



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

December 10, 2019

Re: Animal Welfare Assurance  
A4094-01 [OLAW Case 10]

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 December 6, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Indiana University- Bloomington, following up on an initial telephone report on November 26, 2019. According to the information provided, OLAW understands that mice were overcrowded in a cage for a euthanasia procedure. This incident also violated institutional policy and the protocol.

The corrective actions consisted of counseling the individual responsible and the Principal Investigator (PI). Due to concerns about adverse animal events in this laboratory, the Institutional Animal Care and Use Committee (IACUC) suspended the protocol. The IACUC directed the PI and staff to undergo online and hands on training and to have the PI present information to the IACUC regarding proposed research and animal welfare regulations. The laboratory was placed on enhanced post-approval monitoring, the PI was counseled on animal welfare expectations, the animals on the protocol were transferred to a holding protocol, the NIH grant will not be charged for any animal activities, and the NIH Program Official was notified about the suspension.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair



OFFICE OF  
RESEARCH COMPLIANCE  
INDIANA UNIVERSITY

December 6, 2019

Axel Wolff, MS, DVM, Deputy Director  
Division of Compliance Oversight  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Email: [olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

Re: Notice of Noncompliance for Assurance D16-00587; Indiana University-Bloomington

Dear Dr. Wolff,

This letter reports a new incident of noncompliance with the PHS Policy and adverse animal event at Indiana University, Bloomington campus. The event occurred in one research laboratory. A verbal, preliminary report was given to you on November 26, 2019.

In September of 2019, a Laboratory Animal Resource (LAR) veterinarian discovered a cage of euthanized mice that was overcrowded. It was determined that the responsible research personnel did not conduct this activity in accordance with the approved IACUC protocol and policy, nor with the recommendations as outlined in the 8<sup>th</sup> edition of the *Guide*. The veterinarian discussed the matter with the responsible individual and PI. The IACUC Manager followed up with the PI and research personnel, reviewing the event and related IACUC protocol and policy. The IACUC Chairperson, Attending Veterinarian, and IACUC Manager also met separately with the PI and the PI's Dean.

The IACUC discussed this matter at three fully convened Committee meetings, held on September 30, 2019, October 28, 2019, and November 25, 2019. The Membership acknowledged ongoing efforts by the LAR veterinarians and IACUC Manager to support and educate the PI and research personnel.

As the IACUC and LAR veterinarians remain concerned about the reoccurrence of unrelated noncompliance and adverse animal welfare events, the IACUC moved to suspend the related IACUC protocol, beginning on December 2, 2019 and concluding on January 2, 2020. During this time, the PI and research personnel will undergo a series of retraining activities as directed by the IACUC and implemented by LAR veterinarians and the IACUC Manager. These training requirements include, but are not limited to:

- Successful completion of regulatory and species-specific online training modules.
- Scheduling and completion of hands-on training with an IUB veterinarian.
- Having the PI provide a presentation to the IACUC during the January 2020 meeting describing his research aims and how animal welfare regulations apply.

Axel Wolff, MS, DVM, Deputy Director

Date, 2019

Notice of Noncompliance for Assurance D-16-00587; Indiana University-Bloomington

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- Additional post-approval monitoring visits by the IACUC Manager, a LAR veterinarian, or LAR registered veterinary technician once the suspension has been lifted.

The IACUC and LAR veterinarians have emphasized to the PI that the University and our research community take on an ethical, professional, and legal obligation to protect the welfare and ensure the appropriate care of the research animals, while complying with all relevant laws, regulations, and University policies.

This suspended protocol covers activities on the NIH's National Eye Institute award 1R01EY029071-01A1; the program official is copied on this notification. For the period of the suspension, animals have been placed on a holding protocol under the supervision of the Attending Veterinarian and no animal costs will be charged to any federal grants. 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 Chair

Karen Rogers, DVM, DACLAM, Attending Veterinarian

(b) (6)

Eric Swank, Executive Director, RIICE

(b) (6)

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, December 09, 2019 8:32 AM  
**To:** Vice President for Research; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** RE: Noncompliance Report D16-00587

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:** Vice President for Research [mailto:vpr@iu.edu]  
**Sent:** Friday, December 06, 2019 4:46 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** Noncompliance Report D16-00587

Good afternoon,

Please find the noncompliance report D16-00587 attached.

Most sincerely,  
(b) (6)



## Initial Report of Noncompliance

By: and

Date: 11/26/19

Time: 11:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Indiana U - Bloomington

Assurance number: A4094

Did incident involve PHS funded activity? yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Inappropriate euthanasia - overcrowding in box

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Suspend protocol, retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_