



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

January 4, 2022

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

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 June 4, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Boston University. According to the information provided, OLAW understands that on May 20, 2021, the Animal Science Center (ASC) alerted six investigators that the number of animals used had exceeded the number approved in the IACUC protocol. A total of 4,891 mice and 65,661 zebrafish were bred in excess. During the audit it was found that the tracking spreadsheet used by ASC was not capturing all animal use. Animal studies were PHS supported across multiple grants.

As a corrective measure, the Post-Approval Monitoring (PAM) Program Manager notified each investigator that animals were placed on the holding protocol and no work could be done until amendments for the increase in number were submitted and approved. In August 2021, ASC was scheduled to implement an animal operations software module integrated with IACUC software to permit accurate tracking of animal use.

OLAW appreciates the prompt consideration of this matter by Boston University which is consistent with the philosophy of institutional self-regulation and OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. Based on the information provided, this case has been forwarded to the Office of Policy for Extramural Research Administration (OPERA) at NIH for further consideration.

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

Diane Dean, Senior Advisor, OPERA

Joel Snyderman, Director, Division of Grants Compliance and Oversight, OPERA

Ki-Cha Flash-Zapata, Deputy Director, Division of Grants Compliance and Oversight, OPERA

Boston University Office of Research Compliance
 85 East Newton Street, Suite 810
 Boston, Massachusetts 02218
 T 617-358-7883 F 617-358-7888
www.bu.edu/researchsupport/compliance/



June 4, 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.

On 5/20/21, the Animal Science Center (ASC) alerted six investigators that the number of animals used had exceeded the number approved in the IACUC protocols. A total of 4,891 mice and 65,661 zebrafish were bred in excess. During the audit it was found that the tracking spreadsheet used by ASC was not capturing all the animal use. Investigators were asked to submit an amendment to these IACUC protocols.

The IACUC discussed the incident at its June 1, 2021 meeting. The Committee accepted the following corrective and preventive actions:

- Animals on site exceeding the approved number were placed on the holding protocol.
- The Post-Approval Monitoring (PAM) Program Manager notified each PI that animals would be moved to the holding protocol and that no work could be done until the protocol amendment is approved.
- Three amendments are currently under review, and one has been approved.
- In August 2021, ASC is implementing an animal operations software module integrated with the IACUC software that will permit more accurate tracking of animal numbers.

The animals were supported by:

R01DK117161
 R01HL092961
 R01CA215059
 R01DK102911, R56EB027729
 R01CA175382, R01HL132325
 R01GM111615

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, June 7, 2021 7:11 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

From: (b) (6)
Sent: Friday, June 4, 2021 1:42 PM
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 5/20/21.

Sincerely,

(b) (6)