



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) 480-3387

February 7, 2020

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

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 February 5, 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 8, 2019 notification by telephone and interim report received on November 25, 2019.

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: a postdoctoral researcher that conducted Transverse Aortic Constriction (TAC) procedures on 12 rats without IACUC review and approval. The discovery was made during the Principal Investigator's scheduled semiannual IACUC inspection. The PI was asked to voluntarily cease initiation of any new animal work and compose a corrective action plan. The interim report states the PI's corrective action plan included the following:

- Ensuring all lab staff have read and understood their animal use protocols.
- Barring the postdoctoral researcher involved in the incident from conducting additional animal work.
- Removal of the TAC surgery from the protocol and returning to the original left anterior descending (LAD) coronary artery ligation surgery written into the animal use protocol.
- Completing retraining on the LAD ligation surgery for all necessary individuals.

The IACUC formally suspended the laboratory's IACUC protocols and requested the PI and their staff undergo refresher training (hands on and online training). After completion of these items, the PI was informed that they could then petition the Committee for reinstatement of animal use privileges. The final report states the PI and their staff have completed all of the items needed for reinstatement of animal use privileges and the Committee voted unanimously at their regularly convened meeting in November 2019 to restore said privileges with several conditions. Those conditions include:

- Submitting monthly reports to the IACUC regarding the number of animals used, survival rate for surgeries and any adverse events for at least 6 months.

- Continuation of observation of surgical procedures (specifically LAD ligations and stereotaxic injections) by the clinical veterinarian and IACUC members designated as experts in these procedures.

The report states that continued observations of surgical procedures will be at the discretion of the IACUC. The IACUC Office has contacted the funding agency (NHLBI) and unallowable costs have been removed from the grant appropriately.

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. 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 Contact

February 05, 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 #01585. This incident was first reported to OLAW via a phone call made on July 8, 2019 by (b) (6). An interim report was also submitted on December 2, 2019.

The animals involved in this matter were rats. While conducting the Principal Investigator's scheduled semiannual IACUC inspection, it was discovered that a postdoctoral researcher in the PI's laboratory had conducted a Transverse Aortic Constriction (TAC) procedure on twelve rats without appropriate IACUC review and approval.

The PI was asked to voluntarily cease initiation of any new animal work and compose a corrective action plan stipulating how they would prevent any future recurrences going forward. The IACUC, in turn, formally suspended the laboratory's IACUC protocols, and also requested that the PI and their staff undergo refresher training, including both hands-on and online (AALAS Learning Library) training. After successful completion of these items, the PI was informed that they could then petition the Committee for reinstatement of animal use privileges.

The PI and their support staff have since successfully completed all of the items needed for reinstatement of animal use privileges and the Committee voted unanimously at their regularly convened monthly meeting in November 2019 to restore said privileges with several conditions. Conditions included submitting monthly reports to the IACUC regarding the number of animals used, survival rate for surgeries, and any adverse events for at least six months, as well as continued observation of any surgical procedures (specifically LAD ligations and stereotaxic injections) by the Clinical Veterinarian and IACUC members designated as experts in these procedures. Continued observation of surgical procedures will be at the discretion of the IACUC.

Finally, the IACUC Office has contacted the funding agency, the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and unallowable costs have been removed from the grant appropriately.

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



November 25, 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

INTERIM REPORT

Dear Dr. Morse,

Thomas Jefferson University, in accordance with Animal Welfare Assurance #D16-00051 (A3085-01) and PHS Policy IV.F.3., provides this interim report of a noncompliance regarding Animal Use Protocol #01585. This incident was first reported to OLAW via a phone call made on July 08, 2019 by (b) (6)

The animals involved in this matter were rats. In conducting the Principal Investigator's scheduled semiannual IACUC inspection in June 2019, the IACUC Specialist recognized that surgical records indicated that a Transverse Aortic Constriction (TAC) procedure had been conducted in several rats in 2018. Being familiar with the protocol, the IACUC Specialist was under the impression that the TAC surgery hadn't been added to the protocol until early 2019. After confirming these details, the IACUC Specialist and IACUC Regulatory Affairs Manager returned to discuss the matter with the postdoctoral researcher. The individual admitted to conducting the TAC surgeries without appropriate IACUC review and approval.

The IACUC Chair promptly requested that the PI voluntarily cease initiation of any new animal work until further notice. Additional investigation was also conducted, revealing that twelve rats underwent the TAC surgery before the procedure was properly added to the animal use protocol. Further, all noncompliant surgeries were conducted by the one postdoctoral researcher. The PI was asked to attend the upcoming IACUC meeting to provide the Committee with some insight on why this situation occurred. The Committee requested that the PI generate a corrective and preventative action plan to be reviewed by the Committee at the next convened IACUC meeting.

