

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

October 20, 2021

Re: Animal Welfare Assurance A3255-01 [OLAW Case 2P]

Dr. Christopher S. Brown
Institutional Official
Vice President for Research
University of Alabama- Birmingham
1720 2nd Ave. S, 720C
Birmingham, AL 35294-0107

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 18, 2021 letter reporting an adverse event involving a research pig at the University of Alabama at Birmingham, following up on an initial telephone report on August 2, 2021. According to the information provided, OLAW understands that a pig on a training study died under anesthesia. The animal was observed to be stressed before the procedure and this may have contributed to the death. Also, the animal had been ordered under a non-survival training protocol but was used for a survival training and had not been transferred to that protocol.

The preventive action consisted of retraining the veterinary staff involved on ordering procedures, protocol transfers, on ensuring that personnel are familiar with the approved protocol procedures, and on not conducting procedures on animals which appear stressed. Pigs will no longer be used in this training procedure. The incident has been reported to the USDA Veterinary Medical Officer.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair Robert Gibbens, D.V.M., USDA-APHIS-AC



Institutional Animal Care and Use Committee (IACUC)

October 18, 2021

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Assurance # A3255-01

Dear Dr. Morse:

Below is the description of adverse events related to a mechanical issue and an unapproved deviation from the IACUC-approved protocol. A preliminary report was filed for these events on August 2, 2021.

Adverse event due to mechanical issue: Due to miscommunication between maintenance personnel and failure to adhere to documented maintenance procedures, animal program staff were not alerted to alarms associated with the HVAC system for one animal facility. While temperatures for the majority of the facility did not fall outside of Guide standards, a colony of 80 trout died or were euthanized when their tank temperatures became too warm during the 24-hour period the HVAC system was not functioning. The responsible maintenance department has disciplined the employees involved and corrections are underway to ensure animal program staff are directly notified by system alarms rather than through maintenance staff. The investigator is also in the process of evaluating equipment that will help control water temperatures at the tank level. The incident did not involve PHS funds.

Adverse event due to deviation from approved protocol: Two pigs were ordered under an approved, nonsurvival, training protocol, but were used for a survival training event covered by a different approved protocol without being properly transferred. During a demonstration of proper anesthesia induction and monitoring by program vet staff, one of the pigs failed to recover from the anesthesia. Staff noted that the animal was visibly stressed before anesthesia and it is believed this is the reason it did not recover. The vet staff members have been retrained and reminded of the importance of following procedures for ordering and transferring animals under the correct protocols; being familiar with the approved protocol procedures; and not conducting even minor procedures in visibly stressed animals. As a result of this incident, pigs will no longer be used in this training event. This incident did not involve PHS funds and has already been reported to the USDA VMO.

If you require additional information or clarification, please do not hesitate to let me know.

Sincere	(b) (6)	
Christo	pher S. Brown, Ph.D.	
Institutional Official and Vice President for Research		
cc:		(b) (6)
	Robert A. Kesterson, Ph.D., IACUC Chair	
		(b) (6)

OFFICE OF RESEARCH

Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Wednesday, October 20, 2021 7:15 AM

To:

(b) (6)

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Adverse event report

Thank you for this report,

(b) (6) We will send a response soon.

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

From:

(b) (6)

Sent: Monday, October 18, 2021 1:27 PM

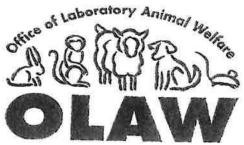
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: Adverse event report

Please see attached a final report for incidents sent as a preliminary report in August.

Thank you,

(b) (6)



Initial Report of Noncompliance

By: (6) (6)
Date: 8/2/21 Time: 10:25 Name of Person reporting: Telephone #: Fax #: Email:
Name of Institution: Assurance number: A3255
Did incident involve PHS funded activity?Yes Funding component: Was funding component contacted (if necessary):
What happened? Pry dudn't go through acceleration period, died under anestheria. Training study for net teals Species involved: P16 Personnel involved: Dates and times: Animal deaths: 1
Projected plan and schedule for correction/prevention (if known):
Projected submission to OLAW of final report from Institutional Official:
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