



3775-IR

Office of the Vice Provost for Research Institutional Animal Care and Use Committee October 26, 2022

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 serious and continuing noncompliance with the PHS Policy and suspension of animal activities by the IACUC. This letter provides a summary of the issues and resolution to OLAW as reported to the IACUC.

On August 30, 2022 the following non-compliances were reported to the IACUC under (b) (6) IACUC protocol #B2020-91: injections in mice via an unapproved route/location, failure to provide their required analgesia, inadequate supportive care and monitoring, and failure to euthanize mice upon reaching the approved humane endpoints.

The PI was asked to respond to the claims of noncompliance in a letter to the IACUC. In it he refuted most of the allegations and took no responsibility for his actions. At the October 5, 2022 IACUC meeting, Committee members discussed the allegations, the PI's response, and reviewed information provided by the Comparative Medicine Service (CMS) which supported the claims. The documentation from CMS included a previous training outline, photographs of ulcer measurements, and e-mails between the researchers and CMS staff. The Committee also reviewed the PI's noncompliance history, which included minor non-compliances and another serious incident reported to OLAW earlier this year on May 16, 2022. The IACUC voted to consider these incidents Significant and approved the following corrective actions:

- (b) (6) was immediately terminated as Principal Investigator of protocol #B2020-91. His
 privilege to act as PI on any future IACUC protocols at Tufts have been permanently revoked.
- 2. (b) (6) was suspended from all animal user privileges on any IACUC protocol at Tufts for a period of one year, at which time he may apply to the IACUC to lift this suspension.
- 3. The Senior Director of CMS was approved as temporary PI for protocol #B2020-91 and CMS assumed responsibility for the care, monitoring, and breeding of mice until a new PI is identified.
- 4. A new PI must complete all personnel requirements and submit a Change in PI form to the IACUC by Oct. 27, 2022. If a new PI has not been instated by this date, the protocol will be terminated at the next IACUC meeting.
- 5. All protocol personnel must complete 3 hands-on trainings with CMS (Orientation training, Rodents 101, and Rodents 102) to verify competency. Current animal users must complete these trainings by Nov. 9, 2022. All new animal users must complete this training before they can receive IACUC clearance to work with animals.
- 6. Additional IACUC oversight will be required in the form of monthly progress reports and IACUC inspections for the final year the protocol is active.

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

Sincerely,

(b) (6)

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

McCoy, Devora (NIH/OD) [E]

From: (b) (6)

Sent: Wednesday, October 26, 2022 4:47 PM

To: OLAW Division of Compliance Oversight (NIH/OD)

Cc: Hinds, Philip W.

Subject: [EXTERNAL] OLAW Report for Tufts University, D16-00459 (A3775-01)

Attachments: Tufts OLAW notification Ramadan 102622.pdf

Follow Up Flag: Follow up Flag Status: Flagged

Hello,

Please find attached a report of serious noncompliance with the PHS Policy and suspension of animal activities by the IACUC at Tufts University, D16-00459 (A3775-01).

Regards,	
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McCoy, Devora (NIH/OD) [E]

From:

Sent: To:	Thursday, October 27, 2022 12:16 PM
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: OLAW Report for Tufts University, D16-00459 (A3775-01)
Good afternoon (b) (6)	
Thank you for sending this repor	t and we will send an official response soon.
Best, Devora	
Devora McCoy, BS, MBA Program Analyst Division of Compliance Oversigh Office of Laboratory Animal Welf National Institutes of Health 301-435-2390	
Cc: Hinds, Philip W. <phil.hinds@ Subject: [EXTERNAL] OLAW Report Hello,</phil.hinds@ 	e Oversight (NIH/OD) <olawdco@od.nih.gov> Otufts.edu> Ort for Tufts University, D16-00459 (A3775-01) of serious noncompliance with the PHS Policy and suspension of animal activities</olawdco@od.nih.gov>
Regards,	
	(b) (6)

OLAW Division of Compliance Oversight (NIH/OD)