



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

March 14, 2019

Re: Animal Welfare Assurance
A3195-01 [OLAW Case 4U]

Dr. Mary Klotman
Dean, School of Medicine and
Vice Chancellor for Health Affairs
Duke University Medical Center
Duke South Clinic – 200 Trent Drive
(b) (4) Davidson Building
Durham, NC 27710

Dear Dr. Klotman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 5, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Duke University, following up on an initial telephone report on February 1, 2019. According to the information provided, OLAW understands that three newly weaned mice died due to lack of food. Following weaning, the mice were placed in a cage with hydration gel and bedding but no food. The problem was not noted by husbandry staff during the daily health check.

The corrective actions consisted of retraining the laboratory staff on weaning procedures including provision of food/water, refining the weaning practices, retraining the animal care staff on the appropriate conduct of daily health checks, counseling the Principal Investigator, and refining institutional procedures to ensure provision of food. The animal caretaker responsible is no longer employed by animal resources.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Note that when the same issue occurs in close proximity in different laboratories there may be a need to address the matter program wide. OLAW encourages the Institutional Animal Care and Use Committee to raise awareness throughout the animal care and use program about appropriate weaning practices and the requirement to ensure that all animals have access to food/water. Thank you for keeping this Office apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



Duke University
Durham, North Carolina 27705



Office of Animal Welfare Assurance
Campus Mail: Hock Plaza Box 2724
US Mail: 2424 Erwin Road; Suite 606; Durham, NC 27705

Voice: 919.668.6720
Fax: 919.668.6725
<https://sites.duke.edu/oawa/>

March 5, 2019

Duke University
Animal Welfare Assurance # D16-00123 (A3195-01)

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Duke University, in accordance with PHS Policy IV.F.3., provides this report of an incident, which involved an animal activity conducted or supported with PHS-funds or other funds with Office of Laboratory Animal Welfare oversight. This incident was reviewed and determined to be reportable by the Duke Institutional Animal Care & Use Committee (IACUC).

Reportable requirement: Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals.

Preliminary report: This incident was first reported to Dr. Neera Gopee, OLAW, on February 1, 2019 via a telephone call by Anna Hampton Anna Hampton, DVM, DACLAM, DACAW, CPIA, Director, Duke University Office of Animal Welfare Assurance.

Grant/contract number: R01-GM124062-01A1

Number of animals affected: 3 mice

Date: December 05, 2018

Description, outcome, and actions taken: Mice were weaned from the dam. Upon weaning mice were provided hydration gel and extra bedding. Feed was not placed in the cages containing the weaned mice. Approximately 5-days later 3 mice were found dead and there was no food in the cage.

Upon identification of this concern the following corrective measures were taken:

- Laboratory personnel were retrained regarding appropriate mice weaning practices, to include providing food. In addition, the laboratory has refined its weaning practices to help prevent reoccurrence.
- Animal care personnel were retrained on the animal monitoring SOP and the expectations for daily animal cage checks. Note: The animal care personnel involved is no longer an employee of animal resources.
- The Principal Investigator met with the Attending Veterinarian and IACUC Chair to review the concern.
- Animal resources reviewed and refined current processes to ensure provision of food.

Conclusion: The Duke IACUC completed its investigation and performed final review of the issue at the February 28, 2019 IACUC meeting. The Duke IACUC determined that the incident was reportable to regulatory, granting, and oversight bodies, where applicable. In addition, the IACUC determined that the corrective actions were appropriate and no further actions were necessary. The Duke IACUC considers this incident closed.



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The Duke University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Anna Hampton, DVM, IACUC Chair at Anna.Hampton@Duke.edu or (b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dr. Mary E. Klotman
Duke University
Dean, School of Medicine
Vice Chancellor for Health Affairs
Institutional Official

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Wednesday, March 06, 2019 4:37 PM
To: 'Anna Hampton'; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Duke OLAW Report (Assurance # A3195-01)

Thank you for these three final reports Dr. Hampton. We will send official responses to each report soon.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DABT, DACIAM
Acting Director, Division of Policy and Education
Office of Laboratory Animal Welfare, NIH
6700B Rockledge Drive
Bethesda, MD 20892-6910
Phone (301) 594-3657
gopeenv@od.nih.gov

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From: Anna Hampton <anna.hampton@duke.edu>
Sent: Wednesday, March 06, 2019 4:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Subject: Duke OLAW Report (Assurance # A3195-01)

Dear Dr. Gopee,

Please see the attached final reports for Duke University (Assurance # A3195-01 / D16-00123).

Please do not hesitate to contact me if you have any questions or need additional information.

Anna

Anna Hampton, DVM, DACLAM, DACAW, CPIA
Director, Office of Animal Welfare Assurance
Chair, Institutional Animal Care and Use Committee
Duke University
2424 Erwin Road, (b) (5)
Durham, NC 27705
Cell: (b) (6)
Office: (b) (6)
Fax: (b) (6)
Web: sites.duke.edu/oawa/



Initial Report of Noncompliance

By: Neera Gopal

Date: 2-1-19

Time: 10:45 am

Name of Person reporting: Anna Hampton

Telephone #: (b)(6)

Fax #:

Email:

Name of Institution: Duke University

Assurance number: A3195-01

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Three mice died due to inadequate feed. Lab personnel weighed animals and provided transport but no feed. AC staff did not observe missing feed.

Species involved: mice

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 # _____