



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 19, 2019

Re: Animal Welfare Assurance
A3431-01 [OLAW Case 8P]

Dr. Lisa Muto
Executive Dean for Administration
Harvard Medical School
25 Shattuck Street, Gordon Hall -- (b) (4)
Boston, MA 02115

Dear Dr. Muto,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 14, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Harvard Medical School. According to the information provided, OLAW understands that an expired analgesic was used twice in mice. No adverse effects were noted due to use of the drug.

The corrective action consisted of discarding the expired drug, counseling the laboratory staff, and implementing use of a tracking sheet to monitor expiration dates of all drugs used in the laboratory.

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

cc: IACUC Chair



HARVARD MEDICAL SCHOOL

A3431-8P
LISA M. MUTO, PH.D.
EXECUTIVE DEAN FOR ADMINISTRATION
HARVARD MEDICAL SCHOOL
25 SHATTUCK STREET, SUITE 408
BOSTON, MA 02115

February 14, 2019

Brent Morse, DVM
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

FINAL REPORT

RE: Non-Compliance Report: Assurance: **A3431-01**
Harvard Medical Area Standing Committee on Animals (HMA IACUC)
Species: mouse Grant: 5R01HL132255-03

Dear Dr. Morse,

This letter serves as a final report on a recent incident of noncompliance that has not been preliminarily reported to OLAW by the Harvard Medical Area Standing Committee on Animals (HMA IACUC).

During a semi-annual IACUC inspection in December 2018, it was discovered that expired xylazine had likely been used two times. According to the ketamine usage records, the xylazine would have been used twice after it expired in August 2018. There was no apparent harm to the mice as a result of this issue.

In response to this issue, the expired xylazine was properly disposed of. The PI discussed this issue at a lab meeting. In addition, the lab now uses a Google sheet tracking all controlled and non-controlled drugs in the lab.

The Committee is satisfied with the corrective actions mentioned above and considers this incident to be resolved. Please let us know if any additional information is required at this time.

Sincerely,

(b) (6)

Lisa M. Muto, PhD
Executive Dean for Administration
HMA Institutional Animal Care & Use Committee: Institutional Official

CC:

(b) (6)

Brian F. Corning, DVM, DACLAM

Director of the Harvard Center for Comparative Medicine, Harvard Medical School: Attending Veterinarian

Arlene Santos-Diaz, MS

Director, Office of the IACUC, Harvard Medical School

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 14, 2019 3:09 PM
To: HMS-IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report

Thank you for providing this report. 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: HMS-IACUC [mailto:iacuc@hms.harvard.edu]
Sent: Thursday, February 14, 2019 2:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final Report