



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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 6, 2020

Re: Animal Welfare Assurance
A3085-01 [OLAW Case 1L]

Dr. Theodore F. Taraschi
Senior Associate Provost for
Research Conduct and Compliance
Thomas Jefferson University
1020 Locust Street, (b) (4)
Philadelphia, PA 19107

Dear Dr. Taraschi,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 2, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Thomas Jefferson University following up on an initial July 29, 2019 notification by telephone.

According to the information provided, this Office understands that the Thomas Jefferson University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: nine live pups and one euthanized dam found in a plastic bag without any label or tag inside a temporary carcass refrigerator on July 22, 2019. Dam appeared to have been euthanized by carbon dioxide asphyxiation, but a secondary method of euthanasia did not appear to have been employed. The pups were removed from the bag and after receiving permission from the clinical veterinarian, they were humanely euthanized by the IACUC Regulatory Affairs Manager. Based on video surveillance and ear tag, investigators identified the protocol to which the animals belonged. A laboratory staff member admitted that they sacrificed a dam and her pups on July 21st using only carbon dioxide. They stated the reason they did not conduct the required secondary method was because they found themselves without the proper instruments and didn't want to leave the mice and return to the lab to obtain necessary equipment.

The PI was contacted about the matter and voluntarily ceased plans for new experimentation involving mice and prohibited the staff member at fault from conducting any animal work. On August 1, 2019, the PI contacted the IACUC leadership team to inform them the responsible individual had been terminated for violation of Jefferson Code of Conduct. The PI requested permission to continue research projects to avoid allowing certain animals to grow past the age at which they were suitable for particular experiments. After discussion among the IACUC leadership team, it was agreed that to avoid wasting any animals, and because the PI voluntarily halted studies, and based on the actions taken by the PI demonstrating a commitment to compliance, resuming work would be acceptable. The Clinical Veterinarian observed other members of the laboratory euthanize mice and deemed them "very proficient" and should be permitted to continue their work. The IACUC met on August 28, 2019 and found the PI's plans extremely adequate and concluded that the matter required no further action. It is noted that the final report did not including funding source involving the incident.

Based on its assessment of this explanation, OLAW understands that the Thomas Jefferson University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair
IACUC Regulatory Affairs Manager

January 2, 2020

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Morse,

Thomas Jefferson University, in accordance with Animal Welfare Assurance #D16-00051 (A3085-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding Animal Use Protocol #01910. This incident was first reported to OLAW via a phone call made on July 29, 2019 by (b) (6)

The animals involved in this incident were mice. On July 22, 2019, the IACUC Regulatory Affairs Manager was in one of the central animal facilities when they found nine live pups, along with one euthanized dam, in a plastic bag without any label or tag in the animal facility's temporary carcass refrigerator. The dam appeared to have been euthanized by carbon dioxide asphyxiation, but a secondary method of euthanasia did not appear to be employed. The pups were removed from the plastic bag immediately and taken to the nearest procedure room. The IACUC Regulatory Affairs Manager promptly contacted the Clinical Veterinarian requesting permission to euthanize the pups via decapitation. Once granted, he humanely euthanized the pups.

Using video surveillance and the dam's ear tag, investigators were able to identify the protocol to which the animals belonged. The PI's laboratory was interviewed and a laboratory staff member admitted that they sacrificed a dam and her pups on July 21 using only carbon dioxide. They stated that they thought all of the animals were dead based on lack of respiration and the only excuse for not conducting the required secondary method was that they found themselves without the proper instruments and didn't want to leave the mice and return to the laboratory to obtain the necessary equipment.

The PI was contacted about the matter and not only did they voluntarily halt any plans for new experimentation involving mice, but also immediately prohibited the staff member at fault from conducting any animal work moving forward, including revoking their animal facility access. Additionally, the PI indicated that they would be speaking with Human Resources regarding the appropriate disciplinary action to take. The PI, a licensed veterinarian, demonstrated a very dedicated interest in maintaining animal welfare and a high quality, compliant research operation.

