

DEPARTMENT OF HEALTH & HUMAN SERVICES

(b)(4)

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) 402-7065

December 2, 2019

Re: Animal Welfare Assurance A3217-01 [OLAW Case 1B]

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

Dear Ms. Deuser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 15, 2019 letter reporting an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Arizona State University. According to the information provided, OLAW understands that on October 27, 2018, a rat was being tested in a calorimeter chamber. The chamber was connected to a computer that provided data recording as well as air supply to the chamber. The computer's connection to wall power was interrupted, and the batter power was not sufficient to continue overnight, resulting in asphyxiation of the animal.

The IACUC received the PI's initial report on November 15, 2018 and received a summary report of all corrective actions by the PI at the December 20th meeting. Corrective actions included: use of a separate and dedicated power source for the air supply (battery pack has been tested to ensure functionality in the event of being unplugged/loss of power) and posting of signage stating the importance of no power interruptions to the chamber. More than 10 rats have been tested without incident, and PI confirmed there have been no problems with the system.

Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken so far to investigate, correct, and prevent recurrence of the noncompliance. OLAW concurs with the actions taken by Arizona State University Animal Care and Use Committee to comply with the PHS Policy. However, OLAW recommends the IACUC consider taking measures to monitor the environmental settings of these chambers, such as temperature and air flow with the ability to send alerts when these parameters are outside of range. The letter states these experiments run for 23h, therefore, a system monitoring the environmental factors of the chambers would be beneficial. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. OLAW also recognizes the change in point of contact for the position of Assistant Director for the Office of Research Integrity and Assurance.

Page 2 – Ms. Deuser November 27, 2019 OLAW Case A3217-1B

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM Veterinary Medical Officer Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

Knowledge Enterprise
Arizona State University

A3217

Operations

Office of Research Integrity and Assurance

November 15, 2019

Brent Morse, DVM
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: ISTB-1 Species: Rattus norvegicus

Principal Investigator: Wade Van Horn Funding Source: N/A - Unfunded

Incident: Death of a rat while held in a calorimeter chamber

On October 27, 2018, a rat that was being tested in a calorimeter chamber to study energy gaps in intake and expenditure, based on varying diets. The chamber was connected to a computer that provided data recording as well as air supply to the chamber. For an undetermined reason, the computer's connection to wall power was interrupted, and the battery power was not sufficient to continue overnight. The animal, therefore, asphyxiated.

Corrective Action

The PI consulted with an engineer, who advised using a separate power source for the air supply, rather than relying on the computer power. A dedicated battery pack now powers the air pump at all times, while maintaining a full battery pack charge supplied by the wall. Calculations were performed to determine battery size necessary to run 24-hours continuously (experiments run for 23 hours). The battery pack was tested to ensure that in the event of being unplugged or losing power from the wall outlet, the air pump will seamlessly continue to be powered by the battery pack. No further problems with the system have occurred.

The IACUC reviewed the PI's initial report at the fully convened meeting on November 15th, 2018, and asked the PI to provide a summary report of all corrective actions. This report was provided to the committee at the December 20th meeting. In addition to the new power source described above, the PI also posted signage very clearly stating the importance of no power interruptions to the chamber. By the time of the December meeting, more than 10 rats had been tested with no incident. The power supply set-up will be checked during each semi-annual IACUC inspection. The committee was satisfied that the steps taken would provide the required assurance of safety for the animals.

Knowledge Enterprise Arizona State University

Operations

Office of Research Integrity and Assurance

Please let us know if you have any questions.

Sincerely,

(b) (6)

Karen Kibler, PhD Chair, IACUC Assistant Research Professor (b) (6)

Karen.Kibler@asu.edu

(b) (6)

Tamara Deuser, MBA, PMP Institutional Official Associate Vice President (b) (6)

Tamara.Deuser@asu.edu

Wolff, Axel (NIH/OD) [E]	
From: Sent: To: Cc: Subject:	OLAW Division of Compliance Oversight (NIH/OD) Wednesday, November 20, 2019 2:06 PM (b) (6) OLAW Division of Compliance Oversight (NIH/OD) RE: Adverse Event Report under Assurance D16-00136 (A3217)
Thank you for this report,	(b) (6) Dr. Morse will send a response soon.
Axel Wolff, M.S., D.V.M. Deputy Director, OLAW	
From:	(b) (6)
Sent: Wednesday, November 20,	
	e Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>
•	ser <tamara.deuser@asu.edu>; Karen Kibler <karen.kibler@asu.edu>; (b) (6)</karen.kibler@asu.edu></tamara.deuser@asu.edu>
cc. lacuc@asu.edu, famara Deus	(b) (6)
((b) (6)
	rt under Assurance D16-00136 (A3217)
Hello Dr. Morse,	
On behalf of the ASU IACUC, I am	n submitting the final report for the adverse event initially reported last year.
	no longer with ASU. (b) (6) who I have included on this email, has assumed the Office of Research Integrity and Assurance. Our email address of IACUC@asu.edupondence please.
If you have any questions, please co	ntact <u>IACUC@asu.edu</u> .
Thank you,	
	(b) (6)
From: IACUC@asu.edu <iacucas Sent: Tuesday, July 2, 2019 12:34 To:</iacucas 	
10.	(b) (6)
Subject: FW: Adverse Event Repo	ort under Assurance D16-00136 (A3217)

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, 02 July 2019 19:33:44 (UTC+00:00) Monrovia, Reykjavik

To: OLAW Division of Compliance Oversight (NIH/OD); (b) (6)

Cc: IACUC@asu.edu

Subject: RE: Adverse Event Report under Assurance D16-00136 (A3217)

Good afternoon (b) (6)

OLAW has no record of receiving further communication regarding this preliminary report. Please provide a final report if available. Otherwise, please provide and interim report. Thank you.

