



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

May 25, 2017

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

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

Dear Dr. Cate,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 24, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Indiana University. According to the information provided, OLAW understands that on one study, 5000 mouse pups were born but not used experimentally and were then euthanized. These pup numbers had not been included in the protocol because the study had been initially approved under an older protocol form which did not solicit information on pups that were produced but not used.

The corrective action consisted of amending the protocol to account for all pups. The Institutional Animal Care and Use Committee (IACUC) subsequently approved the amendment and revised the protocol form to include a breeding scheme table which will capture offspring not used experimentally. The form will be further revised to ensure that non-experimental pups are included in the total number of animals requested and an explanatory policy will also be produced. Research staff will be trained on these requirements.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director,
Division of Compliance Oversight

cc: IACUC Chair

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

May 24, 2017

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-Bloomington

Dear Dr. Wolff:

This letter reports a new incident of noncompliance with the PHS Policy at Indiana University, Bloomington campus.

During a recent review of a protocol amendment using mice, the IACUC reviewers sought further clarification on additional animal numbers requested by the principal investigator (PI). During this review, it was learned that the PI had not included the number of rodent pups produced but not used for experimental activities in the animal count contained in the original protocol. The study was originally approved in 2014, using an older version of the animal care and use protocol form that asked about animal offspring that would be produced but not subject to manipulations, but did not provide clear instructions for recording the number of mouse pups produced but not used. It should also be noted that there is not currently an IACUC policy or guidance statement on this subject matter.

The IACUC Chair, the IACUC Administrator, and the Attending Veterinarian met with the PI, who noted that the expectation of counting animals was not sufficiently clear in relation to those mice that were not used in an animal study prior to the age of P21. This requirement was explained to the researcher, who subsequently reviewed study records and submitted an amendment to reconcile an estimated 5,000 mouse pups that were previously produced but not used experimentally and were euthanized. The IACUC has issued approval for this amendment.

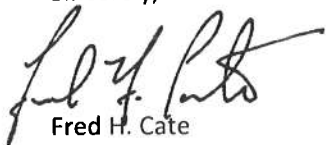
After discussing this circumstance, the Committee acknowledges a programmatic deficiency associated with the counting of rodent offspring produced and the requirement to account for all animals used in research activities. The most recent version of the Animal Care and Use Protocol form now contains a breeding scheme table that requires researchers to include the number of non-experimental offspring generated. Committee Members agreed that the Protocol form should be further revised so that it is understood to include non-experimental rodent offspring in the total number of animals requested.

The IACUC will also develop and adopt a related policy or guidance document that will clearly describe the PHS Policy and expectations for counting non-experimental offspring produced. Additional

education on this subject is being provided to the research community, in particular those researchers breeding transgenic animals, via the Post-Approval Monitoring Program.

This project is funded by NIH award 5R01NS086794-04; the Program Official is copied on this notification. Please don't hesitate to let me know if you have any questions or require any additional information.

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, DACLAM, DVM (Attending Veterinarian)
Secondary Individual (IACUC Administrator)
ndarv Indiv (Executive Director of RIICE)
Secondary Individual (Associate Vice President for Research Compliance)
Roderick A. Corriveau, Ph.D. (Roderick.corriveau@nih.gov)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, May 25, 2017 10:42 AM
To: 'Vice President for Research'
Subject: RE: Notice of Noncompliance for Assurance A-4094-01 (Indiana University)

Thank you for this report, [REDACTED]. We will respond soon.

Axel Wolff

From: Vice President for Research [mailto:vpr@iu.edu]
Sent: Thursday, May 25, 2017 9:23 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>; [REDACTED]
[REDACTED]@indiana.edu>; [REDACTED]@iu.edu>; [REDACTED]@iu.edu>; Corriveau,
Roderick (NIH/NINDS) [E] <roderick.corriveau@nih.gov>
Subject: Notice of Noncompliance for Assurance A-4094-01 (Indiana University)

Dear Dr. Wolff:

Attached here, please find a report of an instance of noncompliance with PHS Policy at Indiana University. This project is funded by NIH award 5R01NS086794-04; the program official is copied on this letter.

Thank you,

[REDACTED]
Secondary Individual

Executive administrative assistant
Office of the Vice President for Research
Bryan Hall, Suite 300 | 107 S. Indiana Avenue | Bloomington, IN 47405
Phone [REDACTED] | Fax [REDACTED] | [REDACTED]@iu.edu

 INDIANA UNIVERSITY