



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR U.S. 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

November 4, 2021

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

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 October 12, 2021 final letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Boston University. A preliminary telephone report was provided on September 30, 2021. According to the information provided, OLAW understands that on September 23, 2021, an Animal Science Center (ACS) technician found two moribund mice that had undergone surgery the previous day and per veterinary order, the animals were humanely euthanized. Two other animals that had undergone surgery the previous day were bright, alert and responsive. There was no documentation of analgesia administration or post-operative records available as described in the approved protocol. The lab member agreed to provide buprenorphine at 1pm on September 23, 2021. The Post-Approval Monitoring (PAM) Program Manager contacted the lab member twice on September 27, 2021 for information and requested surgery and post-operative monitoring records however no records were provided, and the lab member described an issue with the vaporizers during surgery. The vaporizers were checked, and no issues found. On October 4, 2021, the PAM Program Manager reminded the Principal Investigator (PI) and lab member about adherence to approval protocols and provided institutional policies on surgery, recordkeeping and suggested forms. The study was PHS funded.

As a corrective measure, presurgical notification and postsurgical records are to be provided to the veterinarian for the next three months and records are to be maintained at the room level. The IACUC Chair requested that the PI voluntarily stop surgery until retraining as occurred. A meeting between the PI, lab member, PAM Program Manager and Veterinarian was held on October 8, 2021 for training, discussing topics included in the incident, reporting concerns, recordkeeping and switching to buprenorphine sustained-release formula. Additionally, a for-cause PAM visit will be scheduled.

OLAW appreciates the prompt consideration of this matter by Boston University which is consistent with the philosophy of institutional self-regulation. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence.

We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

CC: IACUC contact

October 12, 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 9/30/21.

On 9/23/21, an Animal Science Center (ASC) technician found two moribund mice that had undergone surgery the previous day; these mice were euthanized per veterinary order. Two other mice that also had surgery the previous day were bright, alert, and responsive. There was no documentation of analgesia administration or postoperative records available as described in the approved protocol.

The IACUC discussed the incident at its October 5, 2021 meeting. The Committee accepted the following corrective and preventive actions:

- The lab member agreed to provide buprenorphine at 1 pm on 9/23/21.
- The PAM Program Manager contacted the lab member twice on 9/27/21 for information and requested surgical and post-operative monitoring records. No records were provided, and the lab member described an issue with the vaporizers during surgery.
- The Veterinary Services Manager checked the vaporizers in question and found no issues. The vaporizers have since been used without incident.
- The PAM Program Manager reminded the PI and lab member on 10/4/21 about adherence to the approved protocol and sent institutional policies on surgery, recordkeeping, and suggested forms.

The IACUC further required:

- Surgical records are to be maintained at the room level.
- Presurgical notification and postsurgical records are to be provided to the Veterinarian for the next three months.
- The IACUC Chair requested that the PI voluntarily stop surgery until retraining has occurred.
- A meeting with the PI, lab member, PAM Program Manager, and Veterinarian was held on 10/8/21 for retraining. Topics discussed included the incident, what to do if there are problems, how to keep surgery and post-procedure monitoring records, and switching to Buprenorphine SR.
- A for-cause PAM visit will be scheduled.

The animals were supported by: NIDDK R21DK119740-01 and 1R01HL149759-01

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, October 13, 2021 10:21 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 send a response soon.

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

From: (b) (6)
Sent: Wednesday, October 13, 2021 9:53 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 on 9/23/21.

Sincerely,

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 9/30/21

Time: 10:30

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Boston UAssurance number: A3316Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

2 moribund mice after surgery, 4 mice may have not
received analgesia

Species involved: mice

Personnel involved:

Dates and times:

Animal deaths:

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

Mice euthanized, look at surgery + monitoring records
meet w/ PI + lab

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____