



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

May 18, 2017

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

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

Dear Dr. Taraschi,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 16, 2017 letter reporting the suspension of an animal activity at Thomas Jefferson University, following up on an initial report on March 2, 2017. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee took this action after determining that the Principal Investigator (PI) failed to keep adequate documentation of breeding, monitoring, anesthesia, and euthanasia of mice.

The corrective action consisted of animal care and use program personnel counseling the PI and requiring the submission of monthly animal work reports that include a colony census and description of any phenotypic strains that require monitoring. The PI was counseled that records must not deviate from the approved protocol. The PI was extensively retrained, the laboratory was placed on enhanced post-approval monitoring, and the protocols for grants R01NS097530 and R21NS098393 were subsequently reinstated.

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,

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

cc: IACUC Chair  
Tijuanna DeCoster, Ph.D., NINDS Chief GMO  
Melissa Copeland, M.B.A., Grants Management Specialist



Institutional Care and Use Committee

1020 Locust Street  
Alumni Hall, Suite 348  
Philadelphia, PA 19107  
T 215-503-9135  
iacuc@jefferson.edu

May 16<sup>th</sup>, 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 the mouse protocols 01452 and 01456. This incident was first reported to OLAW on March 2, 2017 in a phone call made by [REDACTED] the IACUC Post-Approval Monitor.

On February 28<sup>th</sup>, the IACUC committee voted to suspend the above mentioned protocols. This decision was based on multiple incidents of insufficient records and documentation relating to the breeding, monitoring, anesthesia, and euthanasia of her animals. The PI was frequently unable to produce such records when requested and was slow/unresponsive when asked to correct these deficiencies. When asked to explain inconsistencies in records, the PI did not seem to understand that without proper records, the IACUC could not verify that monitoring had been done in accordance with approved protocols.

To address the situation, The IACUC Chair, the IACUC Post Approval Monitor, the Attending Veterinarian, the Clinical Veterinarian, and myself have met with the PI to outline the conditions for reinstatement, and for animal work moving forward. The PI will submit monthly animal work reports that include a detailed census of the colony, including but not limited to any strains that may display a phenotype requiring monitoring. In addition, the PI has undergone extensive retraining with the IACUC Post-Approval Monitor and the Clinical Veterinarian. Brief visits from the Post-Approval Monitor will continue to occur on a weekly basis for the foreseeable future. Finally, the IACUC Chair has informed the PI that in the future, provided records must not deviate from what is outlined in the protocol, and that any further failure to maintain these records may result in permanent suspension of animal work at Thomas Jefferson University. A letter explaining these conditions has been personally delivered to the PI by the IACUC Chair. Having been retrained and agreeing to the above conditions, the IACUC reinstated the two protocols on April 25<sup>th</sup>, 2017.

Secondary individual

Secondary individual  
telephone #

## Morse, Brent (NIH/OD) [E]

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, May 16, 2017 3:41 PM  
**To:** Theodore Taraschi; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Larry Harshyne Jr; Judith Daviau; [Secondary individual] [Secondary individual]  
**Subject:** RE: TJU Report to OLAW

Thank you for this report. [Secondary individual] We will send an official response soon.

Regards, Brent Morse

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

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**From:** [Secondary individual] [mailto:[Secondary individual]@jefferson.edu] **On Behalf Of** Theodore Taraschi  
**Sent:** Tuesday, May 16, 2017 3:35 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>; Judith Daviau <Judith.Daviau@jefferson.edu>; [Secondary individual] [mailto:[Secondary individual]@jefferson.edu]; [Secondary individual] [mailto:[Secondary individual]@jefferson.edu]  
**Subject:** TJU Report to OLAW

Good afternoon,

Attached is Thomas Jefferson University Report.

Thank you,  
 [Secondary individual]

[Secondary individual]  
 Office of Research Conduct and Compliance  
**Thomas Jefferson University**  
 1020 Locust Street, Room # [Secondary individual] Philadelphia, PA 19107  
 telephone # [Secondary individual]  
 [Secondary individual]@jefferson.edu

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April 25, 2017

Dr. Hui Zhang, PhD  
Farber Institute for Neuroscience

3085-2

Dear Dr. Zhang,

At its meeting earlier this morning, the IACUC voted to reinstate your animal use privileges effective upon your receipt of this letter. Keycard access to the animal facility will be turned on for you and members of your laboratory. Going forward, the IACUC Committee reiterated, you **MUST FOLLOW** procedures described in your approved animal use protocols. Further deviation from approved animal work will be met with severe penalties which could include revoking animal use privileges while you are employed by Jefferson.

For the next 12 months, the IACUC requests monthly reporting detailing all animal work performed in the previous month. Please include updated animal census reports of your colony every month. Someone from the IACUC will stop by your lab weekly to see how things are progressing and to answer any questions you may have.

Please ensure that all research reports, for grants or publication purposes, are accurate and do not contain copy/paste errors. Further instances of inaccurate reporting may be deemed research misconduct to be handled by other institutional offices.

Please feel free to contact myself of the IACUC office with any questions you may have regarding this suspension.

Sincerely,



Larry Harshyne, PhD  
IACUC Chair, Thomas Jefferson University

Cc  
Theodore Taraschi

Secondary individual

Secondary individual

Secondary individual

Secondary individual

**Wolff, Axel (NIH/OD) [E]**

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**From:** Decoster, Tijuanna (NIH/NINDS) [E]  
**Sent:** Monday, May 01, 2017 11:29 AM  
**To:** Wolff, Axel (NIH/OD) [E]  
**Subject:** FW: Dr. Hui Zhang's IACUC protocol suspension  
**Attachments:** Zhang Re-instatement letter.pdf

Hi Axel,

The grantee has submitted their corrective action plan. Please forward me a copy of OLAWs review for the grant file.

