



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

January 17, 2019

Re: Animal Welfare Assurance
A3775-01 [OLAW Case 11]

Ms. Heather Gipson-Cosier
Associate Vice Provost for Research Compliance
Tufts-University
Tufts Medical Center – Boston Campus
136 Harrison Avenue
Boston, MA 02111

Dear Ms. Gipson-Cosier,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 14, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Tufts University, following up on an initial telephone report on October 15, 2018. According to the information provided, OLAW understands that mice were housed in a laboratory not approved as a satellite facility and were given expired anesthetics and analgesics to conduct perfusions.

The corrective actions consisted of suspending animal use privileges for the Principal Investigator and staff, transferring the mice to a holding protocol, terminating the research protocol, placing the PI on permanent probation, prohibiting the PI from serving as a PI on future protocols, and permanently revoking animal use privileges for the other investigator involved. The PI may apply to be reinstated to work with animals after one year and, if approved, will be monitored for six months.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the Institutional Animal Care and Use Committee. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at Tufts University are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



Office of the Vice Provost for Research
Institutional Animal Care and Use Committee

January 14, 2019

Dr. Axel Wolff
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910, Bethesda, MD 20892

Dear Dr. Wolff:

This letter notifies OLAW of non-compliance that was voted to be significant, as required by the PHS Policy on Humane Care and Use of Laboratory Animals (section IV.F.3). The Tufts University (Boston Campus) Assurance number is D16-00459 (A3775-01). The following non-compliance was found under (b) (6) IACUC protocol #B2018-27. First, eleven occupied mouse cages were found in (b) (6) laboratory. (b) (6) in the laboratory, confirmed that mice are brought to the laboratory, housed for up to 3 days, then euthanized via perfusion under ketamine and xylazine. However, the (b) (6) IACUC protocol does not include approval to remove animals from the centralized facility for any amount of time. Second, it was found that expired ketamine and expired xylazine were used to perfuse these mice.

The IACUC Chair, in consultation with the Attending Veterinarian and Institutional Official, revoked animal facility access for all protocol personnel, including the Principal Investigator, pending a compliance investigation. The animals were transferred onto a holding protocol for continued care.

The PI was notified of the non-compliance and asked to respond to the IACUC. At the IACUC meeting on November 7, 2018, the committee discussed the incidents, the PI's response letter, and past compliance history for both (b) (6) and (b) (6). The IACUC voted the incident to be considered significant and also required the following:

1. (b) (6) current protocol, #B2018-27, was terminated.
2. (b) (6) was suspended from all animal use until November 7, 2019. She must submit a request to the IACUC to be reinstated to work with animals at the end of the suspension. If reinstated, a 6-month monitoring program will be instituted.
3. (b) (6) was placed on permanent probation with periodic review by the IACUC for all animal studies for which she has any involvement. Any subsequent IACUC violation could result in immediate and permanent suspension of approval to work with animals at the institution.
4. (b) (6) was permanently revoked from the privilege to act as a Principal Investigator on any future IACUC protocols.
5. (b) (6) was immediately and permanently suspended from working with animals.

After notification, the PI requested reconsideration. (b) (6) and (b) (6) wrote an appeal letter to be considered. At the January 9, 2019 IACUC meeting, the Committee members reviewed the new appeal and voted to uphold the decisions made at the November IACUC meeting.

This letter provides a summary and resolution to OLAW. There is no NIH funding for this research.

Sincerely,

(b) (6)

Heather Coser, JD, MA
Institutional Official and Associate Vice Provost for Research Compliance
Tufts University

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, January 15, 2019 12:24 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Gipson-Cosier, Heather; (b) (6)
Subject: RE: OLAW Report - Tufts University D16-00459 (A3775-01)

Thank you for providing this report (b) (6) We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

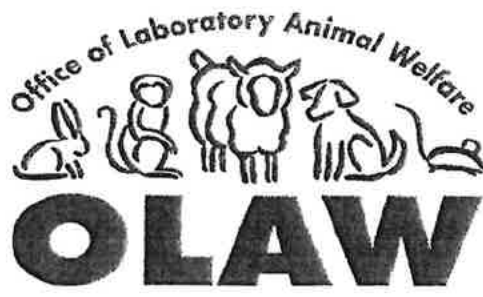
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From: (b) (6)
Sent: Tuesday, January 15, 2019 11:51 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>; (b) (6)
(b) (6)
Subject: OLAW Report - Tufts University D16-00459 (A3775-01)

Hello,
Please find attached a report letter regarding a significant issue of non-compliance at Tufts University, D16-00459 (A3775-01).

Regards,
(b) (6)

(b) (6)



Initial Report of Noncompliance

By: aw

Date: 10/15/18

Time: 11:15

Name of Person reporting: (b) (6)
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: Tufts U
Assurance number: A3775

Did incident involve PHS funded activity? No
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?

Housing in lab in approved state to be used
Used expired ketamine

Species involved: mouse
Personnel involved:
Dates and times:
Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # _____