



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 14, 2017

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

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 November 10, 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 on a surgical study were injected with cells not listed on the protocol, failed to receive the required analgesia and anti-inflammatory drugs, were not observed following surgery, and the surgical records did not document provision of post-surgical analgesia.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) requiring the Principal Investigator (PI) and staff to undertake retraining, to have the veterinarians observe the next five surgeries, and to have the PI submit these surgical records to the IACUC. The PI stopped additional surgeries, developed a corrective action plan, retrained the staff, and amended the protocol.

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 having been informed about this matter and find no cause for further action by this Office.

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

November 10, 2017

Brent Morse, D.V.M., DACLAM
Director, Division of Compliance Oversight
OLAW/NIH
RKI. 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 mice.

An issue of possible animal welfare was discussed at the September and October 2017 full board member meeting. Please find a summary of the reported incident below.

At these SOM IACUC meetings, the committee discussed a report of protocol non-compliance and an IACUC subcommittee report for one of our IACUC protocols. These reports indicated the following:

- The PI's group injected cells that were not in the approved protocol;
- Analgesia was not given per the approved protocol;
- Meloxicam was not given per the approved protocol;
- Post-operative observation was not done per the approved protocol; and
- The surgical records were lacking documentation of post-surgical analgesia.

After significant time in deliberation, the committee members determined that these issues qualify as protocol non-compliance. They further determined that the matter raised animal welfare concerns because the animals did not receive the appropriate analgesia, resulting in their experiencing unnecessary pain and/or distress.

The IACUC members were very concerned with the magnitude of the protocol non-compliance and decided that the PI and all protocol personnel approved on the protocol need do the following:

1. Re-take all of IU's required on-line CITI training courses;
2. LARC Veterinarians must observe the first five animal surgeries performed by anyone listed on this protocol after the above training has been completed;
3. The PI must submit these five surgical records to the IACUC for review and approval; and
4. PI must submit a corrective action plan describing in detail how the PI will ensure that this will not occur in the future.

Brent Morse, D.V.M., DACLAM

November 10, 2017

Non-compliance for Assurance D16-00584 (A 4091-01)

PHS funds (7R01CA203737-03 and 7R21CA185742-03)

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The SOM IACUC Chair followed up with the PI and staff to inform them of the decision made by the SOM IACUC. Once the PI was aware of the issue, he immediately stopped any further surgeries and implemented corrective action by re-training all of his staff regarding the importance of following procedures listed in the approved protocol. The PI has also amended his protocol to ensure that this issue will not occur in the future.

This activity is supported by PHS funds (7R01CA203737-03 and 7R21CA185742-03); the program officials are copied on this letter.

Please do not hesitate to contact me if you have additional 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: [Redacted] (Associate Vice President of Research Compliance)
[Redacted] (Chair, School of Medicine, Chairman, Department of Pediatrics)
Robert Considine, Ph.D. (School of Medicine, IACUC Chair)
Debra Hickman, D.V.M., M.S., DACLAM (Director, Laboratory Animal Resource Center)
[Redacted] (School of Medicine IACUC Director)
[Redacted] (Executive Director of RIICE)
Sudhir B. Kondapaka (NIH Program Official: kondapas@mail.nih.gov)
Michael G Espey (NIH Program Official: sp@nih.gov)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 13, 2017 10:03 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; Kondapaka, Sudhir (NIH/NCI) [E]; Espey, Michael (NIH/NCI) [E]
Subject: RE: Notice of Non-compliance for Assurance D16-00584 (A 4091-01) (Indiana University School of Medicine – Indianapolis)

Thank you for submitting this report to OLAW. 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: Friday, November 10, 2017 1:03 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; Kondapaka, Sudhir (NIH/NCI) [E] <kondapas@mail.nih.gov>; Espey, Michael (NIH/NCI) [E] <michael.espey@nih.gov>
Subject: Notice of Non-compliance for Assurance D16-00584 (A 4091-01) (Indiana University School of Medicine – Indianapolis)


Dear Dr. Morse:

Attached here, please find a report of an instance of non-compliance with PHS Policy at Indiana University. This activity is supported by PHS funds (7R01CA203737-03 and 7R21CA185742-03); the program officials are copied here.

Thank you,

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 | Secondary Individual @iu.edu

 INDIANA UNIVERSITY