

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

March 24, 2022

FOR EXPRESS MAIL Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 480-3387

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

Dr. Matthew Hulver Vice President of Research Arizona State University 300 East University Drive, (b) (4) Tempe, AZ 85287-6111

Dear Dr. Hulver,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 4, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Arizona State University following up on an initial February 9, 2022 notification by email.

According to the information provided, this Office understands that the Arizona State University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: conditions that jeopardized the health or well-being of animals resulting in harm or death to animals. The final report states on February 7, 2022, the IACUC was notified by the Department of Animal Care (DACT) Assistant Director that a pig was euthanized due to a lateral tarsal fracture which occurred during free roaming enrichment. It is stated the animal slipped on the floor and was observed limping when standing again. The animal was observed overnight, and radiographs were taken the next morning. Ultimately, the pig was euthanized, and necropsy findings confirmed the diagnosis of a fracture.

The IACUC Chair met with the Principal Investigator and a DACT representative to discuss the incident on February 14, 2022. It is stated free roaming enrichment had been in use for 3wk without incident and was initiated when the animals were first weighed on a scale outside the pen at the start of the study. In the end, it was decided to strictly confine the animals to their pens where rubber mats are in place to prevent slipping. Also, weighing of animals will occur by moving the scale into the pen and procedures that require the pigs to be removed from the pen will use a pre-anesthetic injection to sedate the animals prior to removal.

It is understood the IACUC Chair notified the committee of the animal death at the convened meeting on February 25, 2022. The corrective actions taken were described to the committee, and the IACUC does not require additional actions at this time.

It is noted that this research is supported by NIH funding. Based on its assessment of this explanation, OLAW understands that the Arizona State University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Dr. Hulver March 24, 2022 OLAW Case A3217-1J

Sincerely,

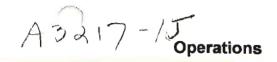
Jacquelyn Tubbs -5 T. Tubbs -5 T. Tubbs -5

Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations





Office of Research Integrity and Assurance

March 4, 2022

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 Condition Resulting in Animal Deal under Animal Welfare Assurance #DIG-00136

Research Facility: BDB Species: Swine Principal Investigator: Kaushal Rege Funding Source: National Institutes of Health Incident: 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

On February 7, 2022, the IACUC was informed by the Department of Animal Care (DACT) Assistant Director that a pig was euthanized unexpectedly due to a lateral tarsal fracture that occurred during free roaming enrichment. The pig slipped on the floor and when she stood up, was found to be limping. The DACT representative stated they then observed the animal overnight and x-rayed the next morning. The pig was euthanized and necropsied to confirm diagnosis.

A preliminary report was sent to OLAW via email on February 9, 2022.

Corrective Action:

The Chair met with the PI and a DACT representative on February 14, 2022 to discuss this matter.

The animals on this protocol were housed in the vivarium. The free roaming enrichment had been in use for three weeks without incident, and had been initiated when the animals were first weighed on a scale outside the pen at the beginning of the study. The pig in this report was not quite as tame as the others, and although no one actually witnessed the fall, the technician did see the pig on the floor before it stood up; the technician believed it had been moving too fast because it was less calm than the others. To move forward, the decision was made that day to keep the pigs strictly confined to their pens where rubber mats are in place to prevent slipping. Weighing will always be accomplished by moving the scale into the pen, and procedures that require the pigs to be removed from the pen will utilize a preanesthetic injection to sedate the animals prior to removal.



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Office of Research Integrity and Assurance

The Chair informed the committee of this animal death at the February 25, 2022, fully convened meeting. The Chair explained to the committee the correction actions that have been taken. The committee acknowledged the information and believed no additional action is required at this time.

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, Ph.D. Institutional Official, Vice President

Matthew.Hulver@asu.edu

Wolff, Axel (NIH/OD) [E]

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From: Sent: To: Cc: Subject:	OLAW Division of Compliance Oversight (NIH/OD) Friday, March 4, 2022 7:06 AM (b) (6) OLAW Division of Compliance Oversight (NIH/OD) RE: Preliminary Report under Assurance D16-00136 (Arizona State University)
Thank you for this report, Axel Wolff	(b) (6) We will send a response soon.
From: Sent: Thursday, March 3, 2022 4: To: OLAW Division of Compliance (b) (6)	ው) (6) 19 PM Oversight (NIH/OD) <olawdco@od.nih.gov>; (b) (6)</olawdco@od.nih.gov>
	<karen.kibler@asu.edu>; Matthew Hulver <matthew.hulver@asu.edu> ary Report under Assurance D16-00136 (Arizona State University)</matthew.hulver@asu.edu></karen.kibler@asu.edu>
CAUTION: This email originated from sender and are confident the conten	outside of the organization. Do not click links or open attachments unless you recognize the t is safe.
Good afternoon,	j.
Please find attached the final rep	ort for the death of a pig, which was initially reported to OLAW on 2/9/2022.
If you have any questions, please	let us know.
Thank you,	
	(b) (б)
Sent: Friday, February 11, 2022 5: To: Cc: OLAW Division of Compliance	ce Oversight (NIH/OD) < <u>olawdco@od.nih.gov</u> > 25 AM (b) (6) Oversight (NIH/OD) < <u>olawdco@od.nih.gov</u> > nder Assurance D16-00136 (Arizona State University)
Thank you for this preliminary rep final report from the IO after the l	ort, ^{(b) (6)} We will start a new case file and look forward to receiving the ACUC has completed its investigation.
Axel Wolff, M.S., D.V.M. Deputy Director, OLAW	
From: Sent: Wednesday, February 9, 202	(b) (6) 22 1:46 PM

To: OLAW Division of Compliance Oversight (NIH/OD) < <u>olawdco@od.nih.gov</u> >	(b) (6)
Cc: Matthew Hulver < <u>Matthew.Hulver@asu.edu</u> >; Karen Kibler < <u>Karen.Kibler@asu.edu></u>	
(b) (6) IACUC@asu.edu <iacucasu.edu@mainex1.asu.edu></iacucasu.edu@mainex1.asu.edu>	
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Subject: [EXTERNAL] Preliminary Report under Assurance D16-00136 (Arizona State University)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Good afternoon,

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On behalf of the ASU IACUC, I am submitting a preliminary report of a death of a pig due to a lateral tarsal fracture that occurred during free roaming enrichment. The IACUC is reviewing this matter and a follow up message with a final report will be provided when the inquiry is complete.

If you have any questions, please contact me.

Thank you,

(b) (6)

Wolff, Axel (NIH/OD) [E]

A3217-1J

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Friday, February 11, 2022 7:25 AM
To:	(b) (6)
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Preliminary Report under Assurance D16-00136 (Arizona State University)

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. Deputy Director, OLAW

 From:
 (b) (6)

 Sent: Wednesday, February 9, 2022 1:46 PM

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

 Cc: Matthew Hulver <Matthew.Hulver@asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>;

 (b) (6)

 (b) (6)

 (b) (6)

 IACUC@asu.edu <IACUCasu.edu@mainex1.asu.edu>

 Subject: [EXTERNAL] Preliminary Report under Assurance D16-00136 (Arizona State University)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

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If you have any questions, please contact me.

Thank you,

(b) (6)