



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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 1N)

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 a PI self-reported that expired ketamine had been used to anesthetize 30 mice for a brief non-surgical procedure. The lab member who had used the drug confirmed that the mice were fully anesthetized during the procedure with no complications and that they recovered uneventfully. It was stated that the mice were assigned to an activity receiving PHS funding.

Preventive and corrective actions included the PI counseling the lab member of the importance to check the expiration date every time prior to use. The PI also labeled the drug as expired and relocated the bottle to the expired drug storage area. It was subsequently destroyed.

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: **4R01EY022054-05, 5R01EY016144-14**

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.

While performing an audit, a PI discovered that a lab member used an anesthetic for 30 mice for a brief non-surgical procedure; however, the anesthetic had expired 6 weeks before. The PI immediately labeled the bottle as expired and relocated the bottle to the expired drug storage area while awaiting proper disposal procedures. The PI then met with the individual who had used the expired drug and emphasized the need to check the expiration date every time prior to use. The lab member confirmed that the mice were fully anesthetized during the procedure with no complications, and that they recovered uneventfully. The PI then self-reported this incident to the IACUC.

The IACUC appreciated the PI's diligence in overseeing his records and notifying the IACUC of an incident that had the potential to jeopardize the well-being of animals, even though, in this case, there were no noted clinical concerns. Due to these corrective actions, the BWH IACUC considers this issue resolved and the PI has had the drugs destroyed.

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



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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 Women'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: *2:00*Name of Person reporting: *Kathryn Holtmans, Dir. Resch Sub.*Telephone #: *[Redacted]*Fax #: *[Redacted]*Email: *[Redacted]*

(b) (6)

Name of Institution: *Brigham + W*Assurance number: *A4752*Did incident involve PHS funded activity? *Yes*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*PI self-reported expired Ketamine used on 30 rats for short-term procedure*Species involved: *Rats*Personnel involved: *PI*

Dates and times: _____

Animal deaths: _____

No, no negative effects.

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

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____