



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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January 31, 2018

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

Dr. Theodore F. Taraschi
Vice President for Research
Thomas Jefferson University
1020 Walnut Street, Room #
Philadelphia, PA 19107-5587

Dear Dr. Taraschi,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 14, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Thomas Jefferson University. According to the information provided, OLAW understands that during a laboratory inspection conducted on October and November 2016, it was discovered that expired Ketamine and Buprenorphine had been used in mice in three different laboratories on three separate occasions. Although corrective measures were implemented at the time of the inspection, the noncompliance incidents were neither reviewed at a convened IACUC meeting nor reported to the Institutional Official (IO) for subsequent prompt reporting to this Office.

The corrective actions consisted of the IACUC retraining all three laboratories on the use of analgesics prior to their expiration date, reviewing the reverse distribution process for discarding expired controlled drugs, enhancing oversight of the laboratories and revising the Policy on the Management of Controlled Substances to include repercussions for failure to comply with regulatory mandates. Laboratory deficiencies are now reviewed at IACUC meetings and recorded in the meeting minutes which is subsequently provided to the IO in an effort to ensure prompt reporting to OLAW.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Signature

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



Jefferson

REGISTRATION
ANIMAL CARE
THOMAS JEFFERSON UNIVERSITY
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Philadelphia, PA 19107
T 215-955-1000
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December 14, 2017

Brent Morse, DVM, DACLAM
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
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 a series of three incidents that occurred in October and November 2016 but were not reported to OLAW at the time. The species involved in these incidents was mice. OLAW was made aware of this matter and oversight in an e-mail sent on November 17, 2017 by [REDACTED] IACUC Regulatory Affairs Manager, to Dr. Brent Morse.

In October and November 2016, through the laboratory inspection process, three instances were identified involving the suspected use of expired analgesics or anesthetics in live mice. Each instance took place in a different laboratory. The following dates and pharmaceuticals were noted:

- October 24, 2016 – Buprenorphine
- November 17, 2016 – Buprenorphine
- November 18, 2016 – Ketamine

After discovering these issues, the IACUC team retrained each of the three laboratories emphasizing that drugs that control pain must be used before their expiration date. The reverse distribution process employed by Jefferson to remove expired controlled substances from the premises was also explained.

Since these occurrences, these laboratories have been monitored and there has been no repeat of this issue. To bolster the University's stance on this issue, the Policy on the Management of Controlled Substances was updated in November 2016 to include repercussions for investigators who fail to comply with regulatory standards.

The institution recognizes that this finding not only highlights the issue regarding the use of expired anesthetics and analgesics in laboratories, but also the oversight in prompt reporting. While other items have been identified and reported to OLAW during the past three years, these events were not. They were identified during laboratory inspections. Although corrective action was taken, thorough discussion of the laboratory inspection findings did not take place at a convened IACUC meeting, nor were they reported to the Institutional Official (IO). This process has been modified since that time such that laboratory deficiencies are now discussed in detail at IACUC meetings and recorded in the meeting minutes. A copy of each meeting's minutes is provided to the IO. This allows for both the IACUC and the IO to assure that prompt reporting to OLAW occurs.

Obtained by Rise

In addition, the IACUC had a robust discussion at the last convened meeting on November 28th, 2017 on the topic of OLAW reportable issues. The "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals" (NOT-OD-05-034) was distributed to all members of the IACUC and the IO.

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 [ACUC Member] IACUC Regulatory Affairs Manager, at [ACUC Member]@jefferson.edu or [Phone Number]

Thank you for your consideration of this matter.

Sincerely,

Signature

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