



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

November 14, 2019

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

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 November 13, 2019 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 telephone report on July 8, 2019. According to the information provided, OLAW understands that expired ketamine was administered to an animal (mouse or rat?). Another collaborating Principal Investigator (PI) also used the same expired drug on animals.

The corrective action consisted of removing the expired bottle and directing the PI to discard it in accordance with institutional policies. The PIs and staff were retrained on controlled substance policies, all investigators were required to certify understanding that expired anesthetics/analgesics are not be given to animals, and Institutional Animal Care and Use Committee (IACUC) members met with each animal user to discuss expired drug use policy and consequences of noncompliance. A programmatic change was made to require that all investigators are present during their laboratories' inspection.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Please remember to state the species of animal involved in noncompliant activities. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair
IACUC Regulatory Affairs Manager

November 13, 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 Protocols #01086 and 01338. The species on these protocols is mouse. This incident was first reported to OLAW via a phone call made on July 08, 2019 by (b) (6)

In conducting the PI's scheduled semiannual IACUC inspection, the IACUC Specialist discovered that ketamine was administered to a live animal after its expiration date. During an interview, the researcher admitted that he had used the expired ketamine after a surgical procedure. He explained that he was having difficulties acquiring the substance due to a market shortage for the drug, but had finally managed to place an order that should be arriving that same week. The IACUC Specialist immediately sealed the expired drugs into a chain of custody bag, rendering the substances inaccessible, and the PI was instructed to contact Environmental Health and Safety to properly dispose of the substances onsite via the Stryker Cactus Smart Sink System®. In addition, the PI in question holds the DEA license for several other collaborating PIs in his department and it was determined that a researcher from one of these collaborators had also administered the same bottle of expired ketamine to animals for one of their surgical procedures labs.

In an effort to avoid such issues from occurring in the future, both PIs, along with their respective staff members, underwent controlled substance refresher training via the AALAS Learning Library. 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 and to stress the gravity of the situation, IACUC Leadership decided that all investigators would be required to sign a document that explicitly states that they understand and acknowledge that the use of expired substances in animals, particularly anesthetics and analgesics, is prohibited. A member of either the IACUC Office or the IACUC itself met with every investigator at the Institution who engages in animal research in person to re-educate them on expired substance usage and the potential repercussions that may occur should they not comply. The laboratory was reminded that a possible outcome of failing to comply with the mandate is immediate and indefinite suspension of all animal activities.

Another precautionary measure the program instituted was the requirement that all investigators be present for their scheduled laboratory inspections, rather than having staff members conduct the inspections on their behalf. The reason for this change in procedure is to ensure that investigators are fully engaged in current practices in their laboratories.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, November 14, 2019 7:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [A3085-01] TJU Final Report - 190612

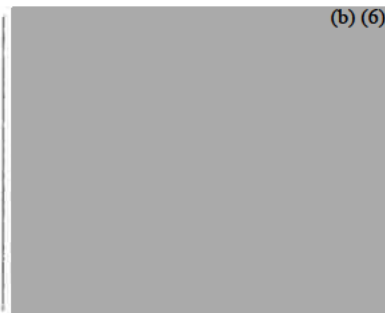
Thank you for this report, (b) (6) We will send a response soon.
Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Wednesday, November 13, 2019 3:41 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 - 190612

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 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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Initial Report of Noncompliance

By: *[Signature]*

Date: 7/8/19

Time: 2:40

Name of Person reporting:
Telephone #:
Fax #:
Email:

(b) (6)
(b) (6)

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? Expired anesthetic used (Ketamine)
+ perhaps buprenorphine

Species involved: Unknown if mice, rats or both
Personnel involved: Research staff
Dates and times: Late June 2019, IACUC informed
Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # _____