



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
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
Facsimile: (301) 402-7065

January 9, 2017

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

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 January 5, 2017 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 report on December 16, 2016. According to the information provided, OLAW understands that two live research mice were found in the carcass refrigerator due to a failure to use a secondary physical method of euthanasia to ensure death following exposure to CO2.

The corrective actions consisted of counseling and retraining the laboratory staff on the proper conduct of euthanasia including use of secondary physical methods. The protocol was amended to include a secondary physical method of euthanasia, the institutional euthanasia policy was amended to include a secondary physical method, and all animal users were provided with the revised policy and will be retrained on it.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. In future, please remember to indicate whether the study involved was PHS-supported and provide the relevant grant number(s) if so. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Director,
Division of Compliance Oversight

cc: IACUC Chair

January 5, 2017

Axel Wolff, DVM
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. Wolff:

Thomas Jefferson University, in accordance with Assurance #D16-00051 (A3085-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident associated with mouse protocol #01451. This incident was first reported to OLAW, on December 16, 2016 via email by (b) (6)

On December 9, 2016, the Clinical Veterinarian found two live mice in the refrigerator/morgue of the animal facility. They were found in a disposal box with a tag that contained the PI's name and protocol number on it with the above date. We are assuming that the mice may have been improperly euthanized via CO₂ inhalation and that no secondary form of confirmation of death was performed.

The IACUC Chair, IACUC Regulatory Affairs Manager, IACUC Post Approval Monitor, and the Attending Veterinarian spoke with one of the PI's lab staff about the animals in question on December 9, 2016. The Clinical Veterinarian and the Post Approval Monitor met with the lab again on December 12, 2016 to retrain the staff on proper use of CO₂ on mice as well as secondary forms of confirmation of death including cervical dislocation and thoracotomies.

The following corrective action plan was implemented after the incident:

1. Lab Staff were retrained by the Clinical Veterinarian on the proper methods involving the use of CO₂ on mice. They were also retrained on how to properly perform cervical dislocation and thoracotomy.
2. The IACUC has required that the above mentioned protocol be amended to include a secondary physical form of confirmation of death that must be followed.
3. The IACUC is amending their Euthanasia Policy to state that all protocols must include a secondary physical form of confirmation of death unless there is a scientific justification prohibiting it being done.
4. The IACUC will send out the updated policy to all animal users on campus and conduct one-on-one information sessions with all labs.

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)

(b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Theodore F. Taraschi, Ph.D.
Vice President for Research
Institutional Official
Thomas Jefferson University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 09, 2017 8:02 AM
To: (b) (6)
Subject: RE: TJU Reports of Noncompliance

Thanks for these reports. We'll respond soon.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: (b) (6)
Sent: Friday, January 06, 2017 3:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Theodore Taraschi <Theodore.Taraschi@jefferson.edu>; (b) (6)
(b) (6)
Subject: TJU Reports of Noncompliance

Good afternoon,

Attached are Thomas Jefferson University Reports of noncompliance.

Thank you,

(b) (6)

(b) (6)



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A3085-y

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 16, 2016 10:51 AM
To: (b) (6)
Subject: RE: Preliminary Notification of a Reportable Issue

Thank you for this preliminary report, (b) (6). We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: (b) (6)
Sent: Friday, December 16, 2016 10:24 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Preliminary Notification of a Reportable Issue

To Whom it May Concern,

As per the guidance on the OLAW website please accept this email as our preliminary notification of a reportable offence that has recently occurred at our institution.

Name and contact information of person reporting –

(b) (6)

Name of institution – Thomas Jefferson University

Assurance number (see list of domestic and foreign Assured institutions) – #D16-00051(A3085-01)

Funding component and if contacted (for situations related to PHS-supported activities) – This is being investigated. Contact with the granting agencies has not been performed as of yet.

Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths) –

On 12/09/2016 two live mice were found in the freezer/morgue of the animal facility. They were found in a disposal box with a tag that contained the PI's name and protocol number on it with the date of 12/09/16. We do not believe the animals were there for very long. We are assuming that they had been improperly euthanized via CO2 inhalation and that no secondary form of confirmation of death was performed.

Plan and schedule for correction and prevention (if known) –

The IACUC Chair, IACUC Regulatory Affairs Manager, IACUC Post Approval Monitor, and the Attending Veterinarian spoke with one of the PI's lab staff about the animal in question on 12/09/16. The Clinical Veterinarian and the Post Approval Monitor met with the full lab on 12/12/2016 to retrain the staff on proper use of CO2 on mice as well as secondary forms of confirmation of death including cervical dislocation and thoracotomies. Full corrective/preventative measures are being discussed.

Timeframe for final report from the Institutional Official – A final report should be submitted within 30 days.



(b) (6)



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