



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) 402-7065

April 10, 2019

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

G. Michael Purdy, Ph.D.
Executive Vice President for Research
Columbia University Medical Center
535 West 116th St. — (b) (4) Low Library MC 4310
New York, NY 10027

Dear Dr. Purdy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 27, 2019 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 made by Dr. Shepherd on October 26, 2018. According to the information provided, OLAW understands that on October 22, 2018 the Executive Director of the IACUC was notified by a veterinarian that a guinea pig had been dosed with a strain of virus that had not been approved by the IACUC or the IBC. There were no animal health issues associated with this oversight. Subsequent to an IACUC and EH&S investigation, the IACUC imposed the following corrective measures: regulatory and veterinary online retraining for all laboratory personnel and posting current copies of applicable protocols in the investigator's laboratory to ensure they are available to all laboratory members. The IACUC has also approved a modification to the approved protocol for use of the additional strain of virus in the research in question. This activity was funded by the PHS (5R01DK093094-06).

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,

(b) (6)

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

cc: IACUC Contact

Mary Jo Shepherd, DVM, IACUC Office Director
Dr. Robert M. Gibbens, USDA, APHIS, AC
Bob Pike, Chief Grants Management Officer, NIDDK

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

March 27, 2019

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. Wolff,

On October 26, 2018, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident in which one guinea pig was dosed with a viral strain prior to Institutional Animal Care and Use Committee ("IACUC" or the "Committee") and Institutional Biosafety Committee ("IBC") approval. The research under the associated protocol (AAQ6425) was supported by the Public Health Service under NIH grant # 5RO1 DK093094-06

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

Background and Investigation

On October 22, 2018, a veterinarian from the Institute of Comparative Medicine ("ICM") notified Dr. Mary Jo Shepherd, Executive Director of the IACUC, that one guinea pig had been dosed with a strain of a virus without approval by the IACUC or the IBC. The approved protocol described research with another strain of the virus, and a modification to add the second strain was under review by the IACUC and the IBC at the time of the incident.

Dr. Shepherd notified the IACUC Chair when she learned of the incident and an investigation was initiated. Initially the IACUC investigative team, along with the Biological Safety Associate Director and Associate Manager from the University's Office of Environmental Health & Safety ("EH&S"), met with the principal investigator and his lead researcher to discuss the incident. The IACUC investigative team then met again with the EH&S representatives and separately with the principal investigator and his lead researcher.

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 10, 2019. Following review of the facts and discussion, the Committee voted to impose the following corrective measures:

1. The investigator was required to fully implement and continue to adhere to his plan for correction, which included regulatory and veterinary online retraining for all laboratory personnel and posting current copies of applicable protocols in his laboratory to ensure they are available to all laboratory members.

The IBC and IACUC have since approved a protocol modification for use of the additional strain of the virus in the research in question.

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)

G. Michael Purdy, Ph.D.
Executive Vice President for Research

cc:

(b) (6)

Brian Karolewski, D.V.M.
MJ Shepherd, D.V.M.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 29, 2019 6:52 AM
To: Shepherd, Mary J.
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Columbia University Compliance Reports

Thanks for these 3 reports, MJ. We will send responses soon.
Axel Wolff

From: Shepherd, Mary J. <ms4387@cumc.columbia.edu>
Sent: Thursday, March 28, 2019 2:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Columbia University Compliance Reports

Attached are three compliance reports from Columbia University. Please let me know if you have any questions or concerns. Thank you. MJ

Mary Jo (MJ) Shepherd, DVM, CPIA
Executive Director of the Office of the IACUC
Columbia University
(b) (6)

Initial Report of Noncompliance

By: 

Date: 10/26/18

Time: 2:05

Name of Person reporting: M. J. Shepard, DVM
Telephone #: (b) (6)

Telephone #:

Fax #:

Email:

Name of Institution: Columbia U.
Assurance number: A3007

Assurance number: A3007

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? One animal dosed w/ virus that had yet to be approved by IACUC or BSC.

Species involved: G, P.

Personnel involved:

Dates and times: Notified on 10/22/18

Animal deaths: No, animal is fine.

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

Projected submission to OLA W of final report from Institutional Official:

OFFICE USE ONLY

Case # _____