



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

July 25, 2019

Re: Animal Welfare Assurance
#A3152-01 (OLAW Case 1A)

James Weyhenmeyer, Ph.D.
Vice President for Research
Auburn University
(b) (4) Sanford Hall
Auburn University, AL 36849-0001

Dear Dr. Weyhenmeyer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 15, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Auburn University. According to the information provided, OLAW understands that hazardous drugs had been given to animals although this activity had not been approved by the Institutional Animal Care and Use Committee (IACUC) and was performed in an area not approved for handling of such agents. Two graduate students were involved and one had not read the protocol while the other had read it but used the hazardous drugs on animals anyway. This activity put animal care staff at risk of exposure to the agents.

The corrective actions consisted of the IACUC suspending the animal use privileges of the Principal Investigator (PI), Co-PI, and the two students and requiring retraining on IACUC policies, use of hazardous materials, use of the rodent vivaria, and on ethical conduct of research. Upon completion of the training, the investigators must meet with the IACUC. The suspension was appealed by the Co-PI but was upheld by the IACUC.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Please remember to specify the species involved in the noncompliance report. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



AUBURN

UNIVERSITY

Office of Research Compliance
IACUC Administration
115 Ramsay Hall Basement
Auburn University, AL 36849

Telephone: 334-844-5978
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IACUCadmin@auburn.edu

July 15, 2019

Dr. Brent Morse
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-7982
olawdco@mail.nih.gov

Assurance Number: D16-00092 (A3152-01)

Dr. Morse:

This is a report of non-compliance and revocation of animal care and use privileges of a Principal Investigator (PI), a Co-Investigator (Co-I), and two graduate students at Auburn University. The animal activity at issue was not funded by PHS or NSF, but the activity took place in a facility included in the OLAW assurance referenced above.

Review of the situation:

On May 9, 2019 the Director of Laboratory Animal Health sent an email to the PI and Co-I informing them that medical records indicated that hazardous drugs had been given to their animals without IACUC approval and in a location not approved for safe handling of hazardous drugs. The email requested clarification of the situation. The Co-I responded that although the administration of hazardous drugs had been planned, they had not been given to live animals and instead were injected post mortem. The next day, the hazardous drug entry in the medical record was found to have been blacked out. However, further documentation of hazardous drug administration was found on associated cage cards. The Director called the IACUC Chair to report the incident and request an investigation.

Over the next several days, the IACUC Chair conducted phone calls with the PI and Co-I. The PI indicated that the Co-I was responsible for conducting the animal procedures. Subsequently, the IACUC Chair and the Director conducted another phone call with the Co-I. The Co-I acknowledged that the hazardous drugs were not on the approved protocol and that due to miscommunication between the Co-I and the students, the drugs were given to the animals while they were alive rather than post-euthanasia. As the Co-I took responsibility for the error, the investigation was not pursued further.

On June 6, 2019, the incident was presented to the IACUC for discussion. The discussion resulted in the IACUC requesting that interviews of the two graduate students be conducted by the Director and IACUC Chair. Interviews of the two students indicated that the number of animal protocols on which they worked was very high, so effective communication among laboratory members appeared inadequate.

One student had not read the animal protocol. The other student had read the protocol but despite this knowledge had proceeded to administer the hazardous drugs. Neither student routinely read the protocols on which they worked. Moreover, there was an apparent lack of concern that they had conducted activities without IACUC approval and had put animal care workers at risk by using unauthorized hazardous agents in an animal care room not approved for safe handling of such drugs.

Decisions by the IACUC:

Based on the investigation, the IACUC identified several concerns related to 1) animal care and use, 2) appropriate communication among laboratory members regarding animal treatment, 3) appropriate handling of hazardous agents and regard for the well-being of others impacted by these actions, 4) familiarity with IACUC protocols and policies, and 5) general ethical conduct expected of researchers.

In light of these concerns, at the IACUC meeting on June 20, 2019, the IACUC voted to:

- 1) Suspend the PI, Co-I and 2 graduate students from conducting any animal activities at Auburn University for a period not less than six months.
- 2) Require successful retraining by completion of required IACUC training modules (online)
- 3) Require successful retraining on the use of hazardous materials
- 4) Require successful retraining on the use of the two primary rodent vivaria on the Auburn University campus
- 5) Require successful retraining on the Ethical Conduct of Research (administered by the Auburn University Office of Research Compliance)
- 6) Require a post-training interview with members of the IACUC
- 7) The suspensions of the individuals, as well as the IACUC-approved protocol, will continue until the above requirements are met by the individuals identified.

After consultation with the Institutional Official, letters indicating the above actions were sent to the PI, Co-I, and the two graduate students on July 8, 2019.

An appeal letter was submitted from the Co-I to the IACUC Chair on July 10, 2019. The letter was discussed at the next IACUC meeting on July 11, 2019. The IACUC voted to maintain its' decision of June 20, 2019 without change.

If any additional information is required, please contact the Office of Research Compliance at (b) (6) or IACUCAdmin@auburn.edu.

Sincerely,
(b) (6)

James Weyhenmeyer, Ph.D.
Auburn University Institutional Official
Vice President for Research

(b) (6)

Timothy D. Braden, Ph.D.
Auburn University IACUC Chair
Associate Professor
Anatomy, Physiology & Pharmacology

cc: University Veterinarian – Dr. P. Rynders

(b) (6)



Director, Office of Research Compliance – Ms. N. Johnson

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, July 23, 2019 7:19 AM
To: IACUC Admin; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Timothy Braden; James Weyhenmeyer
Subject: RE: AU Reportable Situation Report

Thank you for providing this report. We will send an official response soon.

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: IACUC Admin [mailto:OARPROG@auburn.edu]
Sent: Monday, July 22, 2019 3:22 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Timothy Braden <bradetd@auburn.edu>; James Weyhenmeyer <jweyhenmeyer@auburn.edu>
Subject: AU Reportable Situation Report

Good afternoon,

Please see the attached memo concerning a reportable situation from Auburn University (D16-00092/A3152-01).

If you have any questions or need additional information, please contact us at IACUCAdmin@auburn.edu or (b) (6)

Thank you,

(b) (6)



(b) (6)