



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

February 14, 2019

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

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 February 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 during veterinary rounds, it was discovered that monitoring documentation was missing from experimental rat cages and experimental rats had gone beyond the endpoint described in the protocol. Upon investigation, it was determined that the lab member in charge of the study had a personal emergency which kept him away from the lab and the lab member who took over was not monitoring the animals as described in the protocol. The animals were assigned to a study receiving PHS funding.

Corrective and preventive actions included representatives from the IACUC and Veterinary Staff meeting with the laboratory to review humane endpoints, monitoring and documentation requirements, as well as potential improvements to the model.

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
Director of Research Subjects Protection and Laboratory Safety Compliance



BRIGHAM AND WOMEN'S HOSPITAL

Institutional Animal Care and Use Committee

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

February 11, 2019

FINAL REPORT

Non-Compliance Report: Assurance **A4752-01**
Brigham and Women's Hospital IACUC
Funding: **5P01HL048743-22**

Dear Dr. Morse,

This letter serves as a final report on a resolved issue of non-compliance that has been reviewed by the Brigham and Women's Hospital Institutional Animal Care and Use Committee.

During veterinary rounds, it was discovered that monitoring documentation was missing from experimental rat cages and experimental rats had gone beyond the endpoint described in the protocol. Upon investigation, it was determined that lab member in charge of the study had a personal emergency which kept him away from the lab and the lab member who took over was not monitoring the animals as described in the protocol. Once the concern was brought to the PI's attention, he immediately recognized the need for better training for all lab members around monitoring during this experiment, which was fairly new to the lab.

Representatives from the IACUC and Veterinary Staff met with the entire laboratory to review humane endpoints, monitoring and documentation requirements, as well as potential improvements to the model. Due to these corrective actions, the BWH IACUC considers this issue resolved.

Thank you 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 Administration and Compliance 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

A Teaching Affiliate

of Harvard Medical School

A FOUNDING MEMBER OF



Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 13, 2019 2:55 PM
To: Holthaus, Kathryn; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Moriarty, Allison P.; Mukundan, Srinivasan, Jr., M.D., Ph.D.; Hoggatt, Amber
Subject: RE: Noncompliance Reports A4752-01

Thank you for these reports Ms. Holthaus. We will send official responses 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: Wednesday, February 13, 2019 2:50 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: 'accredit@aaalac.org' <accredit@aaalac.org>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; (b) (6) Moriarty, Allison P. <AMORIARTY@BWH.HARVARD.EDU>; Mukundan, Srinivasan, Jr., M.D., Ph.D. <smukundan@bwh.harvard.edu>; Hoggatt, Amber <ahoggatt1@bwh.harvard.edu>
Subject: Noncompliance Reports A4752-01

Dear Dr. Morse,

Thank you for speaking with me last week regarding three preliminary reports of noncompliance that were reviewed and discussed at a recent IACUC meeting at Brigham and Woman's Hospital, AWA# # D16-00941 (A4752-01). Please find the final reports attached to this email (in one PDF). Thank you in advance for your review of these incidents and please let us know if any further action is required at this time.

Best 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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Initial Report of Noncompliance

By: *[Signature]*Date: *2/6/19*Time: *2:15*Name of Person reporting: *Kathryn Holthaus*Telephone #: *[Redacted]* (b) (6)

Fax #:

Email:

Name of Institution: *Brigham + Womens Hosp.*Assurance number: *A4752*Did incident involve PHS funded activity? ☐

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? *Vet rounds - found mice w/ poor body condition. Not measuring BW during water restriction.*Species involved: *Mice*Personnel involved: *Researcher*

Dates and times:

Animal deaths: *No*

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

No more restriction conducted.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____