

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

May 23, 2022

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 402-7065

Re: Animal Welfare Assurance A3775-01 [OLAW Case 10]

Dr. Philip Hinds Senior Director of Research Compliance Tufts-New England Medical Center 136 Harrison Avenue Boston, MA 02111

Dear Dr. Hinds,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 16, 2022, letter reporting an instance of noncompliance at Tufts University School of Medicine. OLAW understands that on March 17, 2022, Comparative Medicine Services (CMS) found a cage containing an adult male with a litter of dead and moribund neonatal mouse pups. Apparently, laboratory personnel removed the dam prematurely from the cage despite receiving multiple trainings on colony management and overcrowded cages, including identification of male and female mice. The animal activity in question was not supported by PHS funds.

The corrective actions consisted of the Principal Investigator (PI) revoking active animal work for the responsible researchers and hiring CMS's Rodent Breeding Service to manage the breeding colonies. The IACUC also required all members of the laboratory, including the PI, to complete CMS Orientation, Rodents 101, and Rodents 102 training within six months.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

S

Neera V. Gopee - Digitally signed by Neera V. Gopee -S

Date: 2022.05.23 11:14:07 -04'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

cc: IACUC Chair



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

May 16, 2022

3775-1Q

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 Assurance number D16-00459 (A3775-01) and PHS Policy IV.F.3., provides this report of a Serious deviation from the provisions of the Guide. This letter provides a summary of the issues and resolution to OLAW as reported to the IACUC.

On March 17, 2022, Tufts Comparative Medicine Services (CMS) found a cage of mice containing one adult male with a litter of dead and moribund neonatal pups. Further investigation revealed the dam was misidentified as male and removed from the cage prematurely. This occurred despite multiple trainings laboratory members received on colony management and overcrowded cages, which included identification of male and female mice. To prevent future incidents, the Principal Investigator removed the responsible scientists from active animal work and hired CMS's Rodent Breeding Service (RBS) to take over management of their breeding colonies.

At the IACUC's last convened meeting, members discussed the circumstances surrounding the death of the mice and were provided a brief history of similar issues CMS has encountered with this laboratory. The Committee agreed with the corrective measure of hiring RBS to take over management of their breeding colony. However, the lack of knowledge in basic biology displayed by laboratory staff (i.e., inability to distinguish male from female mice) was concerning given the Category E animal models approved in the protocol. Since neonatal animals were not left with their mother until weaning age, the colony was not managed in accordance with the principals of animal reduction, and laboratory personnel were not adequately trained or qualified in the basic principles of laboratory animal science to ensure animal well-being, the IACUC voted for the incident to be considered a Serious deviation from the provisions of the Guide.

Further, the IACUC voted to require additional training for all members of the laboratory, including the PI. The laboratory was given 6 months to complete the following 3 CMS trainings:

1) CMS Orientation training, 2) Rodents 101, and 3) Rodents 102.

There are no NIH grants associated with this research.

Tufts University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard.

Sincerely,

(b) (6)

Philip Hinds, PhD Senior Director of Research Compliance Institutional Official Tufts University School of Medicine

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Wednesday, May 18, 2022 7:02 AM
To:	(b) (6)
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: OLAW Report for Tufts University, D16-00459 (A3775-01)

Thank you for this report. We will send a response soon.

Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

From:

(b) (6)

Sent: Monday, May 16, 2022 12:54 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc: Hinds, Philip W. <Phil.Hinds@tufts.edu> Subject: [EXTERNAL] OLAW Report for Tufts University, D16-00459 (A3775-01)

Good morning,

Please find attached a report letter regarding a serious deviation from the provisions of the Guide at Tufts University, D16-00459 (A3775-01).

Regards,

(b) (6)