



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) 480-3387

March 17, 2020

Re: Animal Welfare Assurance  
A3632-01 [OLAW Case 1H]

Ellen Reinsch-Friese, M.H.  
Wright State University  
Office of Research and Sponsored Programs  
3640 Colonel Glenn Hwy.  
Dayton, OH 45435-0001

Dear Ms. Reinsch-Friese,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 13, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Wright State University following up on an initial March 9, 2020 notification by telephone.

According to the information provided, this Office understands that the Wright State University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: unauthorized personnel conducting IACUC approved activities. On February 28, 2020 an animal care technician reported a concern regarding a student's biosafety handling practices of caging and a deceased mouse in the laboratory animal facility. During a preliminary investigation, it was discovered that while the student was performing IACUC approved activities, the student was not approved by the IACUC to be working on the protocol. The Principal Investigator (PI) was advised to immediately halt the student's activities with mice, and the individual's access to the vivarium was removed. The Institutional Biosafety Officer was notified of the concerns for follow-up.

An IACUC subcommittee met on March 5, 2020 to investigate the matter. The following corrective actions were recommended by the subcommittee and presented for approval to the IACUC on March 12, 2020.

- PI must undergo additional training. The following training modules must be completed by March 30, 2020 through [www.citiprogram.org](http://www.citiprogram.org).
  - Working with the IACUC: Investigators, staff and students.
  - Any outstanding safety training associated with this protocol.
    - Lab Chemical Safety
    - Initial Biosafety Training
    - Hazardous Communication
    - OSHA Blood Borne Pathogen

- The PI will review the animal use and biosafety protocols and amend as needed to add anyone in his laboratory who will be handling animals and/or will be working with biohazardous materials. PI will also remove personnel who are no longer active. The PI will also ensure that all personnel working on this protocol have completed all training requirements.
- The PI will provide a progress report on training and activities which have occurred on this protocol by April 12, 2020 to the subcommittee.
- The PI must meet with the Laboratory Animal Resources clinical veterinarian to review procedures performed on this protocol, to ensure proper techniques and documentation. The clinical veterinarian will work with the investigator to monitor the use of animals on this protocol, then will update the IACUC for determination of further necessity by June 5, 2020.
- The Laboratory Animal Resources department has reviewed and reinforced their process to identify personnel who request entry into the facility as a corrective action measure by assuring an individual is listed on an animal protocol before they are granted admittance to the animal vivarium.

It is noted that the activities described in the report were not supported by PHS funds. Based on its assessment of this explanation, OLAW understands that Wright State University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Chair

**Tubbs, Jai (NIH/OD) [E]**

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**From:** Tubbs, Jai (NIH/OD) [E]  
**Sent:** Monday, March 16, 2020 7:22 AM  
**To:** (b) (6)  
**Cc:** Dudley, Emily Suzanne; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Wright State University (D16-00383) Correspondence

Good morning (b) (6)

Thank you for the final report. We will send an official response soon.

Kind Regards,

J Tubbs

**From:** (b) (6)  
**Sent:** Friday, March 13, 2020 6:09 PM  
**To:** Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>  
**Cc:** Dudley, Emily Suzanne <emily.dudley@wright.edu>  
**Subject:** Wright State University (D16-00383) Correspondence

Dr. Tubbs,

Please see the attached letter regarding an incident of non-compliance.  
Please let me know if further clarifications are needed.

Best,

WRIGHT STATE  
UNIVERSITY

(b) (6)



March 13, 2020

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
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(937) 775-2425  
fax: (937) 775-3781  
rsp@wright.edu  
www.wright.edu

Reference: Animal Welfare Assurance Number D16-00383 (A3632-01)  
Wright State University

Dear Dr. Tubbs:

In compliance with *The PHS Policy on Humane Care and Use of Laboratory Animals* (Policy), "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals" [NOT-OD-05-034, February 24, 2005, Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research], and Wright State University's Animal Welfare Assurance (D16-00383/A3632-01), the purpose of this letter is to report an occurrence of noncompliance with the PHS Policy. This is a follow-up to the preliminary report made by telephone on March 9, 2020. The activities described in this report are not supported by an NIH grant.

On Friday, February 28, 2020, an animal care technician reported a concern regarding a student's biosafety handling practices of caging and a deceased mouse in the laboratory animal facility. During a preliminary investigation with the principal investigator, attending veterinarian, vivarium manager, and representative from Environmental Health and Safety, it was discovered that although the student was performing IACUC approved activities, the student was not approved by the IACUC to be working on this protocol. The PI was advised to immediately halt the student's activities with mice, and the student's access to the vivarium was removed. The Institutional Biosafety Officer was notified of the concerns for follow-up.

An IACUC subcommittee to investigate this matter met on March 5, 2020. The following corrective actions were recommended by the subcommittee and presented for approval to the IACUC on March 12, 2020.

- The principal investigator must undergo additional training. The following training modules available through [www.citiprogram.org](http://www.citiprogram.org) **must be completed by March 30, 2020.**
  - Working with the IACUC: Investigators, staff and students (Basic Course)
  - Any outstanding safety training associated with this protocol
    - Lab Chemical Safety
    - Initial Biosafety Training
    - Hazardous Communication
    - OSHA Blood borne Pathogen

- The PI will review the animal use and biosafety protocols and amend as needed to add anyone in his laboratory who will be handling animals and/or will be working with biohazardous materials. The protocols will also be updated to remove personnel who are no longer active. The PI will ensure that all personnel working on this protocol have completed all training requirements.
- The principal investigator will provide the IACUC investigation subcommittee with a progress report on training and activities which have occurred on this protocol by April 12, 2020.
- The principal investigator must meet with the LAR clinical veterinarian to review procedures performed on this protocol, to ensure proper techniques and documentation. The clinical veterinarian will work with the investigator to monitor the use of animals on this protocol to ensure compliance, then will update the IACUC for determination of further necessity by June 5, 2020.
- The Laboratory Animal Resources department has reviewed and reinforced their process to identify personnel who request entry into the facility as a corrective action measure by assuring an individual is listed on an animal protocol before he or she is granted admittance to the animal vivarium.

Wright State University regrets this unfortunate deviation from the requirements of the PHS Policy. If you have any additional questions or need clarification, please contact Dr. Emily S. Dudley, Director of Laboratory Animal Resources (b) (6), or Dr. Adrian Corbett, Chair of the Institutional Animal Care and Use Committee (b) (6) at Wright State University.

Sincerely,

(b) (6)

Ellen Reinsch-Friese, M.H.  
Institutional Official  
Interim Vice Provost for Research

(b) (6)

Adrian Corbett, Ph.D.  
Chair, WSU-IACUC

cc: James Swearengen, D.V.M., AAALAC Int.



## Initial Report of Noncompliance

By: Tubbs

Date: 03/09/2020

Time: 909 A

Name of Person reporting: Emily Dubla

Telephone #: [REDACTED] (b) (6)

Fax #:

Email:

Name of Institution: Wright State Univ.

Assurance number: D16-00383

Did incident involve PHS funded activity? N

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

improper  
Technician reported biosafety practices, mouse carcass not disposed of properly,  
BSC not being used properly by student. Student not on protocol

Species involved: mouse

Personnel involved: "Student"

Dates and times: Feb 28

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

~ 90d response expected, subcommittee formed

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_