



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

March 13, 2020

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

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 20, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Thomas Jefferson University following up on an initial December 19, 2019 notification by telephone.

According to the information provided, this Office understands that Thomas Jefferson University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: a principal investigator conducting animal-related activities without appropriate IACUC review and approval. The final report states that the PI was utilizing a murine cell line in his experimental work but at the time he was only approved for the use of human cell lines to generate tumor xenograft models in animals. Also, the murine cell line had not undergone all of the appropriate rodent pathogen testing that is required by the institution. The PI and his support staff stated that they were under the impression that the murine cell line was already listed and approved for use on their animal use protocol. After discussion at the subsequent IACUC meeting, the Chair requested that the PI cease performance of this particular procedure until the appropriate IMPACT (pathogen) testing had been conducted and the amendment to add the cell line to the protocol had been submitted, reviewed and approved by the IACUC. Corrective actions included:

- PI amending the protocol to include the murine cell line and having the cell line tested for all the required murine pathogens, which he successfully did.
- The PI and his staff underwent re-education regarding IMPACT testing procedures and the importance of adhering to animal use protocols.

It is noted that this project is supported by PHS funds and that the IACUC Office has been in contact with the appropriate individuals at the funding agency. Based on its assessment of this explanation, OLAW understands that 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



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

February 20, 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 #00314. This incident was first reported to OLAW via a phone call made on December 19, 2019 by (b) (6) at the time.

The animals involved in this matter were mice. While conducting the Principal Investigator's scheduled semiannual IACUC inspection, it was discovered that he had been conducting animal-related activities without appropriate IACUC review and approval. Specifically, the PI was utilizing a murine cell line in his experimental work but at the time he was only approved for the use of human cell lines to generate tumor xenograft models in animals. Additionally, the murine cell line being used had not undergone all of the appropriate rodent pathogen testing that is required by the Institution. The PI and his support staff stated that they were under the impression that the murine cell line was already listed and approved for use on their animal use protocol. After discussion at the subsequent IACUC meeting, the IACUC Chair requested that the PI cease performance of this particular procedure until the appropriate IMPACT (pathogen) testing had been conducted and the amendment to add the cell line to the protocol had been submitted, reviewed, and approved by the IACUC.

Corrective measures included the PI amending the protocol to include the murine cell line and having the cell line tested for all of the required murine pathogens, which he successfully did. In addition, the PI and his staff underwent re-education regarding IMPACT testing procedures and the importance of adhering to animal use protocols.

The IACUC Office has been in contact with the appropriate individuals at the funding agency, the National Cancer Institute (NCI) of the National Institutes of Health (NIH), and unallowable costs will be 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) or (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, February 21, 2020 11:17 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [A3085-01] TJU Final Report - 191126

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

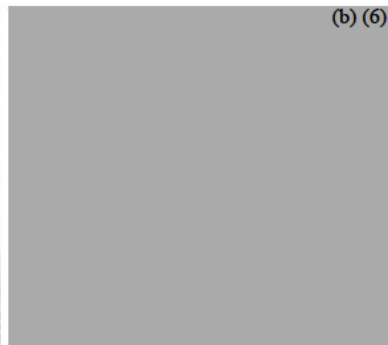
Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Friday, February 21, 2020 10:36 AM
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 - 191126

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 December 19, 2019. Please don't hesitate to contact us if you have any questions, concerns, or comments.

Sincerely,
(b) (6)



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