



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) 480-3387

June 27, 2023

Re: Animal Welfare Assurance  
A3217-01 [OLAW Case 10]

Matthew Hulver, Ph.D.  
Vice President of Research  
Arizona State University  
300 East University Drive, (b) (4)  
PO Box 877205  
Tempe, AZ 85287

Dear Dr. Hulver,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 7, 2023, letter reporting a series of noncompliance at Arizona State University (ASU), following up on two separate email notifications on May 23, 2023, and May 31, 2023. According to the information provided, OLAW understands that on May 3, 2023, the IACUC Chair was notified that laboratory personnel failed to respond to an urgent notification, which resulted in the loss of five mouse pups on a PHS-supported study. Several subsequent non-animal welfare issues ensued and the IACUC partially suspended the Principal Investigator's (PI's) protocol at a convened meeting on May 25, 2023.

The corrective actions consisted of the IACUC Chair meeting with the PI immediately following the May 3, 2023, notification of the incident to discuss the laboratory's continuing noncompliance, the potential for protocol suspension and the need for participation of an additional faculty member. A senior faculty member was subsequently added to the protocol and, along with the IACUC Chair and Attending Veterinarian, was also included in all communications from animal care personnel to the laboratory regarding animal welfare. On May 3, 2023, the Institutional Official (IO) and PI's academic unit Director were notified of the potential for protocol suspension by the IACUC. At the May 25, 2023, convened meeting, the IACUC voted to impose significant restrictions on the research activities and rescind approval for those restricted activities on the currently approved protocol. Consequently, the PI is required to submit a revised protocol limited exclusively to the breeding colonies and visual monitoring of ongoing studies. The IACUC will terminate the currently approved protocol should the PI fail to complete the revisions or agree to the IACUC-imposed restrictions and both the IO and academic unit Director were both notified of the IACUC's decision. On May 26, 2023, the IACUC Chair informed the PI and some laboratory personnel of the IACUC's decision to restrict animal research activities and require submission of a revised protocol. A warning that further significant animal welfare issues or repeated failure to follow ASU IACUC or OLAW guidelines will be the basis for immediate termination of the protocol was also discussed. The PI was provided the opportunity to request a hearing for an appeal of the IACUC's decision, per ASU's Policies and Procedures Manual, and agreed to the terms and conditions imposed by the IACUC. A team of mentors were provided by the academic unit Director to help the PI. The PI also implemented internal changes to ensure laboratory personnel responds to all alerts and validate each other in an attempt to eliminate noncompliance issues. The IACUC will convene in September 2023, to reevaluate and determine whether the revised protocol activities will be allowed to continue based on the laboratory's performance and consider any requested reinstatement of animal activities. OLAW will be kept apprised of any updates from the September meeting, or if anything changes before such time.

Based on its assessment of this report, OLAW is satisfied that appropriate actions have been taken to prevent recurrence of the noncompliance. We commend your support as Institutional Official and the IACUC on your efforts in developing a program of excellence and find no cause for further action by this Office.

Sincerely,

**Neera V. Gopee -S**

Digitally signed by Neera V.

Gopee -S

Date: 2023.06.27 14:28:04 -04'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Associate Director, Animal Welfare Policy  
Office of Laboratory Animal Welfare  
National Institutes of Health

cc: IACUC Chair

June 7, 2023

Brent Morse, DVM  
Division of Compliance Oversight  
Office of Laboratory Welfare  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892-7892

Re: Case numbers: A3217-10 and A3217-1P; Report of loss of five mice due to conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals; and IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

NIH Funding: K22 CA241803; "Metabolic and epigenetic drivers of stem cells in obesity and cancer"

On February 3, 2023, we submitted a final report regarding several instances of non-compliance for this lab (Case A3217-1M). We provided a 5-point plan of action to assist the Principal Investigator (PI) in preventing further non-compliances. A two-month follow-up evaluation was conducted at the April 27<sup>th</sup> convened IACUC meeting.

On May 3<sup>rd</sup>, the Chair was notified of a failure by the lab to respond to an urgent notification regarding animal welfare, resulting in the loss of five mouse pups. As a result of this incident and several additional non-welfare issues that followed, the PI's protocol was partially suspended at the convened meeting on May 25<sup>th</sup>, 2023.

A preliminary report was sent to OLAW by email on May 31<sup>st</sup>.

Steps were immediately taken following the May 3<sup>rd</sup> notice to the Chair:

- 1) The Chair met with the PI on May 3<sup>rd</sup> to discuss the lab's continuing difficulties in meeting expectations, the potential for the committee to suspend the protocol, and the need for the additional faculty member's participation.
- 2) A senior faculty member was added to the protocol and, along with both the IACUC Chair and the Attending Veterinarian, was added to all communications pertaining to animal welfare from animal care staff to the lab.
- 3) The IO and PI's academic unit Director were notified on May 3<sup>rd</sup> of the potential for an action at the May 25<sup>th</sup> convened meeting of the IACUC to suspend the protocol.

On May 25<sup>th</sup> the committee was updated on the lab's continuing difficulties, including the welfare issue the first week of May. A summary of the past months was reviewed and the committee discussed various options for moving forward. A motion proposed to continue the protocol with no changes was unanimously disapproved by vote. A motion proposed to severely restrict

research activities on the protocol and to rescind approval for those restricted activities on the current protocol was approved by vote. The PI is required to submit a revised protocol for review at the June convened meeting that will include only the breeding colonies and visual monitoring of ongoing studies; these limited activities will preserve non-replaceable strains and prevent waste of animals. Failure of the PI to complete the revisions or to agree to the restrictions will result in the termination of the current protocol in its entirety. The IO and academic unit Director were notified of the committee's decision.

