



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

January 9, 2017

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

Dr. Fred H. Cate
Vice President for Research
Indiana University-Bloomington
Carmichael Center
530 E. Kirkwood Avenue – Suite 202
Bloomington, IN 47408-4003

Dear Dr. Cate,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 22, 2016 letter regarding noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Indiana University, which had not been preceded by a preliminary report to OLAW. According to the information provided, OLAW understands that the IACUC identified several instances of noncompliance involving inappropriate breeding procedures which resulted in the housing of mice under overcrowding conditions; unapproved animal transfers to related protocols; and failure to report the generation of novel mouse phenotypes of compromised health. The associated animal activities were PHS funded.

The corrective actions consisted of mandating the researcher to contact and submit animal transfer requests prior to reassigning animals; requiring all responsible laboratory personnel to review the amended protocol with the Laboratory Animal Resources (LAR) veterinarian and IACUC Administrator; authorizing the LAR staff to separate animals housed in overcrowded cages and charging the Principal Investigator (PI) a fee for the transfer; requiring prompt notification of newly identified phenotypes and the IACUC counseling the PI on the implementation of additional sanctions, including revocation of animal use privileges for any future violations. The PHS funding component has also been notified of the noncompliance.

Please be advised that OLAW recommends prompt preliminary reporting of noncompliance issues, with submission of a follow-up thorough report once corrective action has been taken. 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 being informed of these matters and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

**INDIANA UNIVERSITY****OFFICE OF THE VICE PRESIDENT
FOR RESEARCH**

December 22, 2016

Axel V. Wolff, MS, DVM
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; Indiana University

Dear Dr. Wolff:

This letter reports noncompliance with the PHS Policy and the eighth edition of the *Guide for the Care and Use of Laboratory Animals* at the Indiana University Bloomington campus.

In January of 2016, I submitted a letter to you detailing another noncompliance event for the animal research laboratory that is the subject of this communication. At that time, the IACUC determined that the laboratory had conducted an activity (toe clipping procedure in mice) that was not approved by the IACUC, nor was it listed on the related research protocol. To address this matter, the LAR veterinarians and IACUC Administrator worked with the researcher and laboratory staff to ensure that they understood compliance procedures and requirements, as well as to provide hands on training.

The results of the current IACUC investigation of noncompliance involve conducting procedures and processes that were not approved by the Committee and include improper animal breeding practices, where adult mice were not removed from cages at suitable time intervals and where overcrowding occurred; inappropriate animal transfers, where the transfers were not listed on the related protocols; and a lack of reporting new phenotypes that impaired the health and welfare of animals.

After reviewing the facts, the Bloomington IACUC concluded that these circumstances constituted noncompliance, in which laboratory personnel did not follow IACUC-approved activities in the related protocol despite training and guidance provided by the LAR veterinarians and IACUC Administrator. This incident was determined to be reportable to the Office of Laboratory Animal Welfare and the corresponding NIH funding agency.

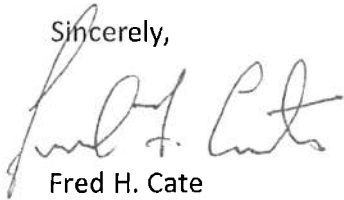
December 22, 2016
Axel V. Wolff, MS, DVM
Notice of Noncompliance for Assurance A-4094-01
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Moving forward, improvements required of the laboratory by the IACUC to remedy this matter and to ensure compliance as well as the health and welfare of animals include: requiring the researcher to contact the LAR office and submit animal transfer requests before animals are transferred, requiring all members of the laboratory to review the amended protocol with a LAR veterinarian and the IACUC Administrator, authorizing LAR staff to separate animals observed in overcrowded cages within 24 hours of discovery and charging the PI a fee for this service, and requiring the prompt reporting of new phenotypes as they occur. Further, the IACUC counseled the Investigator that additional incidents of noncompliance can lead to additional sanctions, which may include a suspension of animal use. The PI has communicated that he understands these requirements and will work with veterinary and compliance personnel to resolve this matter.

The IACUC, the LAR veterinarians, the IACUC Administrator, and I all take this matter very seriously. We will all be working even more assiduously than usual to ensure that there is no repetition.

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,



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)
Secondary Individual (IACUC Administrator)
Secondary Individual (Dean, School of Optometry)
Secondary Individual (Executive Director of RIICE)
Secondary Individual (Associate Vice President for Research Compliance)
George A. McKie, PhD, DVM (Program Official – NEI) mckiegeo@mail.nih.gov

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 22, 2016 1:08 PM
To: Secondary Individual OLAW Division of Compliance Oversight (NIH/OD)
Cc: Kamendulis, Lisa M.; Rogers, Karen; Secondary Individual; Secondary Individual; Secondary Individual; Secondary Individual; McKie, George (NIH/NEI) [E]; Secondary Individual; Secondary Individual; Secondary Individual.
Subject: RE: Notice of noncompliance for Assurance A-4094-01: Indiana University

Good afternoon,

Thank you for submitting this report. We will send an official response soon.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
 Animal Welfare Program Specialist
 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: Secondary Individual [mailto:Secondary Individual@iu.edu]
Sent: Thursday, December 22, 2016 11:27 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Kamendulis, Lisa M. <lkamendu@indiana.edu>; Rogers, Karen <rogerkar@iu.edu>; Secondary Individual; Secondary Individual@indiana.edu; Secondary Individual@indiana.edu; Secondary Individual@iu.edu; Secondary Individual@indiana.edu; Secondary Individual@iu.edu; McKie, George (NIH/NEI) [E] <mckiegeo@nei.nih.gov>; Secondary Individual; Secondary Individual@iu.edu; Secondary Individual@iu.edu; Secondary Individual@iu.edu
Subject: Notice of noncompliance for Assurance A-4094-01: Indiana University

Dear Dr. Wolff:

Attached here, please find a notice of noncompliance for Assurance A-4094-01 (Indiana University), from Vice President for Research Fred Cate.

This activity is supported by PHS funds (7R01EY021501-05). The program official is copied on this notice.

Thank you,

Secondary Individual

Secondary Individual

Executive administrative assistant
 Office of the Vice President for Research
 Bryan Hall, Room # 107 S. Indiana Avenue | Bloomington, IN 47405

Phone Phone Number | Fax Phone Number | ndary Indi@iu.edu

Ψ INDIANA UNIVERSITY