

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

October 3, 2019

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

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

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

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 September 30, 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 anesthetized mice were euthanized with non-pharmaceutical grade pentobarbital. No problems were reported with the euthanasia procedure.

The corrective actions consisted of stopping use of the drug and amending the protocol to describe use of a different euthanasia method.

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



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

September 30, 2019

FINAL REPORT

Non-Compliance Report: Assurance A4752-01 Sponsor: 1R01Al134989-01AI and 5K08Al132723-03 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. During a semi-annual IACUC inspection, it was discovered that non-USP grade pentobarbital had been used two times to euthanize mice which were already under anesthesia with ketamine/xylazine anesthesia. The lab members reported no observable adverse effects from the pentobarbital and the euthanasia went as expected. After review of the protocol, the IACUC suggested alternative euthanasia methods that maybe easier for the lab and suggested amending the protocol to remove the pentobarbital and using one of these alternatives for this study. Regardless, the lab immediately stopped their use of the non-USP grade pentobarbital so the IACUC considers this matter resolved.

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

Sincergly

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 FOUNDI NG MEMBER OF



A 4752-11

Morse, Brent (NIH/OD) [E]

From:	x.	OLAW Division of Compliance Oversight (NIH/OD)	
Sent:		Monday, September 30, 2019 12:01 PM	
То:	5	Holthaus, Kathryn; OLAW Division of Compliance Oversight (NIH/OD)	
Cc:		(b) (б)	Moriarty, Allison P.; Hoggatt, Amber; Mukundan,
		Srinivasan, Jr., M.D., Ph.D.	
Subject:		RE: Noncompliance Reports A4752-01	

Thank you for providing 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: Monday, September 30, 2019 11:39 AM

To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: (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>; 'accredit@aaalac.org' <accredit@aaalac.org> 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. 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) <u>kholthaus@bwh.harvard.edu</u> <u>brighamandwomens.org</u>

BRIGHAM HEALTH BRIGHAM AND WOMEN'S HOSPITAL

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