



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

October 16, 2017

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

Ms. Ellen Reinsch-Friese
Interim Vice President for Research
Wright State University
3640 Colonel Glenn Highway
loom University Hall
Dayton, OH 45435

Dear Ms. Reinsch-Friese,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 6, 2017 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 telephone report on September 13, 2017. According to the information provided, OLAW understands that three rats died in a hypoxic chamber because a student researcher had failed to turn on the oxygen at the appropriate time.

The corrective actions consisted of stopping additional experiments until the equipment could be evaluated, which was subsequently found to be working properly. To prevent a recurrence, two individuals will now be placing animals in the chamber and adjusting gases. A checklist will be used to document oxygen levels, time, and individual responsible and an oxygen sensor will be installed to measure levels constantly.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to 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



WRIGHT STATE UNIVERSITY

Office of Research and Sponsored Programs
3640 Colonel Glenn Hwy.
Dayton, OH 45435-0001
(937) 775-2425
FAX (937) 775-3781
email: rsp@wright.edu
wright.edu/rsp

October 6th, 2017

Brent Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

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

Dear Dr. Morse:

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 report an occurrence of noncompliance with the PHS Policy and the result of the initial investigation. Dr. Emily Dudley relayed a preliminary report of this event by telephone to Dr. Morse on 9/14/17. The research described in this report is not supported by an NIH grant.

On September 3, 2017, a researcher at Wright State University self-reported that three animals (rats) being used on an approved animal protocol had expired in a hypoxic chamber. The study involved placing the animals in a chamber and switching from oxygen to nitrogen and vice versa at specific intervals. When the deaths were identified, ongoing experiments were immediately halted by the researcher until the equipment could be properly evaluated for mechanical deficiency. The equipment was found to be operating correctly and it was concluded that the oxygen had not been turned on at the appropriate time by a student researcher and the animals expired due to anoxia.

A subcommittee of the IACUC was formed immediately upon notification of the protocol violation and met on September 11, 2017. The following corrective actions were formally communicated to the investigator and accepted by the IACUC at a full committee meeting on October 5, 2017:

Brent Morse, D.V.M., DACLAM
Page Two
October 6th, 2017

- One individual has historically been assigned to place the animals in the chamber and adjust the gases. To avoid this situation from reoccurring in the future, we recommend that two individuals work together to ensure all steps of this process are completed.
- The investigator will implement a procedural checklist for students and other laboratory personnel to use when placing animals in the chamber. The checklist will require recording of the oxygen level in the chamber, the time, and initials of the person placing the animals in the chamber prior to leaving the room. This will ensure visual confirmation of proper oxygen levels within the chamber and the checklist will become part of the research record.
- The addition of an inline oxygen sensor is strongly recommended (if not already present) so that oxygen levels in the chamber are continually recorded.

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 Dudley, Director of Laboratory Animal Resources [Phone Number] or Dr. Adrian M. Corbett, Chair of the Institutional Animal Care and Use Committee [Phone Number] at Wright State University.

Sincerely,

Signature

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

Signature

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

cc: [Secondary Individual] AAALAC

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, October 10, 2017 2:34 PM
To: Secondary Individual
Subject: RE: Wright State University (D16-00383) Correspondence

Thank you for sending this report. We will send an official response soon. We will also update your Assurance records at OLAW to reflect the changes you have sent.

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: Secondary Individual [mailto:Secondary Individual@wright.edu]
Sent: Tuesday, October 10, 2017 11:38 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Secondary Individual@aaalac.org
Subject: Wright State University (D16-00383) Correspondence

Drs. Morse and Secondary Individual

Please see the attached letter regarding an incident of noncompliance.

At this time I would also like to inform OLAW and AAALAC of the following IACUC leadership changes:

Institutional Official:
Ellen Reinsch-Friese, M.H.
ellen.friese@wright.edu
Phone Number

Head Veterinarian:
Emily S. Dudley, D.V.M., DACAW
emily.dudley@wright.edu
Phone Number

IACUC Chair:
Adrian M. Corbett, Ph.D.
adrian.corbett@wright.edu
Phone Number

If you need additional information, please let me know.

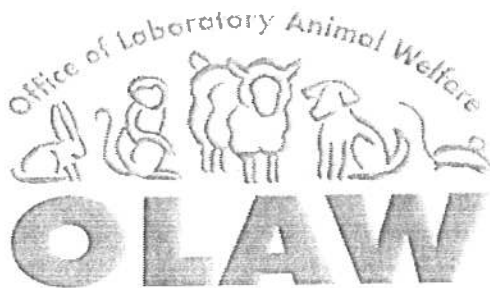
Best,

WRIGHT STATE UNIVERSITY

Secondary Individual | Compliance Coordinator

3640 Colonel Glenn Hwy|201J UH|Dayton, OH 45435

Phone: Phone Number Secondary Individual@wright.edu



Initial Report of Noncompliance

By: BGMDate: 9/13/17Time: VoicemailName of Person reporting: Emily Dudley, DVM

Telephone #:

Fax #:

Email:

Phone Number

Name of Institution:

Assurance number:

Wright State Univ
A3632Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? 3 rats found dead in hypoxia chamber.Species involved: RatPersonnel involved: None studentDates and times: 9/13/17, eveningAnimal deaths: Yes, 3 rats

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

After ICUC meeting early Oct.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____