



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 1K]

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 March 13, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Tufts University. According to the information provided, OLAW understands that rats undergoing heart surgeries failed to receive the required post-operative analgesia, the rats were not weighed as stated, the rats were not monitored at the frequency stated, and the survival surgery card was not used.

The corrective actions consisted of the Principal Investigator (PI) ensuring that the laboratory staff is aware of the content of the protocol and relevant guidelines and policies. The staff must follow the protocol, the PI will observe a surgery before allowing staff to perform it independently, all necessary drugs will be available, and the individual responsible was retrained.

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 institution to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair



March 13, 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:

We are writing to notify OLAW of the circumstances and actions taken with respect to the following issue of non-compliance, 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).

One rat underwent heterotopic heart implantation under (b) (6) IACUC protocol entitled "MURINE Heterotopic Heart Transplant Technique." The following noncompliance ensued:

- Post-operative analgesia was not provided as required in the protocol (one initial dose of Buprenorphine-SR then PRN (q 48-72 hours)).
- The weight of the rat wasn't taken prior to surgery or once a week thereafter and the rat was not monitored three times a day for three days, as required in the protocol.
- The Rodent Survival Surgery card wasn't used as required in the IACUC Policy on Conducting Survival Surgery in Rodents.

In her response to the IACUC, the Principal Investigator explained how the procedure is technically difficult and has a steep learning curve. Previous attempts had been unsuccessful in that the transplanted hearts did not begin beating and rats were euthanized while still under anesthesia. In this case, the analgesic wasn't administered because the surgeon did not expect to recover the rat from surgery. However, she proceeded to recover the rat when the transplanted heart began beating.

To prevent any future recurrences, the PI implemented the following corrective action plan:

1. The PI will ensure all researchers are well informed of the IACUC's requirements by reviewing the IACUC protocol, IACUC Policies, and the Guidelines for Conducting Survival Surgical Procedures.
2. All research staff will carefully review and adhere to approved protocols and emphasize animal welfare, particularly during transitions in experimental conditions/procedures.
3. The PI will observe each research staff member conduct at least one survival surgery before allowing them to perform survival surgery without direct supervision.
4. The PI will ensure all lab staff have access to necessary drugs before initiating survival surgery.
5. The researcher who performed the surgery has already been retrained on pre- and post-operative care by a clinical veterinarian in Tufts Comparative Medicine Service.

The issue was voted to be significant at the last convened meeting of the IACUC. This letter provides a summary of the issue and resolution to OLAW as voted by the IACUC. There is no NIH funding for this research.

If you have any questions, please contact us. Thank you.

Sincerely,

(b) (6)

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 22, 2019 8:14 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Report - Tufts University D16-00459 (A3775-01)

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: Thursday, March 21, 2019 11:56 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>; (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)