



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

November 8, 2017

Re: Animal Welfare Assurance  
A4091-01 [OLAW Case 3W]

Dr. Fred H. Cate  
Vice President for Research  
Office of Research Administration  
Indiana University School of Medicine  
530 E. Kirkwood Ave. — Room #  
Bloomington, IN 47408

Dear Dr. Cate,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 3, 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 mice failed to receive the required analgesia following minor survival surgery.

The corrective action consisted of the Principal Investigator stopping additional surgeries and retraining the staff on following the procedures as approved in the protocol. The protocol was amended to include use of extended release analgesics.

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 institution to comply with the PHS Policy.

Sincerely,

Signature

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



# INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT  
FOR RESEARCH

October 3, 2017

Brent Morse, D.V.M., D.A.C.L.A.M.  
Director, Division of Compliance Oversight  
OLAW/NIH  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
[olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

RE: Notice of Non-compliance for Assurance D16-00584 (A4091-01): Indiana University School of Medicine

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. The incident occurred at the Indiana University School of Medicine, and involved one of our IACUC protocols covering laboratory mice. Please find a summary of the reported incident below.

At the August 2017 School of Medicine IACUC meeting, the committee discussed an issue concerning a group of mice that had not been receiving appropriate analgesics after a minor survival surgery. As soon as the PI became aware of the issue, he immediately stopped any further surgeries and implemented corrective action by re-training all his staff regarding the importance of following procedures listed in the approved protocol. The PI also amended his protocol, adding extended-release analgesics to prevent recurrence of the problem.

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 a reportable animal welfare concern.

This activity is supported by PHS funds (5R01HL060714 and 4R01HL115619). The program officials and IU grant officers are copied on this letter.

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

Sincerely yours,

Signature

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

cc: Secondary Individual (Associate Vice President of Research Compliance)  
Secondary Individual (Chair, School of Medicine, Chairman, Department of Pediatrics)  
 Office of Research Administration – IUPUI – [srsinfo@iupui.edu](mailto:srsinfo@iupui.edu)  
 Robert Considine, Ph.D. (School of Medicine, IACUC Chair)  
 Debra Hickman, D.V.M., M.S., DACLAM (Director, Laboratory Animal Resource Center)  
Secondary Individual (School of Medicine IACUC Director)  
Secondary Individual (Executive Director of RIICE)  
 Charlene Schramm (NIH Program Official – [schrammc@nhlbi.nih.gov](mailto:schrammc@nhlbi.nih.gov))  
 Aruna Natarajan (NIH Program Official – [aruna.natarajan@nih.gov](mailto:aruna.natarajan@nih.gov))

## Morse, Brent (NIH/OD) [E]

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, October 31, 2017 11:42 AM  
**To:** Vice President for Research; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Secondary Individual; Secondary Individual; Considine, Robert V.; Hickman, Debra; Secondary Individual; Secondary Individual; Sponsored Research; Natarajan, Aruna (NIH/NHLBI) [E]; Schramm, Charlene (NIH/NHLBI) [E]  
**Subject:** RE: Notice of noncompliance: Assurance D16-00584 (A4091-01) (IU School of Medicine)

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

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
 Acting 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:** Vice President for Research [mailto:vpr@iu.edu]  
**Sent:** Monday, October 30, 2017 5:47 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Secondary Individual @iu.edu; Secondary Individual @iu.edu; Considine, Robert V. <rconsidi@iu.edu>; Hickman, Debra <hickmand@iupui.edu>; Secondary Individual @iu.edu; Secondary Individual @iu.edu; Sponsored Research <srsinfo@iupui.edu>; Natarajan, Aruna (NIH/NHLBI) [E] <aruna.natarajan@nih.gov>; Schramm, Charlene (NIH/NHLBI) [E] <schrammc@nhlbi.nih.gov>  
**Subject:** Notice of noncompliance: Assurance D16-00584 (A4091-01) (IU School of Medicine)


Dear Dr. Morse:

Attached here, please find a report of an instance of noncompliance with PHS Policy at Indiana University. This project is funded by PHS funds (5R01HL060714 and 4R01HL115619); the program officials are copied here.

Thank you,

Secondary Individual

Executive assistant to the Vice President for Research  
 Bryan Hall Room 107 | 107 S. Indiana Avenue | Bloomington, IN 47405  
 Phone Phone Number | Secondary Individual@iu.edu

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