



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

July 19, 2021

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

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 July 13, 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 July 8, 2021. According to the information provided, OLAW understands that 30 mice were identified with tumors and that the animals were being manipulated in a laboratory although neither the tumor work nor the performance site had been approved by the Institutional Animal Care and Use Committee (IACUC).

The corrective actions consisted of returning the mice to the vivarium, counseling the Principal Investigator on the content of the protocol, transferring the tumor mice to a holding protocol, having the IACUC approve a protocol amendment, and subsequently transferring the mice to the amended 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 IACUC to comply with the PHS Policy.

Sincerely,

[Redacted Signature] (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/



July 13, 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 7/8/21.

On 6/16/21, the veterinarian visited the lab to request return of six cages of mice that had been removed from the vivarium. Thirty mice were observed undergoing tumor measurement with calipers. Transport to the lab and tumor studies were not in the approved protocol.

The IACUC discussed the incident at its July 6, 2021 meeting. The Committee accepted the following corrective and preventive actions:

- The veterinarian required that all cages be returned to the vivarium.
- On 6/16/21, the PAM Program Manager discussed with the PI that the location and tumor work were not approved in the protocol. Tumor work is described in a different protocol for which animals were on the holding protocol pending approval of an amendment.
- The tumor-bearing animals were transferred to the holding protocol until approval of the amendment. The amendment was approved and animals transferred to the appropriate protocol on 6/29/21.

The animals were supported by: HHSN272201800017C.

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: Monday, July 19, 2021 7:43 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: Tuesday, July 13, 2021 11:53 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 6/16/21.

Sincerely,

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 7/8/21

Time: 3:30

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: Boston U

Assurance number: A3316

Did incident involve PHS funded activity? yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

30 mice on tumor study not on protocol, birth location not on protocol,

Species involved: Mice

Personnel involved: _____

Dates and times: _____

Animal deaths: _____

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

Return cages to vivarium. mice put on breeding protocol.

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

OFFICE USE ONLY

Case # _____