

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

August 17, 2018

#### PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 402-7065

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

G. Michael Purdy, Ph.D. Executive Vice President for Research Columbia University Medical Center 535 West 116<sup>th</sup> St. – Low Library MC 4310 New York, NY 10027

Dear Dr. Purdy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 13, 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 February 12, 2018. According to the information provided, OLAW understands that on January 25, 2018 it was determined that mice were being housed in a laboratory for more than 24 hours without IACUC approval and that a method of euthanasia (hypothermia) was being used that was not approved in the protocol or in the AVMA Guidelines for the Euthanasia of Animals. This activity was funded by the PHS.

Corrective actions included counseling of the PI and the laboratory members. The IACUC subsequently imposed the following corrective and preventive measures: veterinary retraining on proper euthanasia methods; online retraining; designation of a lab member to monitor compliance, and; regulatory retraining.

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

## COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

EXECUTIVE VICE PRESIDENT FOR RESEARCH

August 13, 2018

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 2, 2018, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident concerning use of a method of euthanasia not described in the applicable protocol and housing of animals longer than 24 hours in a laboratory outside the central animal facility. The research under the associated protocol (AAAN8856) was supported by the Public Health Service under NIH grants # 5R01EY017061-12, 5R01EY018868-09 and 5R01EY025933-03.

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

#### **Background and Investigation**

On January 25, 2018, during a post approval monitoring visit to a laboratory, two IACUC Compliance and Training Coordinators determined that mouse pups were being euthanized by hypothermia, a method of euthanasia not described in the approved protocol and not approved in the AVMA Guidelines for the Euthanasia of Animals.

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 Attending Veterinarian investigated further. They subsequently met with the principal investigator, his lab members, and the Institute of Comparative Medicine veterinarian who is responsible for the area where the principal investigator's animals are housed, as well as with one of the IACUC Compliance and Training Coordinators who observed the noncompliance involving euthanasia.

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## Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Tuesday, August 14, 2018 11:32 AM
То:	Shepherd, Mary J.; OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Columbia University Compliance Report

Thank you for this report Dr. Shepherd. We will send an official response soon,

#### Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Shepherd, Mary J. [mailto:ms4387@cumc.columbia.edu]
Sent: Tuesday, August 14, 2018 10:04 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Columbia University Compliance Report

Please see attached report and let me know if you have any concerns or questions. Thank you. MJ

Mary Jo (MJ) Shepherd, DVM, CPIA Executive Director of the Office of the IACUC Columbia University 154 Haven Ave. (b) (4) NYC, NY 10032 (b) (6) ms4387@columbia.edu

## Gopee, Neera (NIH/OD) [E]

From: Sent: To: Cc: Subject: Gopee, Neera (NIH/OD) [E] Thursday, July 26, 2018 10:51 AM 'Shepherd, Mary J.' (b) (6) RE: OLAW Request for update on preliminary noncompliance report for A3007-1X

Thank you for your prompt response Dr. Shepherd. I look forward to receiving the final report in the near future.

Best Regards, Neera

From: Shepherd, Mary J. [mailto:ms4387@cumc.columbia.edu] Sent: Thursday, July 26, 2018 10:07 AM To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov> Cc: (b) (6) Subject: RE: OLAW Request for update on preliminary noncompliance report for A3007-1X

Thank you, Dr. Gopee. The letter is undergoing final review with General Counsel and I just nudged them to move this along ASAP. MJ

Mary Jo (MJ) Shepherd, DVM, CPIA Executive Director of the Office of the IACUC Columbia University 154 Haven Ave. (b) (4) NYC, NY 10032 (b) (6)

ms4387@columbia.edu

From: Gopee, Neera (NIH/OD) [E] [mailto:neera.gopee@nih.gov] Sent: Thursday, July 26, 2018 10:03 AM To: Shepherd, Mary J. Cc: (b) (6) Subject: OLAW Request for update on preliminary noncompliance report for A3007-1X

Dear Dr. Shepherd,

I am writing with regards to the non-compliance case which was reported by via telephone on February 12, 2018 involving the unapproved use of a method of euthanasia and housing of animals in excess of 24 hours at Columbia University. To date we do not have a record of receiving further information regarding this preliminary report. OLAW requests that submission of a final or interim report to the OLAW Division of Compliance Oversight (NIH/OD) <u>olawdco@od.nih.gov</u> at your earliest convenience.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

Regards, Neera

A 3007-1X



# **Initial Report of Noncompliance**

By: Qu

Date: 2/12/18

Time: 11:10

Name of Person reporting: MJ Sheelend Telephone #: Fax #: Email:

Name of Institution: Assurance number:

Columbia U A3007

Did incident involve PHS funded activity? <u>Yes</u> Funding component: <u>Was funding component contacted</u> (if necessary):

What happened?

Unapproved metted of cultanning anenals in late aver 24 hrs

Species involved: Personnel involved: Dates and times: Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #