



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) 480-3387

May 12, 2021

Re: Animal Welfare Assurance
A3316-01 [OLAW Case 2R]

Ms. Kate Mellouk
Associate Vice President for Research Compliance
Boston University
85 East Newton St.
Boston, MA 02115

Dear Ms. Mellouk,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 11, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Boston University, following up on an initial telephone report on May 6, 2021. According to the information provided, OLAW understands that twelve mice failed to receive post-procedural analgesia as stated in the approved protocol. One mouse was lethargic and had a rough hair coat.

The corrective actions consisted of treating one mouse, euthanizing one mouse, and directing the laboratory to provide analgesia. The veterinary staff subsequently gave long acting analgesia to all of the mice and the protocol was amended to include this drug. The Principal Investigator and laboratory member were counseled to provide the post-procedural care and monitoring described in the protocol.

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 Contact

Boston University Office of Research Compliance
85 East Newton Street, (b) (4)
Boston, Massachusetts 02218
(b) (6)
www.bu.edu/researchsupport/compliance/



May 11, 2021

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge I, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Morse:

Boston University, in accordance with Assurance D16-00204 (A3316-01) and PHS Policy IV.F.3., provides this final report of serious noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals. A preliminary report of this incident was provided to OLAW via voicemail on 5/6/21.

On 4/9/21 a veterinarian reported that post-procedural buprenorphine administration had been missed by the laboratory on 4/8/21 pm and 4/9/21 am. One mouse was noted to have lethargy, mild hypothermia, rough coat, and clear ocular discharge. Supportive care was provided, and the lab was notified to administer analgesia. Further investigation showed that 6 doses had been missed in other mice between 4/6/21 and 4/9/21. Twelve mice were affected; one was euthanized.

The IACUC discussed the incident at its May 4, 2021 meeting. The Committee accepted the following corrective and preventive actions:

- The lab administered buprenorphine on 4/9/21 pm.
- Veterinary Services administered Buprenorphine SR to surgical animals on 4/10/21.
- The PAM Program Manager and veterinarian met with the PI and lab member on 4/16/21 to review , post-procedural care and monitoring in the approved protocol. An amendment to add Buprenorphine SR was recommended.
- The amendment to add Buprenorphine SR was approved on 4/30/21.

The animals were supported by R01HL133013.

Boston University is committed to protecting the welfare of animals used in research. Should you have any questions regarding this report, please let me know.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)


Kathryn Mellouk, MPA
Associate Vice President for Research Compliance
Institutional Official
Boston University

CC: Animal Welfare Program
Sponsored Programs
AAALAC International

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 12, 2021 8:21 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report - Boston University

Thank you for this report, (b) (6) We will respond soon.

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

From: (b) (6)
Sent: Wednesday, May 12, 2021 8:16 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@AAALAC.org>; Mellouk, Kathryn M. <kateski@bu.edu>; (b) (6)
(b) (6) IACUC <IACUC@bu.edu>
Subject: Final Report - Boston University

OLAW Division of Compliance Oversight:

Please see attached final report regarding an incident 4/6/21 – 4/9/21.

Sincerely,
(b) (6)

(b) (6)



Initial Report of Noncompliance

By:

(b) (6)

Date: 5/6/21

Time: 1:30

Name of Person reporting:

(b) (6)

Telephone #:

(b) (6)

Fax #:

Email:

Name of Institution:

Assurance number:

BOSTON U

A3316

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Post op analgesia not given to 12 mice

Species involved: mouse

Personnel involved: _____

Dates and times: _____

Animal deaths: _____

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

Gave analgesia later, gave long acting analgesia,
 Lab counseled, Amend protocol to give buprenorphine SR

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____