



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

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Office of Laboratory Animal Welfare  
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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

April 16,, 2018

Re: Animal Welfare Assurance  
A3217-01 [OLAW Case Y]

Ms. Tamara Deuser  
Associate Vice President  
Arizona State University  
660 South Mill Avenue, (b) (4)  
Tempe, AZ 85287-6111

Dear Ms. Deuser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 12, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Arizona State University, following up on an initial report on February 2, 2018. According to the information provided, OLAW understands that a mouse pup died while maintained on ice for practice surgery. The animal had been maintained on the ice longer than described in the approved protocol and there was no barrier between the body and the ice. The graduate student involved had not been certified to perform surgery independently and had performed 64 surgeries. The incident had not been reported to the Institutional Animal Care and Use Committee (IACUC).

The corrective action consisted of the IACUC chair counseling the Principal Investigator (PI) and student on reporting adverse events, ensuring staff has training certification, having the PI revise the protocol, and having the student become certified to perform surgery independently. The PI will have another experienced researcher assist with oversight of the laboratory, the laboratory animal and safety standard operating procedures will be updated, a morbidity/mortality log was developed, one laboratory member will ensure that animal handling certifications are in place, laboratory staff will have access to the protocol and will have copies of their portions of the protocol, fewer undergraduates will be involved, the PI will check staff certification before allowing participation in animal activities, and the laboratory staff was counseled by the IACUC chair on animal welfare and following the protocol.

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,

(b) (6)

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

cc: IACUC Chair

April 12, 2018

Brent C. Morse, DVM, DACLAM  
Acting Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Re: Report of Noncompliance under Animal Welfare Assurance #D16-00136

Research Facility: Interdisciplinary Science and Technology Building V  
Species: *Mus musculus*  
Principal Investigator: Samira Kiani  
Funding Source: A portion of the work is funded by DARPA  
Incident: Death of a mouse and personnel training

On January 23<sup>rd</sup>, the IACUC Coordinator was performing an administrative pre-review of the annual review for protocol 16-1479R. While verifying the personnel had appropriate training for the procedures being performed, the Coordinator was informed about an adverse event that had occurred in September 2017, in which a mouse pup died while on ice during a practice surgery. The adverse event was not listed on the annual review and the IACUC had not been informed of the death at the time it happened. The IACUC Office requested additional information about the adverse event from the laboratory. In discussions with the laboratory, the IACUC Chair determined that the protocol was not being followed. The mouse pup was left on the ice for several minutes longer than the time frame allowed by the protocol and without the protocol-specified barrier between the body and ice. Additionally, it was confirmed that the graduate student performing the surgery did not have Level III training certification to perform the surgery independently (without supervision). A total of 64 surgeries were performed between September 23, 2017 and January 18, 2018 by the graduate student; no other adverse events occurred during those surgeries.

#### **Corrective Action**

The Chair met with the Principal Investigator (PI) and graduate student on January 30<sup>th</sup> to determine the appropriate corrective action plan, and to provide additional education on reporting adverse events, as well as the importance of ensuring personnel have training certification. Because the protocol had been amended several times, the Attending Veterinarian recommended submitting a revised protocol to incorporate the amendments and make procedures easier to follow for personnel.

On February 6, 2018, the graduate student was certified to perform the surgery independently.

On February 14<sup>th</sup>, the PI submitted a corrective action plan to the IACUC. The steps included:

1. The PI has an agreement with an experienced faculty researcher to assist in providing oversight of the lab;
2. Updating the lab-specific safety and animal handling standard operating procedures. All incoming and existing staff will read, learn and understand the required steps for proper handling of animals;
3. A folder has been set up in the lab in which personnel are able to record any mortality or morbidity from animal experiments so they can be reported to the PI and the IACUC in a timely manner;
4. A student has been assigned as an Animal Safety Officer to make sure all required trainings and Level III certifications are on file before personnel begin to work with animals;
5. A revised protocol was submitted on February 14, 2018, and will be reviewed by the IACUC.
6. All personnel will be given access to the protocol, which will be kept in a common secure folder. The PI will ensure that personnel have printed out and read their portions of the protocol before doing any experiments;
7. Undergraduate recruitment will become limited, and stringent criteria for additional personnel will be implemented;
8. The PI will personally double check for the status of Level III certification for personnel before they handle animals independently;
9. The Chair will attend a lab meeting to discuss the importance of following procedures in working with animals.

The Chair attended a laboratory meeting on February 16, 2018, and discussed with all lab personnel how animal welfare is protected by following the protocol and being properly trained before performing procedures.

On February 22, 2018, the committee determined that based on the corrective action plan provided, the Principal Investigator is taking the appropriate steps to prevent a reoccurrence.

Sincerely,

(b) (6)

Karen V. Kibler, PhD  
Chair, IACUC  
Assistant Research Professor

(b) (6)  
[Karen.Kibler@asu.edu](mailto:Karen.Kibler@asu.edu)

(b) (6)

Tamara K. Deuser, MBA, PMP  
Institutional Official  
Associate Vice President

(b) (6)  
[Tamara.Deuser@asu.edu](mailto:Tamara.Deuser@asu.edu)

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, April 13, 2018 1:42 PM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Preliminary Report for D16-00136

Thank you for this report, (b) (6) Dr. Morse will respond soon.

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

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**From:** (b) (6)@asu.edu]  
**Sent:** Friday, April 13, 2018 1:33 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Tamara Deuser <Tamara.Deuser@asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; (b) (6)  
(b) (6)  
**Subject:** RE: Preliminary Report for D16-00136

Dr. Morse,  
I have attached the final report for your review.

Please let me know if you have any questions.

Thank you,

(b) (6)

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**From:** (b) (6)  
**Sent:** Friday, February 02, 2018 12:55 PM  
**To:** 'olawdco@od.nih.gov' <olawdco@od.nih.gov>  
**Cc:** Tamara Deuser <Tamara.Deuser@asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; (b) (6)  
(b) (6)  
**Subject:** Preliminary Report for D16-00136

Dr. Morse,  
On behalf of the ASU IACUC, I am making a preliminary report of noncompliance that resulted in animal mortality. The IACUC is investigating the situation and putting corrective actions into place. The IACUC will provide a full report as soon as the investigation and review are complete.

Please let me know if you have any questions.

Thank you,

Wolff, Axel (NIH/OD) [E]

A3217-Y

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, February 05, 2018 7:58 AM  
**To:** (b) (6)  
**Subject:** RE: Preliminary Report for D16-00136

Thank you for this preliminary report. We will start a new case file and look forward to receiving the final report after the IACUC has completed its investigation.

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

**From:** (b) (6)@asu.edu]  
**Sent:** Friday, February 02, 2018 2:55 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Tamara Deuser <Tamara.Deuser@asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; (b) (6)  
(b) (6)  
**Subject:** Preliminary Report for D16-00136

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(b) (6)

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