



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

June 7, 2018

Re: Animal Welfare Assurance
A4094-01 [OLAW Case 1L]

Dr. Fred H. Cate
Vice President for Research
Indiana University-Bloomington
Carmichael Center
530 E. Kirkwood Avenue – (b) (4)
Bloomington, IN 47408-4003

Dear Dr. Cate,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 4, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Indiana University, following up on an initial telephone report on May 22, 2018. According to the information provided, OLAW understands that three mice on a training protocol died after having been returned to the facility before fully recovering from anesthesia. The animals had not been monitored or provided with supplemental heat.

The corrective actions consisted of the Institutional Animal Care and Use Committee requiring enhanced training of personnel conducting these procedures. The veterinarian counseled the laboratory staff on post-procedural monitoring, heat support, and using an anesthetic reversal agent. The Principal Investigator was counseled on maintaining compliance.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair



INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

June 4, 2018

Brent Morse, DVM, Acting Director
Division of Compliance Oversight
OLAW/NIH
RKL 1, Suite 360, MSC 7982
Bethesda, MD 20892-7982
Email: olawdco@mail.nih.gov

Re: Notice of Adverse Animal Event for Assurance D16-00587; Indiana University-Bloomington

Dear Dr. Morse:

This letter reports an unanticipated adverse animal event at Indiana University, Bloomington campus. This event occurred in one research laboratory. A verbal, preliminary report was given to Dr. Axel Wolff on May 22, 2018.

In April of 2018, animal care staff discovered a cage with three deceased mice. Upon investigation, the clinical veterinarian learned that the animals had been dosed with an IACUC-approved, injectable anesthetic and were used in a training activity involving a corneal abrasion survival procedure. After speaking with the responsible lab individual, the clinical veterinarian found that it was likely that the animals had not been fully recovered from anesthesia before being returned to their colony.

The Bloomington IACUC convened on May 21, 2018 and discussed this circumstance. The committee concluded that the laboratory had conducted activities as approved in their IACUC protocol. However, the committee identified several areas requiring improvement in the training mechanism. The IACUC further noted that the clinical veterinarian had subsequently met several times with laboratory personnel, providing additional guidance that included the use of an anesthetic reversal agent, application of heat support during and following the procedure, and a review of post-procedural monitoring.

The IACUC Chairperson, the IACUC Administrator, and Attending Veterinarian have met with the PI and his Dean to review this matter, discuss IACUC and regulatory expectations, and explore how the veterinary staff may proactively support the laboratory. Because this is not the first incident involving this lab, I also have communicated with the PI and his Dean to stress the importance of full and consistent compliance.

This project is funded by the NIH's National Eye Institute award 7R01EY021501-05; the program official is copied on this notification. Please feel welcome to contact us with any questions.

Sincerely,

(b) (6)

Fred H. Cate
Vice President for Research
Distinguished Professor and C. Ben Dutton Professor of Law

Cc: Lisa Kamendulis, PhD (IACUC Chairperson)

(b) (6)

Karen Rogers, DACLAM, DVM (Attending Veterinarian)

(b) (6)

George A. McKie, DVM (mckiegeo@mail.nih.gov)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 04, 2018 1:21 PM
To: Vice President for Research; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Kamendulis, Lisa M.; Rogers, Karen;
(b) (6)
Subject: RE: Notice of Adverse Animal Event for Assurance D16-00587

Thank you for providing this final report. I will forward this information to Dr. Wolff. He will send an official response soon.

Regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Vice President for Research [mailto:vpr@iu.edu]
Sent: Monday, June 04, 2018 1:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Kamendulis, Lisa M.
<lkamendu@indiana.edu>; Rogers, Karen <rogerkar@iu.edu>; (b) (6)
(b) (6)
Subject: Notice of Adverse Animal Event for Assurance D16-00587

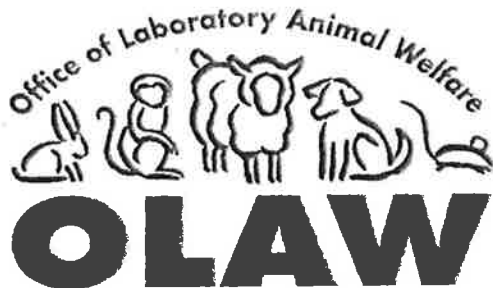
Dear Dr. Morse,

Attached you will find a letter to report an adverse animal event for assurance D16-00587, Indiana University-Bloomington. This project is funded by the NIH's National Eye Institute award 7R01EY021501-05.

Thank you,

(b) (6)

 INDIANA UNIVERSITY



Initial Report of Noncompliance

By: AWDate: 5/22/18Time: 11:15

Name of Person reporting:

Telephone #:

(b) (6)

Fax #:

Email:

Name of Institution:

Indiana U - Bloomington

Assurance number:

A4094Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Training exercise done, head trainer not there, 3 mice died after anesthesia. No thermal support or reversal drugs.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths: 3

Projected plan and schedule for correction/prevention (if known): _____

Take mouse temperature, observe closely & provide supportive care

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____