

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
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Bethesda, Maryland 20817
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August 1, 2018

Re: Animal Welfare Assurance A3007-01 [OLAW Case 1W]

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 July 31, 2018 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 December 28, 2017. According to the information provided, OLAW understands that on December 13, 2017 four cages of mice were found without food, water or bedding in a procedure room in the Institute of Comparative Medicine ("ICM"). The procedure being conducted was not described in the associated protocol. This activity was funded by the PHS by grant #5R35CA210088-02.

Corrective actions included counseling of the PI and the laboratory manager by the Executive Director of the IACUC and the IACUC Chair. The IACUC subsequently imposed the following corrective and preventive measures: veterinary retraining; online retraining; lab-tailored compliance training, and; a protocol modification.

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

Crystal Wolfrey, Chief Grants Management Officer, NCI

COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

EXECUTIVE VICE PRESIDENT FOR RESEARCH

July 31, 2018

Brent Morse, D.V.M.
Acting 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 December 28, 2017, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident concerning conduct of a procedure in mice without approval by the Institutional Animal Care and Use Committee ("IACUC" or the "Committee"). The research under the associated protocol (AAAO1952) was supported by the Public Health Service under NIH grant # 5R35CA210088-02. This letter reports the results of a review of the incident and the corrective actions taken by the IACUC.

Background and Investigation

On December 13, 2017, two IACUC Compliance and training Coordinators were conducting a routine monitoring visit to an Institute of Comparative Medicine ("ICM") procedure room where they observed 4 cages of mice without food, water or bedding. The IACUC staff members determined that the procedure being conducted was not described in the protocol under which the animals were being used.

The Executive Director of the IACUC, Dr. Mary Jo Shepherd, notified the IACUC Chair when she learned of the incident, and Dr. Shepherd and the Chair investigated further. The investigative team subsequently met with the principal investigator as well as with the principal investigator's laboratory manager. The investigator submitted a proposed plan of correction for the noncompliance that had occurred.

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 May 3, 2018. 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 veterinary retraining, online retraining, lab tailored compliance training and a protocol modification.

Sincerely, ______(b) (b)

G. Michael Purdy, Ph.D.

Executive Vice President for Research

cc: (b) (6)
MJ Shepherd, D.V.M.

(b) (4)

(b) (6)



Initial Report of Noncompliance

OLAW By: MAN
Date: 1/2/18 * Time: 4:10
Name of Person reporting: M.J. Cheshed Telephone #: Fax #: Email:
Name of Institution: Assurance number: A 3 00 7
Did incident involve PHS funded activity? \(\sum_{\text{LL}} \) Funding component: Was funding component contacted (if necessary):
What happened? Wice found % food or water in procedure non. Procedures were from expired protocol.
Species involved: Will Personnel involved: PI Dates and times: 12/28/17 Animal deaths:
* Volceman 12/28/17 Projected plan and schedule for correction/prevention (if known):
Projected submission to OLAW of final report from Institutional Official:
OFFICE USE ONLY Case #