On August 1, 2019, the PI contacted the IACUC leadership team to inform them that the responsible individual had been terminated for violation of Jefferson Code of Conduct, ultimately based on this situation. The PI also requested permission to continue with their ongoing animal research projects in order to avoid allowing certain animals to grow past the age at which they were suitable for particular

experiments. After discussion among the IACUC leadership team, it was agreed that (a) to avoid wasting any animals, (b) because the halt on initiating new experiments was voluntary, and (c) based on the actions taken by the PI demonstrating a commitment to compliance, resuming work would be acceptable.

Additionally, it was arranged that the Clinical Veterinarian would observe the other members of the laboratory euthanize mice when the time came to assess proficiency. After doing so, the Clinical Veterinarian confidently reported that the laboratory members were "very proficient" and should be permitted to continue with their work.

Finally, the PI provided a letter to the IACUC detailing the incident and the corrective and preventative actions, all of which had already been taken, to ensure that an incident like this would not reoccur in the future. The IACUC, in its meeting on August 28, 2019, found the PI's plans extremely adequate and concluded that the matter required no further action.

Thomas Jefferson University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact (b) (6)

Thank you for your time and consideration.

Sincerely,

(b) (6)

Theodore F. Taraschi, Ph.D.
Senior Associate Provost for Research Conduct and Compliance
Institutional Official
Thomas Jefferson University

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 02, 2020 1:40 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Theodore Taraschi; (b) (6)
Subject: RE: [A3085-01] TJU Final Report - 190701, 190722

Thank you for these final reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6)
Sent: Thursday, January 02, 2020 9:58 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Theodore Taraschi <Theodore.Taraschi@jefferson.edu>; (b) (6)
Subject: [A3085-01] TJU Final Report - 190701, 190722

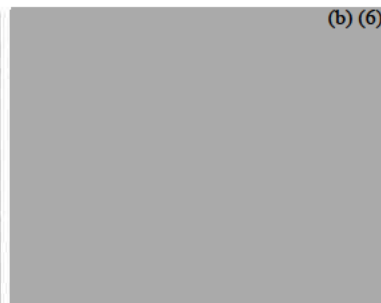
Dear Dr. Morse and the Office of Laboratory Animal Welfare,

On behalf of Dr. Theodore Taraschi, Institutional Official, I am writing to provide two final reports for incidents at Thomas Jefferson University. Please see attached. The preliminary reports were made on July 29, 2019. Please don't hesitate to contact us if you have any questions, concerns, or comments.

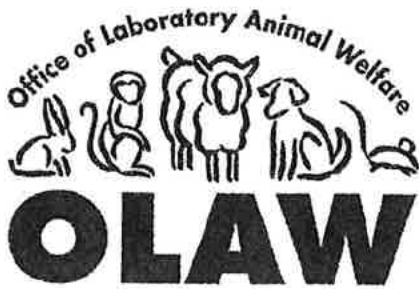
Happy New Year to the entire team!

Sincerely,

(b) (6)



Report Compliance Concerns Anonymously: 1-833-ONE-CODE (663-2633) or [Jefferson.MyComplianceReport.com](https://jefferson.mycompliancereport.com)



Division of Compliance Oversight

Record of Call for Case # A3085-1L

Date & Time	Message	Initials
12/10/19 3:45	Spoke w/ [REDACTED] (b) (6) - OLAW should have final report < 2 wks	Bm



Initial Report of Noncompliance

By: *BSM*Date: *7/29/19*Time: *4:15*Name of Person reporting: (b) (6)Telephone #: (b) (6)

Fax #:

Email:

Name of Institution:

Thomas Jefferson

Assurance number:

*A3085*Did incident involve PHS funded activity? ☐

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? *9 mouse pups in carcass refer. alive.
 Dam was dead. No 2nd method.*

Species involved: *Mouse*Personnel involved: *Researcher*Dates and times: *~ July 24, 2019*

Animal deaths:

Yes

Projected plan and schedule for correction/prevention (if known): _____

*Lab stopped any new animal work.
 Responsible individual on probation.*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____