The PI provided a corrective action plan which included ensuring that all laboratory staff have read and understood their animal use protocols, barring the postdoctoral researcher from conducting any additional animal work, removing the TAC surgery from the protocol and returning to the original left anterior descending (LAD) coronary artery ligation surgery written into the animal use protocol, and completing retraining on the LAD ligation surgery for all necessary individuals. The Committee imposed additional requirements, including completion of all initial animal user training, including hands-on and online (AALAS Learning Library) training.

At this time, the laboratory is in the midst of completing all required training and will petition the IACUC for reinstatement of animal use privileges once all items have been completed.

Finally, the IACUC Office is in contact with the appropriate individuals at the funding agency, the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, December 03, 2019 7:59 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Theodore Taraschi; Larry Harshyne Jr
Subject: RE: [A3085-01] TJU Final Report - 190613

Thank you for providing this interim report. We will use it to update the case file and will await your final report.

Best regards, Brent Morse

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

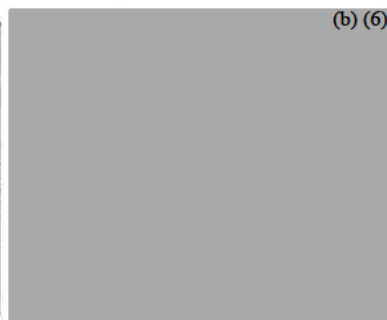
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From: (b) (6)
Sent: Monday, December 02, 2019 3:25 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Theodore Taraschi <Theodore.Taraschi@jefferson.edu>; Larry Harshyne Jr <Larry.HarshyneJr@jefferson.edu>
Subject: [A3085-01] TJU Final Report - 190613

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

On behalf of Dr. Theodore Taraschi, Institutional Official, I am writing to provide an interim report for an incident of noncompliance at Thomas Jefferson University. Please see attached. The preliminary report was made on July 8, 2019. Please don't hesitate to contact us if you have any questions, concerns, or comments.

Sincerely,
(b) (6)



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

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Tubbs, Jai (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 6, 2020 9:22 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Theodore Taraschi; Larry Harshyne Jr; (b) (6)
Subject: RE: [A3085-01] TJU Final Report - 190613

Good morning (b) (6)

Thank you for the report. We will send an official response soon.

Kind Regards,

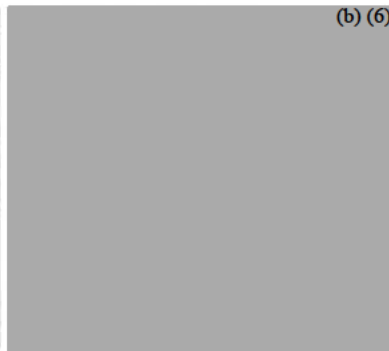
J Tubbs

From: (b) (6)
Sent: Wednesday, February 5, 2020 2:42 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Theodore Taraschi <Theodore.Taraschi@jefferson.edu>; Larry Harshyne Jr <Larry.HarshyneJr@jefferson.edu>; (b) (6)
Subject: [A3085-01] TJU Final Report - 190613

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 that occurred at Thomas Jefferson University. Please see attached. The preliminary report was made on July 8, 2019 and an interim report was made on December 2, 2019. Please don't hesitate to contact us if you have any questions, concerns, or comments.

Sincerely,
(b) (6)



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Tubbs, Jai (NIH/OD) [E]

From: Tubbs, Jai (NIH/OD) [E]
Sent: Monday, January 13, 2020 8:50 AM
To: (b) (6)
Subject: Follow up on preliminary reports for noncompliance

Good morning (b) (6)

I am following up on several open cases from November and one case reported in July 2019. Please provide an interim or final report or status update on the cases described below.

Preliminary report received 07/08/2019 and interim report received 11/25/2019.
Case involved Transverse Aortic Constriction surgery using the rat as an animal model that was not protocol approved.

Preliminary reports received 11/05/2019 ✓
Incident involved animal deaths due to dehydration due to defective water bottle/sipper tube.

Preliminary report received 11/08/2019 ✓
Incident involved animal found dead in a cage due to lack of access to food and water.

Jacquelyn Tubbs, DVM, DACLAM
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health

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Initial Report of Noncompliance

By: [redacted] (b) (6)

Date: 7/8/19

Time: 2:35 (b) (6)

Name of Person reporting [redacted]

Telephone #: [redacted]

Fax #: [redacted]

Email: [redacted]

Name of Institution: Thomas Jefferson U.

Assurance number: A3085

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Trans-aortic constriction performed w/o IACUC approval. Done before amendment approved.

Species involved: ~~mouse~~ Rats

Personnel involved: _____

Dates and times: Late June 2019

Animal deaths: _____

informed IACUC

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

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____