that the investigator outsource mouse breeding to prevent any future noncompliance. The Committee also informed the investigator that any future noncompliance regarding mouse cage overcrowding in the laboratory would result in permanent revocation of the investigator's privilege to breed mice at the University.

At the September 2, 2021, IACUC meeting, the Committee unanimously voted to lift the suspension.

Finally, as required by OLAW Notice NOT-OD-10-081, "Guidance on Confirming Appropriate Charges to NIH Awards during Periods of Noncompliance for Activities Involving Animals", the University confirmed that no unallowable costs for animal activities were charged to the grants supporting the research during the period of suspension of those activities. The University will send a separate confirmation that no such unallowable costs were charged during the suspension period to the NIH Institute/Center funding each award supporting research under the suspended protocol

As stated before, continuing noncompliance is of concern to OLAW, especially on PHS-funded activities. OLAW agrees with the IACUC that the use of public funds, and the use of animals in research, are privileges that must not be abused.

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, stop the ongoing 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, at this time.

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: 2021.10.01 08:30:12
-04'00'

cc: IACUC contact

Mary Jo Shepherd, DVM, IACUC Office Director

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

September 15, 2021

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 June 11, 2021, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of a reportable situation involving mouse cage overcrowding where the associated protocol was suspended by the Institutional Animal Care and Use Committee ("IACUC" or the "Committee") for a period of 3 months. This suspension came after a previous investigation into cage overcrowding in the same laboratory that was originally reported to OLAW via phone on March 10, 2021, followed by a letter dated May 24, 2021. The animals involved are being used in research supported by the Public Health Service under NIH grant numbers 5R01DK100342-09, 5R01DK120650-02, and 1R01HL152293-01.

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

Background

At its April 1, 2021, meeting, the IACUC closed the initial investigation into the mouse cage overcrowding. However, on June 7, 2021, the Institute of Comparative Medicine (ICM) Associate Director notified Dr. Mary Jo Shepherd, Executive Director of the IACUC, that ICM personnel had once again observed overcrowding of mice in the same laboratory, despite counseling, retraining and an IACUC investigation.

The matter was discussed at the June 10, 2021, IACUC meeting, where the Committee voted unanimously to suspend the associated protocol for 3 months.

At the September 2, 2021, IACUC meeting, the Committee unanimously voted to lift the suspension.

Corrective Actions

On August 31, 2021, Dr. Shepherd and an ICM veterinarian provided the Principal Investigator and the members of his laboratory with a refresher training session regarding animal care and use compliance and proper procedures for mouse breeding/housing.

The Committee strongly recommended that the investigator outsource mouse breeding to prevent any future noncompliance. The Committee also informed the investigator that any future noncompliance regarding mouse cage overcrowding in the laboratory would result in permanent revocation of the investigator's privilege to breed mice at the University.

Finally, as required by OLAW Notice NOT-OD-10-081, "Guidance on Confirming Appropriate Charges to NIH Awards during Periods of Noncompliance for Activities Involving Animals", the University hereby confirms that no unallowable costs for animal activities were charged to the grants supporting the research during the period of suspension of those activities. The University will send a separate confirmation that no such unallowable costs were charged during the suspension period to the NIH Institute/Center funding each award supporting research under the suspended 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)

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: Friday, September 17, 2021 7:37 AM
To: Shepherd, Mary Jo
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Report from Columbia University

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

From: Shepherd, Mary Jo <ms4387@cumc.columbia.edu>
Sent: Wednesday, September 15, 2021 3:37 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Shepherd, Mary Jo <ms4387@cumc.columbia.edu>
Subject: Compliance Report from Columbia University

See attached and 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



A 3007-2L
Reopened

Initial Report of Noncompliance

By: (b) (6)

Date: 6/11/21

Time: 2:00

Name of Person reporting: MJ Shepherd

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Columbia U

Assurance number: A3007

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary):

What happened?

Repeat noncompliance. Overcrowded mice in same room, same PI.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Suspend breeding protocol, put mice on holding protocol.
Recommend outsourcing breeding activities.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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FOR EXPRESS MAIL:

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6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

June 1, 2021

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

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 May 24, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Columbia University. According to the information provided, OLAW understands that on March 5, 2021, your institution was notified that a PI's laboratory was having an ongoing issue with overcrowding of mice, despite counseling on permissible mouse housing density. The associated activity was PHS-funded.

Corrective and preventive measure included requiring the investigator to fully implement and continue to adhere to his plan for correction, which included reducing the number of researchers and projects in his laboratory, and personal monitoring of mouse breeding colony management. The investigator and the members of his laboratory were also required to re-review the institutional policy on mouse housing density and to attend a mouse breeding colony management training session with veterinarians. The investigator was also required to identify one individual in the laboratory to be primarily responsible for coordinating mouse breeding.

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. Continuing noncompliance is of concern to OLAW, especially on PHS-funded activities. 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

S

Date: 2021.06.01 08:52:28 -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

OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR RESEARCH

May 24, 2021

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 10, 2021, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of a reportable situation involving mouse cage overcrowding. The animals involved are being used in research supported by the Public Health Service under NIH grant numbers 5R01DK11344-04, 5R01DK100342-09, 5R01DK120650-02, and 1R01HL152293-01.

This letter reports the results of a review of the matter and the corrective actions taken by the Institutional Animal Care and Use Committee ("IACUC" or the "Committee").

Background and Investigation

On March 5, 2021, the Institute of Comparative Medicine (ICM) Associate Director notified Dr. Mary Jo Shepherd, Executive Director of the IACUC, that ICM personnel had identified a principal investigator whose laboratory had an ongoing issue with respect to overcrowding of mice, despite counseling by ICM on permissible mouse housing density.

Dr. Shepherd notified the IACUC Chair when she learned of the issue and an investigation was initiated. The IACUC investigative team (Dr. Shepherd and another IACUC member) met with the principal investigator. They also met separately with an ICM Assistant Director and the ICM facility supervisor responsible for the area where the mice used in the investigator's research are housed.

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR RESEARCH

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 1, 2021. 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 reducing the number of researchers and projects in his laboratory, and personal monitoring of mouse breeding colony management. The investigator and the members of his laboratory were also required to re-review the ICM policy on mouse housing density and to attend a mouse breeding colony management training session with veterinarians in the ICM. The investigator was also required to identify one individual in the laboratory to be primarily responsible for coordinating mouse breeding.

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)

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, May 26, 2021 7:16 AM
To: Shepherd, Mary Jo
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Columbia University Compliance Report

Thanks MJ. We'll send a response soon.
Axel Wolff

From: Shepherd, Mary Jo <ms4387@cumc.columbia.edu>
Sent: Monday, May 24, 2021 3:09 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. MJ

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