The Chair met with the PI and some of the lab personnel on May 26<sup>th</sup> to notify of the committee's decision regarding restricted activities, the requirement for a revised protocol, and the stipulation that any further significant welfare issues or repeated failure to follow ASU IACUC guidelines or OLAW guidelines are grounds for an immediate termination of the protocol.

ASU's Policies and Procedures Manual (PPM) provides any PI the right to request a hearing for an appeal of the committee's decision. The PI was given until 5:00pm on May 31<sup>st</sup> to notify of an intent to request a hearing, and that request was conveyed to the Chair by the deadline.

An emergency convened meeting was held on June 1<sup>st</sup>, and the committee first discussed and approved detailed clarifications of the restricted activities. When the PI joined the meeting, those clarifications were explained and the PI agreed to all restrictions.

A preliminary report was sent to OLAW by email on June 1<sup>st</sup>.

The academic unit Director has provided a team of mentors to assist the PI. The PI, in addition to the reduction of activities, has also made internal changes to ensure that the lab responds to all alerts and members cross-check each other to eliminate noncompliance issues.

Funding sources that are not PHS will be notified of the actions taken by the committee.

At the September convened meeting, the committee will again discuss and determine if the revised protocol activities will be allowed to continue based on the lab's performance. The committee will reevaluate both the lab's performance on the allowed activities, and consider any requested restoration of activities, unless lab actions require termination of the protocol prior to that meeting. Any of the February action plan items that remain applicable will continue to be followed. We will provide an update to OLAW following the September meeting, or if anything changes before that meeting.

Please let us know if you have any questions.

(b) (6)

Karen Kibler, PhD  
Chair, IACUC  
Assistant Research Professor  
Karen.Kibler@asu.edu

(b) (6)

Matthew Hulver, PhD  
Institutional Official, IACUC  
Vice President  
Matthew.Hulver@asu.edu

**McCoy, Devora (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, June 8, 2023 7:44 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report under Assurance D16-00136 (Arizona State University) - Case Nos. A3217-1O and A3217-1P

Good morning (b) (6)

Thank you for sending us this final report for cases A3217-1O and A3217-1P and we will send an official response soon.

Going forward, we do ask that final reports for different case numbers be sent as separate reports.

Thank you,  
Devora

Devora McCoy, BS, MBA ([pronunciation](#))  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

**From:** (b) (6)  
**Sent:** Wednesday, June 7, 2023 6:13 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Cc:** Karen Kibler <[Karen.Kibler@asu.edu](mailto:Karen.Kibler@asu.edu)>; (b) (6)  
(b) (6) Matthew Hulver  
<[Matthew.Hulver@asu.edu](mailto:Matthew.Hulver@asu.edu)>; [IACUC@asu.edu](mailto:IACUC@asu.edu)  
**Subject:** [EXTERNAL] Final Report under Assurance D16-00136 (Arizona State University) - Case Nos. A3217-1O and A3217-1P

Good Afternoon,

On behalf of the ASU IACUC, attached is the final report for case numbers A3217-1O and A3217-1P.

If you have any questions, please don't hesitate to contact me.

Confirmation of receipt is requested.

Thank you,

(b) (6)



Reassigned to  
A3217-10  
~~A3217-1P~~

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Preliminary Report under Assurance D16-00136 (Arizona State University)  
**Date:** Thursday, June 1, 2023 10:00:07 AM  
**Attachments:** image001.png

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Good morning (b) (6)

Thank you for sending us this preliminary report. This report has been assigned OLAW case number **A3217-1P**, so please reference this case number when sending the final report.

Best,  
Devora

Devora McCoy, BS, MBA (pronunciation)  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

**From:** (b) (6)  
**Sent:** Wednesday, May 31, 2023 7:11 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Karen Kibler <Karen.Kibler@asu.edu>; (b) (6)  
(b) (6) Matthew Hulver <Matthew.Hulver@asu.edu>; IACUC@asu.edu;  
(b) (6)  
**Subject:** [EXTERNAL] Preliminary Report under Assurance D16-00136 (Arizona State University)

Good afternoon,

On behalf of ASU IACUC, I am submitting a preliminary report regarding the IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

Before finalizing the report, we would like to discuss the matter with someone, as we were previously advised.

Confirmation of receipt is requested.

Please let me know if you have any questions.

Thank you,

(b) (6)



**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Preliminary Report under Assurance D16-00136 (Arizona State University)  
**Date:** Friday, May 26, 2023 1:10:56 PM  
**Attachments:** image001.png

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Good afternoon (b) (6)

This report has been assigned OLAW case number **A3217-10**, so please reference this case number when sending the final report.

Thanks,  
Devora

Devora McCoy, BS, MBA (pronunciation)  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390

Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

**From:** (b) (6)  
**Sent:** Tuesday, May 23, 2023 2:24 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
(b) (6) Matthew Hulver <Matthew.Hulver@asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; (b) (6) IACUC@asu.edu  
**Subject:** [EXTERNAL] Preliminary Report under Assurance D16-00136 (Arizona State University)

Good morning,

On behalf of ASU IACUC, I am submitting a preliminary report regarding the death of 5 mice due to conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals. The IACUC is investigating this matter and a follow-up message with the final report will be provided when the inquiry is complete.

Please let me know if you have any questions,

(b) (6)



Thank you,

(b) (6)

