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**Wolff, Axel (NIH/OD) [E]**

**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Thursday, February 08, 2018 8:03 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** FW: Re. Notice of Non-compliance for Assurance D16-00584 (A 4091-01): Indiana University School of Medicine-Indianapolis

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, February 08, 2018 8:02 AM  
**To:** 'Vice President for Research' <vpr@iu.edu>  
**Subject:** RE: Re. Notice of Non-compliance for Assurance D16-00584 (A 4091-01): Indiana University School of Medicine-Indianapolis

Thank you for this update. We'll send a final assessment to the IO.  
 Axel Wolff

**From:** Vice President for Research [mailto:vpr@iu.edu]  
**Sent:** Wednesday, February 07, 2018 2:13 PM  
**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)  
 (b) (6) @iupui.edu>; Losh, Megan <meglosh@iu.edu>; Swank, Eric D. <edswank@iu.edu>; Regunathan, Soundar (NIH/NIAAA) [E] <soundar.regunathan@nih.gov>  
**Subject:** Re. Notice of Non-compliance for Assurance D16-00584 (A 4091-01): Indiana University School of Medicine-Indianapolis

Dear Dr. Morse:

As per the correspondence dated February 1, 2018, please see attached the requested additional information about the final outcome of the actions taken in case number A4091-3Z.

Thank you,

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**From:** Ward, Joan (NIH/OD) [E] [mailto:wardjoa@od.nih.gov]  
**Sent:** Friday, February 2, 2018 10:53 AM  
**To:** Vice President for Research <vpr@iu.edu>  
**Cc:** iacuc@iupui.edu; Regunathan, Soundar (NIH/NIAAA) [E] <soundar.regunathan@nih.gov>  
**Subject:** Interim response to OLAW Case A4091-3Z.

Dear Dr. Cate,

Attached please find Dr. Axel Wolff's Interim response to OLAW Case A4091-32.

If you have any questions, feel free to contact us by phone or by email.

Regards,  
Joan

*Joan Ward*  
*Program Specialist*  
*Office of Laboratory Animal Welfare*  
*Notional Institutes of Health*  
*6705 Rockledge Drive, Suite 360*  
*Bethesda, MD 20892*  
*301-594-2506*  
*[wardjoa@od.nih.gov](mailto:wardjoa@od.nih.gov)*

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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](mailto: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 four rats that died as a result of food and water deprivation. The deaths were due to an incorrectly docked cage, which prohibited the rats from accessing their food and water. The LARC staff member that was responsible for husbandry in this LARC room has had performance issues in the past. This issue, along with others performance issues, has been turned over to IU Human Resources.

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 PHS funds (1U01AA024612). 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,

(b) (6)

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

cc:

(b) (6)

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)

Soundar Regunathan (NIH Program Official: [regunathans@mail.nih.gov](mailto:regunathans@mail.nih.gov))

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

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, January 29, 2018 10:30 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.; Regunathan, Soundar (NIH/NIAAA) [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

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, January 29, 2018 10:28 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>; Regunathan, Soundar (NIH/NIAAA) [E] <soundar.regunathan@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 (1U01AA024612); the program official is copied here.

Thank you,

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

**From:** Regunathan, Soundar (NIH/NIAAA) [E]  
**Sent:** Monday, January 29, 2018 10:35 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Notice of Non-compliance for Assurance D16-00584 (A 4091-01): Indiana University School of Medicine—Indianapolis (b) (5)

Hi,

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Or wait for your response.

Thanks

Soundar

Soundar Regunathan, Ph.D.  
Program Director  
Division of Neuroscience and Behavior  
National Institute on Alcohol Abuse and Alcoholism National Institutes of Health  
5635 Fishers Lane  
Room 2065, MSC 9304  
Bethesda, MD 20892-1705  
(for FedEx use Rockville, MD 20857-1705)  
Phone: 301-443-1192  
Fax: 301-443-1650



National Institute  
on Alcohol Abuse  
and Alcoholism

Doing human subjects research? New policies will impact you! [Learn more.](#)

Updated application forms (FORMS-E) are required for due dates of January 25, 2018 and beyond – includes new Human Subject and Clinical Trial Information Form. [Take a tour of the new form.](#)

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, January 29, 2018 10:30 AM  
**To:** Vice President for Research <vpr@iu.edu>; 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>; Regunathan, Soundar (NIH/NIAAA) [E] <soundar.regunathan@nih.gov>  
**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](mailto:vpr@iu.edu)]

**Sent:** Monday, January 29, 2018 10:28 AM

**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>

**Cc:** (b) (6) <[REDACTED]@iu.edu>; Considine, Robert V. <[rconsidi@iu.edu](mailto:rconsidi@iu.edu)>; (b) (6) <[REDACTED]@iu.edu>;

(b) (6) <[\[REDACTED\]@iu.edu](mailto:[REDACTED]@iu.edu)>; Losh, Megan <[meglosh@iu.edu](mailto:meglosh@iu.edu)>; Swank, Eric D. <[edswank@iu.edu](mailto:edswank@iu.edu)>; Regunathan, Soundar (NIH/NIAAA) [E] <[soundar.regunathan@nih.gov](mailto:soundar.regunathan@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 (1U01AA024612); the program official is copied here.

Thank you,

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