



Stop Animal Exploitation NOW!

Anthony P. Monaco, President
Office of the President
Tufts University
Ballou Hall, 2nd Floor
Medford, MA 02155
Via email: anthony.monaco@tufts.edu

4/12/23

President Monaco,

I am writing to you today to insist that Tufts University immediately take action to avert repetition of an extremely disturbing situation which resulted in the suspension of an experimental protocol due to violations of federal regulations and animal abuse.

According to Tufts University correspondence dated 10/26/22 (attached) disciplinary actions have been taken against a Tufts University Principal Investigator for violating federal regulations. These disciplinary actions follow extremely serious violations which were thoroughly documented. Even so, the Investigator apparently attempted to deny the facts.

The correspondence states: ***“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 PHS Policy and suspension of animal activities by the IACUC.***

“On August 30, 2022 the following non-compliances were reported to the IACUC under _____ IACUC Protocol #B2020-91: injections in mice via an unapproved route/location, failure to provide 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 IACUC voted to consider these incidents Significant and approved the following corrective actions:

- 1. _____ was immediately terminated as Principal Investigator for protocol #B2020-91. His privilege to act as PI on any future IACUC protocols at Tufts have been permanently revoked.***
- 2. _____ 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.”

While the actions taken against this Principal Investigator were indeed both justified and significant, they were not sufficient. This principal investigator clearly abused animals, the Tufts report states that his violations included: **“injections in mice via an unapproved route/location, failure to provide required analgesia, inadequate supportive care and monitoring, and failure to euthanize mice upon reaching the approved humane endpoints.”**

These violations were obviously extremely inhumane to the animals, but this is not the only problem here. This **“serious and continuing noncompliance with PHS Policy”** not only abused the animals in the project, this noncompliance also rendered any results which could have come out of the project scientifically meaningless, and forced the experiment to be unreproducible. The purpose of these regulations is to both protect animals from abuse, and to make the experiment consistent, meaning that it is performed the same way every time. With such obvious failure to adhere to the protocol, this project’s results would be incomprehensible, and useless.

Any data obtained from this project so far would also be unpublishable, because scientific journals require adherence to federal regulations and scientific standards. This project has obviously failed to do either of these things.

In the final analysis, this project not only killed animals painfully, but it also generated data which would be inconsistent even in mice, and could not be generalized to any other species. This experiment would not even usefully advance knowledge of murine biology.

This project is not only inhumane, it is also clearly scientifically fraudulent.

Apparently this Principal Investigator also had previous noncompliance issues, according to the report. I have also attached an earlier report which is the documentation of these previous issues.

Anyone who has demonstrated total disregard for both animal welfare and scientific principles should not be allowed to perform any kind of research whatsoever — whether it involves animals or not. This Principal Investigator has clearly demonstrated that he cannot be trusted to follow policies, procedures, or regulations. If anything, the noncompliances by this PI have gotten progressively worse.

Therefore, he must be terminated. This was not a single occurrence. Tufts has generated two separate reports about these noncompliances.

Also, the fact that these issues occurred at Tufts demonstrates that there are serious and ongoing problems with the entire animal research program at Tufts University, and action must be taken to prove that Tufts has taken these issues seriously. Termination of this PI would be a good start.

Therefore, if Tufts University does not terminate this individual, I will be forced to contact AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) International to demand that Tufts’ accreditation be terminated.

This situation cannot be excused. The damage cannot be undone. Therefore the consequences must be severe — Terminate this PI.

Any university, like Tufts, who attempts to present itself as (according to the website) promoting Activism and Social Justice, and also promotes something titled an “Animal Matters Seminar” should not have a Principal Investigator who has systematically abused animals, regardless of species, in its employ.

It is time for the Tufts University to draw a line in the sand and say ‘No More.’ A very clear message must be sent to all employees. Fraudulent/abusive research will not be tolerated, and Tufts University will act out of integrity, even if our staff has failed to do so.

I look forward to hearing from you in the near future.

Sincerely,

Michael A. Budkie, A.H.T.,
Executive Director, SAEN

A3775-1R



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:

1. (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



A3775-1Q

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

May 16, 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 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