



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

April 1, 2022

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

Ms. 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 March 21, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at Columbia University. Your letter supplemented the information contained in an initial telephone report to this office on February 1, 2022. According to the information provided, OLAW understands that a concern was brought forward regarding inadequate record keeping associated with one nonhuman primate (NHP). An IACUC investigative team found that medical records in this case were sparse. The veterinarian responsible for the records had been previously counseled regarding their medical record keeping. The investigation also determined that the communication skills of the responsible veterinarian were sometimes ineffective, and that the veterinarian was sometimes not open to suggestions and ideas of others. The NHP involved was supported by PHS funds.

Several corrective and preventive measures were implemented. The IACUC recommended that the responsible veterinarian be removed from NHP care until further notice, and that permanent removal should be seriously considered. The responsible veterinarian will receive extensive coaching/counseling regarding record keeping and communication. Further, the Attending Veterinarian met with the veterinary staff to discuss proper medical record keeping. The sessions included the importance of the subjective/objective/assessment/plan (SOAP) format for complicated cases, the need to create and follow a treatment plan, documenting discussions with investigators, and developing a records training session for veterinary technicians about entering clinical observations in the medical record.

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 and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel-S

Digitally signed by Robyn M.
Engel-S
Date: 2022.04.01 08:57:57 -0400

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact

Dr. Robert M. Gibbens, USDA, APHIS, Animal Care

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Vice President for Research Operations and Policy
Chief Operating Officer

March 21, 2022

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 1, 2022, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of a reportable situation involving a concern that had been expressed regarding allegations of inadequate record keeping associated with one nonhuman primate (NHP). The IACUC immediately initiated an investigation when the concern was received. The animal involved was being used in research supported by the Public Health Service under NIH grant numbers 5R01MH111703-04 and 5R01MH112142-05.

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 December 1, 2021, the IACUC Executive Director, Dr. Mary Jo Shepherd, received email allegations regarding inadequate record keeping and initial care of an NHP associated with a possible MRI related skin lesion. Dr. Shepherd notified the IACUC Chair when she received the email and an investigation was initiated. The IACUC investigative team (Dr. Shepherd and the IACUC Chair) met with the separately with the individual who brought the concern forward, the Institute of Comparative Medicine ("ICM") veterinary technicians involved with NHP care, the ICM clinical veterinarian responsible for the initial care of the NHP at the time the lesion was first observed, the ICM veterinary resident who was responsible for the subsequent care of the animal over a holiday weekend and the Principal Investigator ("PI") of the protocol the animal was being used under.

The investigative team (veterinarian and pediatric anesthesiologist) also reviewed medical records associated with the skin lesion and determined them to be "sparse" even though the veterinarian responsible for them had previously been previously counseled by the Attending Veterinarian regarding their medical record keeping. Additionally, through interviews with other individuals, the team determined that the communication skills of the veterinarian responsible for the records of concern were sometimes ineffective, and that the veterinarian was sometimes not open to suggestions and ideas of others.

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 January 6, 2022. Following review of the facts and discussion, the Committee imposed the following corrective measures:

1. The Committee advised ICM to remove the veterinarian responsible from NHP care until further notice and to seriously consider removing that individual from NHP care permanently.
2. ICM should provide extensive coaching/counseling to the veterinarian responsible for the initial care of the NHP in question regarding record keeping and communication.
3. The Attending Veterinarian should meet with his veterinary staff to discuss proper medical record keeping. The sessions was held and specifically discussed included the importance of use of the SOAP (subjective/objective/assessment/plan) format for complicated cases, the need to create and follow a treatment plan, inclusion of documentation of discussions with investigators and development of a records training session for veterinary technicians to provide instruction on how they should enter clinical observations in the electronic medical record.

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, March 23, 2022 7:29 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: Monday, March 21, 2022 4:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] Compliance Report from 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.

See attached report from Columbia University. Please 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

A3007-2P



Initial Report of Noncompliance

By: (b) (6)

Date: 2/1/22

Time: 2:00

Name of Person reporting: M.S. Shepherd

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Columbia U

Assurance number: A3007

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Problems found in primate record keeping, too sparse.

Species involved: *NHP*

Personnel involved:

Dates and times:

Animal deaths:

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

Vet involved assigned.

Counsel staff. Records correct now.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____