**OLAW review**

OLAW evaluates and reviews noncompliance reports and the actions taken. OLAW may ask for clarification or other information to assess the case; or recommend certain actions to enhance compliance and prevent recurrence. After OLAW has completed its evaluation of the situation, a report of the findings and acceptance of the corrective actions is e-mailed to the Institutional Official and copied to the IACUC office/contact and any complainants in the case.

Thanks

Tia

Tijuanna E. DeCoster, Ph.D., MPA  
 Chief Grants Management Officer  
 Certified Grants Management Specialist (CGMS)  
 Grants Management Branch  
 National Institute of Neurological Disorders and Stroke  
 6001 Executive Blvd, Suite 32190, MSC 9537  
 Rockville, MD 20852 (Express Mail)  
 Bethesda, MD 20892-9537 (Regular Mail)  
 Branch Phone Number: 301-496-9231  
 Fax Number: 301-402-0219

---

**From:** Copeland, Melissa (NIH/NINDS) [E]  
**Sent:** Monday, May 01, 2017 10:52 AM  
**To:** Decoster, Tijuanna (NIH/NINDS) [E] <decostert@ninds.nih.gov>  
**Subject:** FW: Dr. Hui Zhang's IACUC protocol suspension

See attached.

*Melissa R. Copeland*, M.B.A.  
 Grants Management Specialist

NINDS Division of Extramural Research  
301-496-7460

**From:** Secondary individual [mailto:Secondary individual@jefferson.edu]  
**Sent:** Wednesday, April 26, 2017 3:24 PM  
**To:** Copeland, Melissa (NIH/NINDS) [E] <copelandm@ninds.nih.gov>  
**Cc:** Secondary individual [mailto:Secondary individual@jefferson.edu]  
**Subject:** RE: Dr. Hui Zhang's IACUC protocol suspension

Hi, Melissa. Attached is confirmation that Dr. Zhang's IACUC privileges have been reinstated.

Do you require anything else in order to issue revised NoA's to lift the animal research restriction for grants R01NS097530 and R21NS098393?

Thanks for your assistance.

Secondary individual

Associate Director, Postaward Services  
Office of Research Administration  
Thomas Jefferson University  
125 South 9<sup>th</sup> Street  
Sheridan Bldg., 2<sup>nd</sup> Floor  
Philadelphia, PA 19107  
Phone [telephone #]

Please provide feedback on ORA here



**Jefferson.**

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**From:** Copeland, Melissa (NIH/NINDS) [E] [mailto:copelandm@ninds.nih.gov]  
**Sent:** Wednesday, April 19, 2017 9:32 AM  
**To:** Secondary individual  
**Subject:** RE: Dr. Hui Zhang's IACUC protocol suspension

Secondary individual

Yes, you may continue to charge non-animal related expenditures to the grant during the suspension period.

I will issue the necessary revision revise the term accordingly.

Best regards,

*Melissa R. Copeland*, M.B.A.

Grants Management Specialist  
NINDS Division of Extramural Research  
301-496-7460

**From:** Secondary individual [mailto:Secondary individual@jefferson.edu]  
**Sent:** Thursday, April 13, 2017 1:53 PM  
**To:** Copeland, Melissa (NIH/NINDS) [E] <copelandm@ninds.nih.gov>  
**Subject:** FW: Dr. Hui Zhang's IACUC protocol suspension

Hi, Melissa. I am following up on your email exchange with Secondary individual (attached) regarding appropriate expenses during the IACUC protocol suspension.

Can salary continue to be charged to the grants for **non-animal related activities** during the suspension? For example, experiment design, manuscript writing, data analysis, etc.? In other words, activities that would not require IACUC approval.

The NoA's say "*Funds included in this award may only be used for the maintenance and care of the animals during the period of IACUC suspension. Once the suspension has been lifted, a confirmation must be submitted to and accepted by NINDS staff before studies involving vertebrate animals may resume.*"

Normally, I would assume that expenses related to non-animal work would be ok, but the language on the NoA could be interpreted as NO expenses at all.

Thanks for your assistance.

Secondary individual

Associate Director, Postaward Services  
Office of Research Administration  
Thomas Jefferson University  
125 South 9<sup>th</sup> Street  
Sheridan Bldg., 2<sup>nd</sup> Floor  
Philadelphia, PA 19107  
Phone: telephone #

[Please provide feedback on ORA here](#)



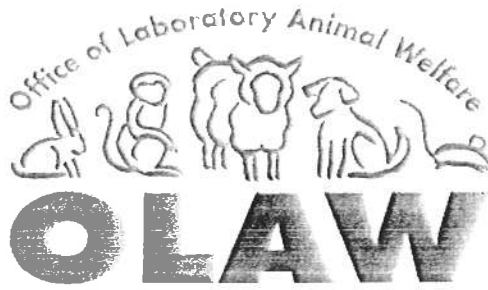
**Jefferson.**

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## Initial Report of Noncompliance

By: awDate: 3/2/17Time: 11:00

Name of Person reporting:

Secondary individual

Telephone #:

telephone #

Fax #:

Email:

Name of Institution:

Thomas Jefferson

Assurance number:

A3085Did incident involve PHS funded activity? yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Uncorrected noncompliance, off protocol euthanasia (decapitation w/out anesthesia), insufficient monitoring records, expired drugs, failure to adhere to quarantine

Species involved: Mouse

Personnel involved: \_\_\_\_\_

Dates and times: \_\_\_\_\_

Animal deaths: \_\_\_\_\_

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

Suspended study. must meet IACUC requirements.

Projected submission to OLAW of final report from Institutional Official: \_\_\_\_\_

OFFICE USE ONLY

Case # \_\_\_\_\_