



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) 402-7065

March 6, 2019

Re: Animal Welfare Assurance
#A3325-01 (OLAW Case 1K)

Dr. Steven Goodman
Vice Chancellor for Research
University of Tennessee Health Science Center
910 Madison Avenue – (b) (4)
Memphis, TN 38163

Dear Dr. Goodman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 28, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Tennessee Health Science Center. According to the information provided, OLAW understands that Avertin was being used as an anesthetic although this had not been approved in the protocol. The laboratory staff decided to use this drug due to difficulties with an inhalant agent and failed to inform the Principal Investigator (PI).

The corrective action consisted of the PI directing the laboratory staff to re-read the protocol. The Institutional Animal Care and Use Committee required the laboratory staff to undertake online retraining as well as hands on retraining by the veterinary staff on use of inhalant anesthesia. The PI was warned about the consequences of future noncompliance.

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. In future, please remember to indicate the species involved. Also, we recommend that any animal concerns, such as failure to recover from anesthesia, be reported to the veterinarian. 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

February 28, 2019

Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
670b Rockledge Drive, Suite 2500, MSC6910
Bethesda, MD 20892

Dr. Morse or Dr. Wolff:

The University of Tennessee Health Science Center (UTHSC), in accordance with Assurance A3325-01 and PHS Policy IV.F.3, reports noncompliance for participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f. The narrative below describes the findings and actions taken in this matter.

On January 30, 2019 the Institutional Animal Care and Use Committee (IACUC) was made aware that members of a research group on campus were using Avertin as an anesthetic agent. Avertin was not included in their approved. Further investigation revealed that research staff unilaterally (i.e., without the PI's knowledge) made the decision to use Avertin based on difficulties associated with their approved use of Isoflurane (specifically, several animals failed to recover from anesthesia).

A quorum of the IACUC examined these findings, during its regular meeting on February 12, 2019. During its deliberations of the incident, the IACUC considered the PI's proactive response to the protocol noncompliance, requiring all members of the research group to re-read the animal use protocol.

Following discussion, the IACUC unanimously voted:

- Require additional training on interactions with the IACUC. It is required that research staff complete the "Refresher: Working with the IACUC" course found in the AALAS Learning Library within 30 days.
- Since the noncompliance was a result of difficulties associated with the use of Isoflurane, research staff are required to complete hands-on training in the proper use of anesthetics provided by the UTHSC Veterinary staff.

These have been completed.

The PI was reminded that any future failure to comply with an approved animal protocol, IACUC procedures, or Lab Animal Care Unit procedures, no matter how minor, could be grounds for immediate suspension of their animal research program.

The protocol associated with the report of non-compliance was PHS funded, USPHS Grant AR-064354-05.

Sincerely,

(b) (6)

Steven R. Goodman PhD
Vice Chancellor for Research

Copied:

(b) (6)

Jeffery Steketee, PhD

IACUC, Chair

(b) (6)

David Hamilton, DVM
AAALACI

Attending Veterinarian

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 28, 2019 2:36 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Goodman, Steven R; (b) (6) Steketee, Jeffery D; (b) (6) Hamilton, David
Subject: RE: Incident Report A-3325-01

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: (b) (6)
Sent: Thursday, February 28, 2019 12:02 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; accredit@aaaalac.org
Cc: Goodman, Steven R <sgoodma5@uthsc.edu>; (b) (6) Steketee, Jeffery D <jstekete@uthsc.edu>; (b) (6) Hamilton, David <dhamilt7@uthsc.edu>
Subject: Incident Report A-3325-01

Incident report attached.

Please contact us if additional information is needed.

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(b) (6)