



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

October 22, 2019

Re: Animal Welfare Assurance
#A4752-01 (OLAW Case 1W)

Ms. Allison P. Moriarty
Vice President, Research Administration
and Compliance
Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115

Dear Ms. Moriarty,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 11, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Brigham and Women's Hospital. According to the information provided, OLAW understands that five mice died subsequent to a new research fellow miscalculating a drug dose and administering a higher dose than what was described in the protocol. The lab identified and self-reported the incident. It was stated that the animals were assigned to an activity receiving PHS funding.

Preventive and corrective actions included the laboratory amending the protocol to clarify the dosing and also providing retraining to the new member.

The consideration of this matter by Brigham and Women's Hospital was consistent with the philosophy of institutional self-identification and self-regulation. Similarly, the actions taken to correct and resolve the issue were appropriate and would be expected to prevent a recurrence of this incident. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

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

cc: IACUC Chair



**BRIGHAM AND
WOMEN'S HOSPITAL**

Institutional Animal Care and Use Committee

14752-1W

Brent Morse, D.V.M., DACLAM
Acting Director, Division of Compliance Oversight Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

October 11, 2019

FINAL REPORT

Non-Compliance Report: Assurance **A4752-01**
Sponsor: 5R21AI130669-02; 5R01AI138999-02
Brigham and Women's Hospital IACUC

Dear Dr. Morse,

This letter serves as a report on an issue of non-compliance that was reviewed by the Brigham and Women's Hospital Institutional Animal Care and Use Committee. A laboratory identified and self-reported that five mice were found to have unexpectedly died during an experiment. The laboratory investigated the incident and determined that a new research fellow had miscalculated a drug dose and gave the mice a higher dose than what was described in the protocol. The laboratory decided to amend the protocol to clarify the dosing and provided retraining to that laboratory member to ensure that this does not occur again. The BWH IACUC encourages laboratories to self-report any adverse events or unexplained deaths and commended this laboratory for bringing this issue to their attention.

Thank you in advance for your review of these incidents. Please let us know if any further action is required at this time.

Sincerely,

(b) (6)

Allison Moriarty
Vice President, Research Operations
Institutional Official for the BWH IACUC

CC: **Amber Hoggatt, DVM, DACLAM**
Attending Veterinarian & Director, Center for Comparative Medicine, Brigham & Women's Hospital

Srinivasan Mukundan, Jr., Ph.D., M.D.
Chairman, Brigham & Women's Hospital Institutional Animal Care and Use Committee

(b) (6)

Kathryn Holthaus, MS, MA
Director of Research Subjects Protection and Laboratory Safety Compliance

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, October 17, 2019 2:54 PM
To: Holthaus, Kathryn; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Moriarty, Allison P.; (b) (6)
Subject: RE: Report of Non-compliance A4752-01

Thank you for this report Ms. Holthaus. 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

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From: Holthaus, Kathryn [mailto:kholthaus@bwh.harvard.edu]
Sent: Thursday, October 17, 2019 2:37 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; (b) (6)
Moriarty, Allison P. <AMORIARTY@BWH.HARVARD.EDU>; (b) (6)
(b) (6) 'accredit@aaalac.org' <accredit@aaalac.org>
Subject: Report of Non-compliance A4752-01

Dear Dr. Morse,
Please find the attached report of non-compliance which was identified and reported to the IACUC by the research laboratory and discussed at a recent meeting of the BWH IACUC. Please let us know if you have any questions.
Kind regards,
Kathryn

Kathryn A. Holthaus, M.S., M.A.

Director of Research Subjects Protection and Laboratory Safety Compliance
Research Administration and Compliance
Office: (b) (6)
kholthaus@bwh.harvard.edu
brighamandwomens.org



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