



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

May 6, 2019

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

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 April 30, 2019 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 April 12, 2019. According to the information provided, OLAW understands that 53 rats were used in a terminal procedure in an area that had not yet been approved for animal use by the Institutional Animal Care and Use Committee (IACUC). The study was supported by NSF grant #1513779.

The corrective action consisted of the Attending Veterinarian, IACUC Administrator, and an IACUC member inspecting the space and finding it acceptable. The protocol was amended to include the procedure space under the protocol and this was subsequently approved by the IACUC. The investigator was counseled on relevant animal use policies and agreed to keep the protocol updated.

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
NSF Animal Welfare Officer



INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT
FOR RESEARCH

April 30, 2019

Axel Wolff, DVM, Deputy 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; NSF Grant 1513779; Indiana University-Bloomington

Dear Dr. Wolff,

This letter reports a new incident of protocol noncompliance at the Indiana University, Bloomington campus with the memorandum of understanding between the NIH and NSF, NOT-OD-15-139. This event occurred in one research laboratory. A verbal, preliminary report was given to you on April 15, 2019.

In March of 2019, 53 purpose-bred rats, aged P1 through P6, were used in a terminal procedure during three separate occasions under an approved IACUC protocol. The facility in which the animals were used had recently undergone renovation, and the PI mistakenly believed that he had submitted an amendment to add the new procedural area.

Renovations to the PI's resident building on campus had been ongoing for 2.5 years. These renovations required the PI to move his animal colony on several occasions. During this time frame, the PI had submitted amendments for the new animal housing and procedural spaces for IACUC review and approval.

Upon realizing his error, the PI promptly worked with the Attending Veterinarian (AV) and the IACUC Administrator (IA) to rectify. The AV, IA, and an IACUC member reviewed the new procedural area on April 11, 2019 and granted approval for its use under the related approved IACUC protocol. The PI submitted the appropriate amendment adding the procedural room, which has been reviewed and approved by the IACUC. In addition, the PI met with the IA on April 17, 2019 to review animal compliance regulations and applicable IACUC policies.

The IACUC met on April 29, 2019 and discussed this issue, finding that a protocol noncompliance event had occurred. Members noted that appropriate steps were taken

to resolve this matter in timely fashion and acknowledged the PI's immediate and full cooperation. The PI assures the Committee of his obligation to keep the protocol updated in the future.

The IACUC finds this matter resolved and requires no further action from the PI. This project is funded by NSF award 1513779. 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 Chair)

(b) (6)

Karen Rogers, DACLAM, DVM (Attending Veterinarian)

Eric Swank (Executive Director of RIICE)

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, May 3, 2019 12:55 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: FW: Notice of Noncompliance for Assurance A-4094-01-D16-00587; NSF Grant 1513779; Indiana University-Bloomington

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 3, 2019 12:55 PM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Subject: RE: Notice of Noncompliance for Assurance A-4094-01-D16-00587; NSF Grant 1513779; Indiana University-Bloomington

Thank you for this report, (b) (6) I will send a response soon.

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

From: Vice President for Research <vpr@iu.edu>
Sent: Friday, May 3, 2019 11:04 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Kamendulis, Lisa M. <lkamendu@indiana.edu>; (b) (6) Rogers, Karen
<rogerkar@iu.edu>; Swank, Eric D. <edswank@iu.edu>; (b) (6)
(b) (6)

Subject: Notice of Noncompliance for Assurance A-4094-01-D16-00587; NSF Grant 1513779; Indiana University-Bloomington

Good morning,

Please find the notice of noncompliance for assurance A-4094-01-D16-00587; NSF Grant 1513779; Indiana University-Bloomington attached.

Sincerely,

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: And

Date: 4/12/19

Time: 11:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Indiana U

Assurance number: A4094

Did incident involve PHS funded activity? NSF

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Young rats decapitated in an area not approved by the IACUC.

Species involved: Rats

Personnel involved:

Dates and times:

Animal deaths:

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

Stop, amend

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____