



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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December 26, 2018

Re: Animal Welfare Assurance
A3775-01 [OLAW Case 1J]

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

Dear Ms. Gipson-Cosier:


The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 13, 2018 letter regarding noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals at Tufts University. According to the information supplied, OLAW understands that expired buprenorphine was administered to mice that underwent dorsal skin graft surgery. The letter indicated that no NIH funding was used for the associated animal activity.

Corrective actions included laboratory procedural changes and assigned responsibilities for storage, access, tracking, and documentation to ensure appropriate handling and identification of expired substances. The laboratory will update their training procedures to emphasize checking substances regularly and using substances within their expiration dates. Additionally, staff will be provided information to increase understanding that use of expired substances can negatively impact animal health and welfare.

OLAW is satisfied that appropriate actions have been taken to address and prevent recurrence of this incident. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

 Jane Na, DVM
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Contact

3775 - 1J



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

December 17, 2018

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:

Tufts University, in accordance with PHS Assurance D16-00459 (A3775-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding the administration of expired buprenorphine to mice that underwent dorsal skin graft surgery under (b) (6)'s IACUC protocol entitled "The Role of Cell-cell Interactions in Early Oral Neoplasia."

Upon learning of the incident, the PI took immediate action by discussing the situation with the staff and students in his laboratory. He explained the seriousness of the oversight and how it affects the well-being of the animals. The issue was reported to the IACUC and the PI was asked to provide corrective actions to prevent any recurrence of the incident.

The following plan of action was implemented by the PI:

- 1- The laboratory administrator will store all drugs and logs in a centralized location and will be the point person for accessing and tracking them. In this way, the laboratory will have a dedicated person focused on making sure drugs and other substances are used properly and in a timely manner. If the administrator is away, the PI will be available to access the drugs and will report their usage to the administrator when they return.
- 2- The laboratory will create scanned copies of drug logs after each use as a backup. Maintaining these logs will help ensure unused substances are returned before they expire.
- 3- The laboratory will update its animal training procedures for staff and students, specifying the importance of checking substances regularly and using them within their expiration dates.
- 4- Staff will be provided more information as to how this type of error can directly impact the health and well-being of the animals being used.

The IACUC reviewed and accepted the corrective action plan as submitted by the PI. At their meeting on Dec. 5, 2018, the issue was voted to be significant. This letter provides a summary of the issue and resolution to OLAW. There was no NIH funding used for this research.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Heather Gibson-Cosier, JD
Associate Vice Provost for Research Compliance
Tufts University

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 19, 2018 2:21 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. 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: Wednesday, December 19, 2018 1:55 PM
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)

Good afternoon,
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)