



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

October 25, 2019

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

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

Dear Dr. Gipson-Cosier,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated October 15, 2019 regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Tufts University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, our office understands that several noncompliances were found in a laboratory with a zebrafish facility beginning on June 14, 2019. The zebrafish were part of an NIH funded activity. The noncompliances included protocol deviations, failure to provide information regarding zebrafish mortalities to the veterinarian, improper husbandry that resulted in animal deaths, and failure to follow corrective measures required as a result of prior noncompliances.

Because of the laboratory's history of repeated noncompliance, the Institutional Animal Care and Use Committee (IACUC) placed the researcher on probation as the Principal Investigator (PI) of the activity, to be re-evaluated after one year. The IACUC will conduct monthly inspections of the laboratory for at least six months. The zebrafish facility will be managed by Tufts Comparative Medicine services rather than the researcher. In addition, the IACUC mandated that failure to follow these requirements, or any further noncompliances may result in IACUC suspension of the activity.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and at this time find no cause for further action by this office. Please be advised that OLAW recommends prompt preliminary reporting of noncompliance issues with submission of a final report once corrective action has been taken, and please contact our office if the corrective actions are not carried out as described. Also, please be aware that results obtained from activities without IACUC approval may encounter obstacles with publication.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW
Animal Welfare Policy Specialist
Office of Laboratory Animal Welfare

cc: IACUC Contact

Obtained by Rise for Animals. Uploaded 08/10/2020

Retrieved from Animal Research Laboratory Overview (ARLO)



October 15, 2019

A3775-1N

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 notifies OLAW of the circumstances and actions regarding serious or continuing non-compliance with PHS Policy and deviation from the provisions of the *Guide*, as required by the PHS Policy on Humane Care and Use of Laboratory Animals (section IV.F.3). Tufts University (Boston Campus) Assurance number is D16-00459 (A3775-01).

Several issues were reported to the IACUC pertaining to Dr. Pamela Yelick's zebrafish colony and are summarized as follows:

1. Protocol noncompliance:
 - a. On June 14, 2019, eleven zebrafish were found dead in tanks kept under low flow conditions for longer than the one-hour timeframe approved in the protocol.
 - b. On April 11, 2019, seven zebrafish were found dead in a tank with a heat rod. The PI later explained that the fish were a disease model for Fibrodysplasia Ossificans Progressiva and as such, would be expected to die from transgene activation after the heating procedure. This lethal phenotype was not addressed in the protocol as required.
2. *Guide* deviations:
 - a. Despite numerous attempts after the June 14, 2019 zebrafish mortalities, the veterinarian was not provided the information necessary to determine a cause or find a resolution to the deaths in a timely manner, as required (*Guide* pg. 106).
 - b. On July 16, 2019, fifty zebrafish were found dead within six overcrowded tanks left off the system overnight. As per the *Guide*, adult zebrafish should be housed 5 fish per liter of water (pg. 83)
3. The Corrective Action Plan that resulted from a previous significant incident, and submitted to OLAW on May 13, 2019, as a method to prevent future noncompliance was not followed as required.

The above issues and Dr. Yelick's responses were discussed at a convened meeting of the IACUC. The IACUC also considered past noncompliance history and the management of the zebrafish facility. They voted to consider the issues significant and required the following stipulations for the PI to be allowed to continue her research:

1. Dr. Yelick may remain PI of the protocol for a probationary period. This status will be re-evaluated after one year.
2. The IACUC will conduct monthly inspections of the PI's laboratory and zebrafish facility for at least 6 months.
3. Tufts Comparative Medicine Services will take over management of the zebrafish facility.

The PI was informed of these stipulations and reminded that any failure to follow these requirements or any subsequent violations could result in suspension of the protocol and/or suspension of the privilege to serve as PI of the protocol. Dr. Yelick confirmed in writing her agreement with these terms.

This letter provides a summary of the issue and resolution to OLAW as voted by the IACUC. The grant that covered the animal work is R21AR072085.

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: Thursday, October 17, 2019 7:30 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: Wednesday, October 16, 2019 2:31 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Heather.Gipson_Cosier@tufts.edu
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)