



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

September 11, 2019

Re: Animal Welfare Assurance
A3153 [OLAW Case 2K]

Randall S. Mason
Vice President, Research Operations
Beth Israel Deaconess Medical Center
330 Brookline Ave., GRZ 6
Boston, Massachusetts 02215

Dear Mr. Mason,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 9, 2019 letter reporting a noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Policy) within the animal care and use program at the Beth Israel Deaconess Medical Center (BIDMC). Your letter supplements information in the initial prompt telephone report on June 20, 2019. According to the information provided, OLAW understands that on June 5, 2019 your IACUC was informed that a mouse was found in the animal housing room with a tumor that measures 6 cm long and 1 cm wide. The Attending Veterinarian authorized euthanasia of the animal. This activity was PHS funded.

Corrective and preventive actions included the IACUC approval of a corrective action plan by the PI which included monitoring frequency as tumor growth progresses; clarification as to who will monitor the mice and oversee their condition at all times while animals are on study, and; that a monitoring log be maintained inside the animal housing room.

OLAW appreciates the prompt consideration of this matter by Beth Israel Deaconess Medical Center, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, to take corrective actions, and prevent recurrence. OLAW concurs that the issues warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

for
Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



Beth Israel Deaconess
Medical Center



A teaching hospital of
Harvard Medical School

Randall S. Mason
Vice President, Research
Operations
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Axel V. Wolff, M.S., D.V.M.
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

Re: Non-compliance on Beth Israel Deaconess Medical Center (BIDMC) protocol #041-2016 titled "Genetic contributors to brain tumorigenesis in the mouse". This study uses mice and was funded by NIH grant #1UG3CA241685-01 under the title "Uncovering exRNA and protein determinants of secreted vesicle heterogeneity by flow cytometric purification of vesicle subsets from cells and plasma".

September 9, 2019,

Dear Dr. Wolff:

The Institutional Animal Care and Use Committee (IACUC) was informed on June 5th, 2019 by the Attending Veterinarian of the following animal welfare infraction:

- A mouse on the above referenced protocol, was found in the animal housing room, with a tumor that measured 6 cm long and 1 cm wide.

The Principal Investigator was contacted and the mouse was euthanized per authorization of the Attending Veterinarian.

On July 25th, 2019 the IACUC discussed the Principal Investigator's response to their letter dated June 7th, 2019. Collectively, the Committee felt that the response was unsatisfactory, as it did not provide a clear resolution and a plan going forward. The Committee requested additional information and clarity of a monitoring plan while animals are on study and to include monitoring frequency as tumor growth progresses. The Committee requested it be made clear who will monitor the mice and oversee their condition at all times while animals are on study. Finally, the Committee requested that a monitoring log be maintained inside the housing room so as to be available to ARF staff and that will include records of daily measurements once the tumors reach 1.5 cm in size. Our tumor policy limits growth to less than 2 cm.

On September 5th, 2019 the IACUC discussed the Principal Investigator's response to their letter and found that his response adequately addressed the Committee's additional requests, which included an example of the monitoring log that will be used.

Sincerely,

(b) (6)

Randall S. Mason
Institutional Official, Vice President, Research Operations

Cc: Chief, Department of Medicine
Principal Investigator
IACUC Chair
IACUC Administrator
AAALAC, International

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, September 09, 2019 2:34 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: please see 2 attached letters

Thank you for providing these two reports (b) (6) We will send official responses 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: (b) (6)
Sent: Monday, September 09, 2019 10:42 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: please see 2 attached letters

Hello,

Please see the 2 attached letters.

Sincerely,

(b) (6)



Beth Israel Lahey Health 
Beth Israel Deaconess Medical Center



Initial Report of Noncompliance

By: BMDate: 6/26/19Time: VoicemailName of Person reporting: (b) (6)Telephone #: (b) (6)Fax #: (b) (6)Email: (b) (6)Name of Institution: Beth Israel Deaconess

Assurance number: _____

Did incident involve PHS funded activity? Yes, (ROI)

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Mouse found w/ 6cm x 1cm tumor
Euthanized by vet.

Species involved: MousePersonnel involved: Researcher

Dates and times: _____

Animal deaths: _____

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

IACUC meets 7/25/19

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

OFFICE USE ONLY

Case # _____