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A 4091-4B

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INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT
FOR RESEARCH

January 23, 2018

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 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 about improper identification and genotyping of adult mice. The PI laboratory personnel were observed using ear notching and toe clipping on adult animals, neither of which are approved on this protocol. The IACUC members were very concerned with the magnitude of the above noted deficiencies. As a result, the IACUC members requested that all individuals listed on the protocol responsible for genotyping retake the CITI online training courses and a LARC hands on Animal Identification Technique course. These trainings were completed by all individuals responsible for genotyping.

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 protocol non-compliance and an animal welfare concern.

This activity is supported by PHS funds (5R01HL056416 and 1R01HL112669). The program official is copied on this letter.

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

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

cc:

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Robert Considine, Ph.D. (School of Medicine IACUC Chair)

(b) (6)

Megan Losh, M.P.A., CPIA (School of Medicine IACUC Director)

Eric Swank (Executive Director of RIICE)

John Thomas (NIH Program Official: thomasj@nhlbi.nih.gov)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 29, 2018 10:28 AM
To: Vice President for Research; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Considine, Robert V.; (b) (6) Losh, Megan; Swank, Eric D.; Thomas, John W (NIH/NHLBI) [E]
Subject: RE: Notice of Non-compliance for Assurance D16-00584 (A 4091-01): Indiana University School of Medicine—Indianapolis

Thank you for 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

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From: Vice President for Research [mailto:vpr@iu.edu]
Sent: Monday, January 29, 2018 10:25 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) @iu.edu>; Considine, Robert V. <rconsidi@iu.edu>; (b) (6) @iupui.edu>; Losh, Megan <meglosh@iu.edu>; Swank, Eric D. <edswank@iu.edu>; Thomas, John W (NIH/NHLBI) [E] <thomasj@nhlbi.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 School of Medicine—Indianapolis. This activity is supported by PHS funds (5R01HL056416 and 1R01HL112669); the program official is copied here.

Thank you,

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