



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

July 17, 2019

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

Dr. Theodore F. Taraschi
Vice President for Research
Thomas Jefferson University
1020 Walnut Street, (b) (4)
Philadelphia, PA 19107-5587

Dear Dr. Taraschi,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 11 and 27, and July 11, 2019 letters reporting three serious deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Thomas Jefferson University, following up on an initial telephone report on March 29, 2019. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Two mice died of starvation. A change in husbandry procedures had been made whereby clean cages are no longer loaded with food prior to use but have specialized diets added once the cage is put into use. It is believed that this change led to the incident.

Corrective action: Signs have been placed in the animal room reminding husbandry and research staff to add food to cages before placing them on the rack. The husbandry staff was counseled to double check all cages for food and water.

- 2) An investigator using a biohazardous agent failed to note this in the protocol, failed to receive approval from the Institutional Biosafety Committee (IBC), and failed to label the cages with biohazard warnings. The Principal Investigator (PI) claimed he had not received appropriate training on the biohazard policies.

Corrective action: The work was stopped and the PI submitted a request for IBC approval. The approval was obtained, the PI and staff were retrained, all animal users were reminded about the institutional biohazard procedures, institutional efforts are underway to improve training for new investigators, and a new protocol management system will be implemented which allows flagging of hazards.

- 3) One litter of mice died and another was wet but survived after their cages flooded. A condensation switch had failed and this caused water to accumulate in the ceiling and flooded the rooms below.

Corrective actions: Repairs were made to the ceiling to allow water to drain and to access the plumbing and new condensation switches were installed. All other switches were checked and a preventative maintenance program has been implemented.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in each situation to correct and prevent recurrence of the problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Please remember to always state the species involved (#2) and to provide the grant number(s) of any projects supported by NIH or NSF. Thank you for informing OLAW about these matters.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
IACUC Regulatory Affairs Manager

July 11, 2019

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 an adverse event regarding Animal Use Protocol #01727. The species on this protocol is mouse. This incident was first reported to OLAW via a phone call made on March 29, 2019 by (b) (6)

On the evening of February 13, 2019, an authorized animal user was providing care to his animal colony in the vivarium when he noticed an abundance of water on the floor in one of the common hallways. He immediately informed the Clinical Veterinarian. The Clinical Veterinarian, in turn, contacted one of the animal vivarium supervisors who notified Jefferson Facility Services of the issue. Facility Services was immediately dispatched to the scene and after assessing the problem, discovered that a condensation switch in the animal room had malfunctioned, causing an accumulation of water in the ceiling and subsequently, minor flooding in the vivarium. Facility Services shut down the broken condensation switch and contacted animal facility staff to report that the issue had been resolved. Unfortunately, Facilities failed to also turn off another corresponding condensation line, causing more water to enter the vivarium throughout the night. The next morning, animal care staff arrived to the facility and discovered that three animal housing rooms in total were affected by the flooding. Most of the animals were unaffected; however, two cages, each with pups and a dam, experienced flooding in their respective cages. The Clinical Veterinarian attempted to revive the affected animals and was successful in resuscitating one of the litters but, regrettably, the other litter was unable to be saved.

Before beginning repairs on the condensation switch, Facilities first drilled a small hole in the ceiling to allow the amassed water to sufficiently drain. Next, an access hatch was installed in the ceiling to allow for easier accessibility to the overhead plumbing. Spackling and repainting of the damaged ceiling was also performed. New condensation switches were purchased and installed on April 30, 2019. Presently, all condensation switches throughout the vivarium are being checked and replaced as needed. A robust program of preventative maintenance has been instituted by the Institution to prevent similar events from occurring in the future.

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: Monday, July 15, 2019 12:39 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Theodore Taraschi; (b) (6)
Subject: RE: [A3085-01] TJU Final Report - 190330

Thank you for this final report (b) (6) We will send an official response soon.

Best regards, Brent Morse

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

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From: (b) (6)
Sent: Monday, July 15, 2019 8:17 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 - 190330

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

On behalf of Dr. Theodore Taraschi, Institutional Official, I am writing to provide the final report for an incident of noncompliance at Thomas Jefferson University. Please see attached. This is the last final report of the three that were preliminarily reported on March 29, 2019. Please don't hesitate to contact us if you have any questions, concerns, or comments.

Sincerely,

(b) (6)



(b) (6)

Report Compliance Concerns Anonymously: 1-833-ONE-CODE (663-2633) or Jefferson.MyComplianceReport.com

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Jefferson

Philadelphia University +
Thomas Jefferson University

1020 Locust Street
Alumni Hall, Suite M-41F
Philadelphia, PA 19107
T 215-955-3900
F 215-955-4050

June 27, 2019

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 #01830. The species on this protocol is mouse. This incident was first reported to OLAW via a phone call made on March 29, 2019 by (b) (6)

While reviewing the PI's protocol for its triennial review, one of the reviewers noticed that the PI mentioned use of adeno-associated virus (AAV) in one of his proposed experiments. However, the PI had not included this biohazard in the "Hazards" section of the animal use protocol where it should have been appropriately placed, nor had he attached the required Institutional Biosafety Committee (IBC) documentation indicating authorization to use AAV. The reviewer immediately brought this matter to the attention of the IACUC Specialist for further investigation. Upon investigation, it was found that the PI had never acquired the proper IBC approvals to utilize this biohazardous substance. The PI informed the IACUC Specialist that he was not using the biohazard at the present time but had done so in the past year. Additionally, it was found that the labels that should be placed on cages with hazards to caution animal users were not used, potentially placing animal care staff at risk. The PI stated that he did not purposely ignore the rules and guidelines for working with hazardous materials in the vivarium, but rather that he was unaware of the proper procedures to follow because he was never formally trained.

