



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

July 8, 2019

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

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 June 26, 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 the humane endpoints described in the protocol were exceeded for five mice and some animals had not been monitored at the frequency described in the protocol. Also, an experimental substance was not given by the described route which caused clinical concerns.

The corrective actions consisted of the veterinarian counseling the laboratory member responsible on humane endpoints and adhering to the protocol. The Principal Investigator was directed to amend the protocol to increase monitoring of animals approaching the humane endpoint and to submit the staff training plan to the Institutional Animal Care and Use Committee.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Director of Research Subjects Protection and Laboratory Safety Compliance

A4752-15



# 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

June 26, 2019

## **FINAL REPORT**

Non-Compliance Report: Assurance **A4752-01**  
Brigham and Women's Hospital IACUC  
Funding: **4P01CA120964-10**

Dear Dr. Morse,

This letter serves as a report on a non-compliant incident that has been reviewed by the Brigham and Women's Hospital Institutional Animal Care and Use Committee. During veterinary rounds, 5 mice were found to have exceeded the humane endpoints described in the protocol, some animals were not monitored at the frequency described in the protocol, and there was variation in the administration of a substance approved on the protocol that resulted in some clinical concerns not expected on the protocol.

The laboratory member overseeing this study met with the veterinarian promptly to review the institutional guidelines on humane endpoints for this specific experiment. They also discussed the requirement of adhering to the approved IACUC protocol. The PI was advised to submit an amendment to increase the monitoring of the animals approaching later acceptable humane endpoints, as well as provide the training plan that was utilized by the PI to assure lab members adhere to procedural descriptions and monitoring plans. Once the amendment is approved and the training plan submitted, the IACUC will consider 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 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

A Teaching Affiliate  
of Harvard Medical School

A FOUNDING MEMBER OF



**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, July 2, 2019 7:50 AM  
**To:** Holthaus, Kathryn  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Noncompliance Reports A4752-01

Thank you for this report, Ms. Holthaus. We will send responses soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

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**From:** Holthaus, Kathryn <kholthaus@bwh.harvard.edu>  
**Sent:** Monday, July 1, 2019 4:23 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** 'accredit@aaalac.org' <accredit@aaalac.org>; (b) (6) Moriarty, Allison P. <AMORIARTY@BWH.HARVARD.EDU>; Hoggatt, Amber <ahoggatt1@bwh.harvard.edu>; Mukundan, Srinivasan, Jr., M.D., Ph.D. <smukundan@bwh.harvard.edu>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Subject:** Noncompliance Reports A4752-01

Dear Dr. Morse,

Please find attached to this email, two reports of noncompliance that were reviewed and discussed at a recent meeting of the Brigham and Woman's Hospital IACUC, AWA# # D16-00941 (A4752-01). 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](mailto:kholthaus@bwh.harvard.edu)  
[brighamandwomens.org](http://brighamandwomens.org)

**BRIGHAM HEALTH**  
 **BRIGHAM AND  
WOMEN'S HOSPITAL**

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