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

February 8, 2018

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

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 February 7, 2018 letter reporting an adverse event involving mice and an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Indiana University- Bloomington, following up on an initial telephone report on February 2, 2018. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

1) One mouse died after its cage fell to the ground due to being dislodged by a dangling power cord.

Corrective action: The cord was secured to prevent contact with the cage rack, staff now routinely checks on the cord, and empty cages have been placed on the top of the rack so no cages can be displaced. The current rack will soon be replaced with a new one.

2) A CO2 euthanasia chamber had been used to euthanize mice but was left unattended overnight with the gas flowing. The required secondary physical method of euthanasia to ensure death had not been conducted and staff failed to stay with the animals until the procedure was completed.

Corrective action: The investigator and staff were counseled. The investigator may have the animal care staff perform euthanasia.

Based on its assessment of these explanations, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. 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

February 7, 2018

Brent Morse, D.V.M., Acting Director
Division of Compliance Oversight
OLAW/NIH
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Email: olawdco@mail.nih.gov

Re: Notice of Noncompliance for Assurance A-4094-01–D16-00587; Indiana University-Bloomington

Dear Dr. Morse:

This letter reports a new incident of noncompliance with the PHS Policy and an unanticipated adverse animal event at Indiana University, Bloomington campus. These events occurred in one research laboratory. A verbal, preliminary report was given to Dr. Axel Wolff on February 2, 2018.

In December of 2017, a laboratory using purpose-bred mice reported to animal care staff an unanticipated animal death. It was determined that a power cord for a circular IVC cage rack had become dislodged and dangled downward to the cage level. The cord became entangled around a cage and displaced it upward and out of the rack. Consequently, the cage fell from the rack and resulted in the death of one mouse out of three.

The cord has now been secured so as not to make contact with the rack. The Laboratory Animal Resources (LAR) staff and laboratory personnel are routinely checking its placement. The LAR group now places empty cages at the top of the rack so that no cages can become displaced from their location. Since this rack has had two recent malfunctions, LAR is looking to replace this rack with a new one.

During the IACUC's January 2018 meeting, the committee determined that an accident had occurred with unintended consequences, resulting in an unanticipated animal death. The measures taken to prevent recurrence were deemed acceptable.

Also in December of 2017, animal care staff discovered a cage of deceased mice in a procedural area with an attached CO_2 tank that was still flowing. After animal care staff consulted with the researcher responsible for animal use in this area, it was determined that laboratory personnel had left the room during the euthanasia procedure and then neglected to return.

In following up on this matter during the January 2018 meeting, the IACUC determined that a protocol violation had occurred, in that a secondary method to assure euthanasia had not been performed as outlined in the protocol. In addition, research personnel are expected to remain with animals undergoing euthanasia until the procedure has been completed.

The IACUC administrator spoke with the researcher and members of the laboratory, highlighting the regulating agencies' and IACUC's expectations for conducting humane euthanasia procedures. The researcher noted that he has had two laboratory meetings reviewing this incident. He has instructed laboratory members to conduct euthanasia at the end of the day and as a sole task, remaining in the area until the euthanasia procedure has been completed. The researcher will also contact the attending veterinarian, to discuss the possibility of contracting with the animal care staff to perform the euthanasia procedures.

This project is funded by 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) [redacted]

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

cc: Lisa Kamendulis, Ph.D. (IACUC Chair)
Karen Rogers, DACLAM, D.V.M. (Attending Veterinarian)
(b) (6) [redacted]
Eric Swank (Executive Director of RIICE)
(b) (6) [redacted]
George A. McKie, D.V.M. (mckiegeo@mail.nih.gov)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 08, 2018 8:00 AM
To: 'Vice President for Research'
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Notice of Noncompliance for Assurance A-4094-01–D16-00587: Indiana University–Bloomington

Thank you for this report. We will send a response soon.

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

From: Vice President for Research [mailto:vpr@iu.edu]
Sent: Wednesday, February 07, 2018 1:58 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Kamendulis, Lisa M. <lkamendu@indiana.edu>; Rogers, Karen <rogerkar@iu.edu>; (b) (6) (b) (6) @indiana.edu>; Swank, Eric D. <edswank@iu.edu>; (b) (6) @iu.edu>; McKie, George (NIH/NEI) [E] <george.mckie@nih.gov>
Subject: Notice of Noncompliance for Assurance A-4094-01–D16-00587: Indiana University–Bloomington

Dear Dr. Morse:

Attached here, please find a report of an instance of noncompliance with PHS Policy and an unanticipated adverse animal event at Indiana University–Bloomington. This activity is funded by NIH's National Eye Institute award 7R01EY021501-05; the program official is copied here.

Thank you,
(b)

(b) (6)

A4094-1K

Office of Laboratory Animal Welfare

OLAW

Initial Report of Noncompliance

By: AW

Date: 2/2/18

Time: 8:45

Name of Person reporting: (b) (6)
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: Indiana University
Assurance number: A4094

Did incident involve PHS funded activity? Yes
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?

1) Unanticipated animal death, HVAC hose on mouse caught on cage + fell. Mouse died.
2) CO2 left on overnight in euthanasia chamber, mice did not die. Physical method used. Person left.

Species involved: Mice
Personnel involved:
Dates and times:
Animal deaths:

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

1) Don't put mice on top row. Use clips on hose.
2) Counsel, have 2nd person check before euthanasia

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____