



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 Case 4G]

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 adult mice were genotyped because of lost ear tags although the procedure was not described in the approved protocol and was not performed per IACUC policy standards. It was stated that the animals were assigned to a project that was VA funded.

The corrective actions consisted of adding the tail biopsy procedure in adult mice to the protocol for potential future use. The PI was also counseled regarding the IACUC policy for genotyping adult mice and consulting with veterinary staff when needed.

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  
[olawdlco@mail.nih.gov](mailto:olawdlco@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 mice.

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 adult mice being genotyped because the mice lost their ear tags. Genotyping of adult mice was not described in the protocol nor was the genotyping done according to the IACUC approved policy.

To ensure that this would not occur in the future, the PI amended the protocol to include the standard language for a tail biopsy in adult mice when re-genotyping if needed in the future. Also, the IACUC made the PI aware of the IACUC policy and the importance of consulting with LARC veterinary staff if any difficulties arise during the protocol.

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]**

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**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.

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**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](mailto:meglosh@iu.edu)  
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