Sincerely, Brent Morse

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

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From: OLAW Division of Compliance Oversight (NIH/OD)

Sent: Tuesday, November 13, 2018 8:26 AM

To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)

<olawdco@od.nih.gov>

Cc: Tamara Deuser < Tamara. Deuser@asu.edu >; Karen Kibler < Karen. Kibler@asu.edu >; (6) (6)

(b) (6) IACUC@asu.edu

Subject: RE: Adverse Event Report under Assurance D16-00136

Thank you for submitting this preliminary report. We will open a case file and await further information.

Best regards, Brent Morse

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

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From: (b) (6)

Sent: Friday, November 09, 2018 3:09 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) IACUC@asu.edu

Subject: Adverse Event Report under Assurance D16-00136

Dr. Morse,

On behalf of the ASU IACUC, I am submitting a preliminary report on the unintended death of one rat in a calorimeter chamber. The IACUC is investigating and reviewing the incident and will follow up with a final report when their inquiry is complete.

Please let me know if you have any questions.

Thank you,

(b) (6)

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Tuesday, November 05, 2019 9:48 AM

To:

(NIH/OD)

Cc:

Karen.Kibler@asu.edu

Subject:

RE: Adverse Event Report under Assurance D16-00136 (A3217)

Importance:

High

Hello

(b) (6)

OLAW has two (2) open cases established from preliminary self-reports that are quite old. We need to have either final reports or interim reports with justification for keeping the cases open. Let us know if we can assist in any way. Please let us hear from you by November 18th. Thank you.

Best regards, Brent Morse

Hello

(b) (6)

Can you provide an update please?

Brent C. Morse, DVM, DACLAM

Director

Division of Compliance Oversight
Office of Laboratory Animal Welfare

National Institutes of Health

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From:

(b)(6)

Sent: Monday, July 15, 2019 2:54 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> **Subject:** RE: Adverse Event Report under Assurance D16-00136 (A3217)

Dr. Morse,

I apologize for the delay as I have been out of the office (b) (6) I will look into this and get back to you asap.

Thank you,

и, (b) (б)

From: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov >

Sent: Tuesday, July 02, 2019 12:34 PM

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Wednesday, September 11, 2019 9:32 AM

To:

(b) (6) OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Adverse Event Report under Assurance D16-00136 (A3217)

Hello (b) (6)

Can you provide an update please?

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

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From:

(b) (6)

Sent: Monday, July 15, 2019 2:54 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Subject: RE: Adverse Event Report under Assurance D16-00136 (A3217)

Dr. Morse,

I apologize for the delay as I have been out of the office (b) (6) I will look into this and get back to you asap.

Thank you,

From: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov >

Sent: Tuesday, July 02, 2019 12:34 PM

To: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov >;

(b) (6

Cc: IACUC@asu.edu

Subject: RE: Adverse Event Report under Assurance D16-00136 (A3217)

Good afternoon

(b) (6)

OLAW has no record of receiving further communication regarding this preliminary report. Please provide a final report if available. Otherwise, please provide and interim report. Thank you.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM

(b) (6) From: Sent: Monday, July 15, 2019 2:54 PM To: OLAW Division of Compliance Oversight (NIH/OD) Subject: RE: Adverse Event Report under Assurance D16-00136 (A3217) Dr. Morse, I apologize for the delay as I have been out of the office (b) (6) I will look into this and get back to you asap. Thank you, From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Sent: Tuesday, July 02, 2019 12:34 PM (b)(6)To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Cc: IACUC@asu.edu Subject: RE: Adverse Event Report under Assurance D16-00136 (A3217) (b)(6)Good afternoon OLAW has no record of receiving further communication regarding this preliminary report. Please provide a final report if available. Otherwise, please provide and interim report. Thank you. Sincerely, Brent Morse

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

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From: OLAW Division of Compliance Oversight (NIH/OD)

Sent: Tuesday, November 13, 2018 8:26 AM

(NIH/OD) OLAW Division of Compliance Oversight To:

<olawdco@od.nih.gov>

Cc: Tamara Deuser < Tamara. Deuser@asu. edu >; Karen Kibler < Karen. Kibler@asu. edu >; (b) (6) [ACUC@asu.edu

Subject: RE: Adverse Event Report under Assurance D16-00136

Thank you for submitting this preliminary report. We will open a case file and await further information.

From: Sent: To: Cc: Subject:	OLAW Division of Compliance Oversight (NIH/OD) Tuesday, July 02, 2019 3:34 PM OLAW Division of Compliance Oversight (NIH/OD); Chantelle Shalley IACUC@asu.edu RE: Adverse Event Report under Assurance D16-00136 (A3217)
Good afternoon (b) (6)	
	ceiving further communication regarding this preliminary report. Please provide a final ase provide and interim report. Thank you.
	Sincerely, Brent Morse
_	d any of its attachments are intended for the named recipient(s) only and may contain ged information that should not be distributed to unauthorized individuals. If you have
From: OLAW Division of Complian	
Sent: Tuesday, November 13, 201 To:	L8 8:26 AM (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
<olawdco@od.nih.gov></olawdco@od.nih.gov>	ser@asu.edu>; Karen Kibler <karen.kibler@asu.edu>; (b) (6) (b) (6) (b) (6) (ACUC@asu.edu</karen.kibler@asu.edu>
Subject: RE: Adverse Event Repor	
Thank you for submitting this pre	liminary report. We will open a case file and await further information.
	Best regards, Brent Morse
Brent C. Morse, DVM, DACLAM	

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

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