The PI was instructed to immediately cease all experimentation involving AAV and contact the Institutional Biosafety Officer to begin the process of acquiring all necessary IBC approvals in order to use this hazard in future experiments. The PI submitted all required paperwork and his request to utilize AAV was officially approved by the IBC on March 26, 2019.

In an effort to avoid such issues from occurring in the future, the PI and his staff member underwent hazard usage retraining in the animal vivarium on March 19 and March 27, respectively, and are now fully aware of the proper procedures. The severity of the infraction and the need to prevent such incidents in the future was also emphasized to all involved parties.

Further, as a precautionary measure, the IACUC Office sent out a broadcast e-mail to all animal users at the Institution to remind them of the mandatory procedures that need to be followed when working with hazardous materials in the vivarium.

Additionally, the IACUC, the Office of Animal Resources, the Institutional Biosafety Officer, and other institutional parties have begun exploring options of how to better communicate important information such as this to new faculty at the Institution. The possibility of a brief in-person informational session with new principal investigators is being explored.

Finally, the Institution is in the process of contracting a new protocol management system. This system is expected to include a mechanism by which hazards and chemicals are flagged if the appropriate approvals have not been obtained and documented alongside the IACUC animal use protocol. Such a feature will provide the IACUC, the IACUC Office, and the IBC an efficient and straightforward means of ensuring compliance.

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) at (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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 28, 2019 7:20 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [A3085-01] TJU Final Report - 190329

Thank you for this report, (b) (6) We will send a reply soon.

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

From: (b) (6)
Sent: Thursday, June 27, 2019 4:52 PM
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 - 190329

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

On behalf of Dr. Theodore Taraschi, Institutional Official, I am writing to provide the final report for an incident of noncompliance at Thomas Jefferson University. Please see attached. The preliminary report was made on March 29, 2019. Please don't hesitate to contact us if you have any questions, concerns, or comments.

Sincerely,
(b) (6)



(b) (6)

Report Compliance Concerns Anonymously: 1-833-ONE-CODE (663-2633) or Jefferson.MyComplianceReport.com

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Jefferson

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June 11, 2019

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 an incident involving Animal Use Protocol #02034. The species on this protocol is mouse. This incident was first reported to OLAW via a phone call made on March 29, 2019 by (b) (6)

On January 21, 2019, one of the animal vivarium supervisors notified the PI that a cage of his animals had expired due to apparent starvation. An animal caretaker found the two animals in a clean cage with the cage hopper devoid of food. The PI's laboratory manager brought this matter to the attention of the IACUC Specialist on January 29, because it was her belief that Laboratory Animal Services (LAS) was at fault since she stated that this cage consisted of naïve animals that had not yet been utilized for experimentation. An investigation into the matter was immediately launched, and both staff members of the PI's laboratory and also animal care staff were interviewed to try to determine the root cause of the incident. Ultimately, the investigation did not yield a conclusive answer.

This issue may have arisen as a result of a recent change to the procedures for acquiring new cages. Traditionally, clean cages were loaded with feed prior to use. A change occurred that resulted in multiple diets being used in the room, requiring that the appropriate feed be manually added to the cage by the responsible individual upon placing the cage in use. It is likely that this recent change contributed to this event.

In an effort to avoid such issues from occurring in the future, LAS posted prominent signage in the room to remind both the PI's research staff and the LAS care staff to add feed to the hopper before placing a new cage on the animal vent rack. Also, the Director of the Office of Animal Resources reminded the staff responsible for servicing the room to double-check that all animals in the room have been provided adequate food and water.

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) at (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

HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 15, 2019 12:35 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Theodore Taraschi; (b) (6)
Subject: RE: [A3085-01] TJU Final Report - 190328

Thank you for this final report (b) (6). We will send an official response soon.

Best regards, Brent Morse

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

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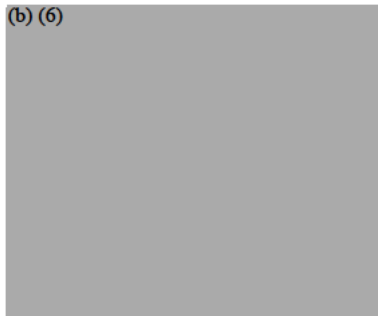
From: (b) (6)
Sent: Monday, July 15, 2019 8:17 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Theodore Taraschi <Theodore.Taraschi@jefferson.edu>; (b) (6)
Subject: [A3085-01] TJU Final Report - 190328

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

On behalf of Dr. Theodore Taraschi, Institutional Official, I am writing to provide the final report for an incident of noncompliance at Thomas Jefferson University. Please see attached. The preliminary report was one of three made on March 29, 2019. Please don't hesitate to contact us if you have any questions, concerns, or comments.

Sincerely,

(b) (6)



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Initial Report of Noncompliance

By: awDate: 3/29/19Time: 12:00Name of Person reporting: (b) (6)Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Thomas Jefferson UAssurance number: A3085Did incident involve PHS funded activity? Not known yet

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

- ✓ 1) 2 mice starved to death, no feed.
- ✓ 2) Steamline burst, water flooded cages. 3 rooms affected, 2 litter affected. I was saved
- ✓ 3) Biohazard used, not labeled on cages or room, no IBC approval

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

- 1) Retrain lab + animal care staff
- 2) Fix pipe. Retrain facilities staff
- 3) PI + staff retrained, notify all PIs

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____