



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

February 21, 2019

Re: Animal Welfare Assurance
A4091-01 [OLAW Case4F]

Dr. Fred H. Cate
Vice President for Research
Office of Research Administration
Indiana University School of Medicine
530 E. Kirkwood Ave. - (b) (4)
Bloomington, IN 47408

Dear Dr. Cate,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 15, 2019 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the Indiana University School of Medicine - Indianapolis. According to the information provided, OLAW understands that an experimental procedure was performed on five rats assigned to a Roudebush VA Medical Center protocol that did not contain the procedure. The rats were transferred to the non-VA protocol once the error was determined. It was stated that the animals were assigned to a project that was VA funded.

The corrective actions consisted of adding the procedure to the VA protocol to remove the need to transfer the animals.

OLAW believes that the corrective measure put in place is consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. OLAW appreciates being informed of this issue and finds no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT
FOR RESEARCH

February 15, 2019

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

RE: Notice of Non-compliance for Assurance D16-00584 (A 4091-01): Indiana University School of Medicine-Indianapolis

Dear Dr. Morse:

This letter reports a new incident of non-compliance with PHS Policy and the Guide for the Care and Use of Laboratory Animals at the Indiana University School of Medicine for one of our IACUC protocols covering laboratory rats.

An issue of possible animal welfare was discussed at a SOM IACUC full board committee meeting. Please find a summary of the reported incident below.

The committee discussed a report of the failure to transfer five rats from the VA PI's protocol to a non-VA PI's protocol prior to performing experiments approved under the non-VA protocol. Once the issue was discovered, the PI transferred the rats to the protocol covering the procedures performed on the rats.

To ensure that this would not occur in the future, the IACUC requested that the PI amend the protocol to include the surgery so the transfer was not needed.

After significant time in deliberation and based on their understanding of the facts presented, federal regulations, and expectations, the IACUC committee members determined that this issue qualifies as an animal welfare concern.

This activity is supported by Roudebush VA Medical Center, IN-538. The director of the center is copied on this letter.

Please do not hesitate to contact me if you have any questions after receiving this letter.

Sincerely yours,

(b) (6)

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

cc:

(b) (6)

Matthew R. Allen (School of Medicine, IACUC Chair)
Debra Hickman, D.V.M., M.S., DACLAM (Director, Laboratory Animal Resource Center)
Megan Losh, M.P.A., CPIA (School of Medicine IACUC Director)
Eric Swank (Executive Director of RIICE)
Laura Gibson (Roudebush VA Medical Center, IN-538)
Brian Hancock (Roudebush VA Medical Center, IN-538)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, February 19, 2019 8:38 AM
To: Losh, Megan; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Gibson, Laura
Subject: RE: Non-compliance DI6-00584

Thank You for providing these reports Ms. Losh. We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
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: Losh, Megan [mailto:meglosh@iu.edu]
Sent: Friday, February 15, 2019 5:23 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gibson, Laura <Laura.Gibson@va.gov>
Subject: Non-compliance DI6-00584

Dear OLAW,

please find attached two report for Assurance DI6-00584 (A 4091-01): Indiana University School of Medicine - Indianapolis.

Thank you,

Mégan Losh, MPA, CPIA
Director, School of Medicine IACUC
Office of Research Compliance
Office of Vice President for Research
Indiana University
meglosh@iu.edu

(b) (6)