



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) 402-7065

August 28, 2019

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8L]

Mr. George A. Huber
Vice Chancellor for Research Conduct
and Compliance
University of Pittsburgh
Suite (b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 23, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. According to the information provided, OLAW understands that ten rats died in a hypoxia chamber. The low oxygen alarm had sounded and an investigator turned it off but failed to report the incident to animal care staff and nitrogen continued flowing into the chamber and further reduced the oxygen level.

The corrective actions consisted of retraining the husbandry and research staff as well as the room users on not turning off the alarm and on notifying animal care staff. The alarm was covered with a box to prevent tampering, the alarm may be linked to a personnel contacting system, and the investigator will ensure that all laboratory staff is aware of the content of the protocol.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



University of Pittsburgh

*Office of the Senior Vice Chancellor for Research
Research Conduct and Compliance Office*

Suite 401, Hiebert Building
3500 Fifth Avenue
Pittsburgh, PA 15213
Phone: 412-624-2202
Fax: 412-646-4010
ghuber@pitt.edu

George A. Huber, JD, MSIE, MSSM
Vice Chancellor for
Research Conduct and Compliance
Professor of Health Policy & Management

August 23, 2019

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh's Animal Care and Use Program (Assurance number D16-00118), I am writing to report a violation of Public Health Service (PHS) Policy. At its meeting on July 15, 2019, the University's Institutional Animal Care and Use Committee (IACUC) determined that a violation of the following PHS Policies had occurred:

- PHS Policy IV.C.1.d., requiring that "the living conditions of animals will be appropriate for their species and contribute to their health and comfort."

The incident occurred on May 21, 2019, and was as follows:

An audible alarm for a hypoxia unit sounded, indicating low oxygen levels ($\pm 0.5\%$ O₂ levels triggers the alarm). An unidentified investigator (animal room is shared by multiple investigators and their lab personnel) shut off the alarm but did not report the alarm to animal care personnel. Turning off the alarm results in the inability of the system to regulate nitrogen levels, therefore nitrogen continued to flow in to the chamber, reducing oxygen levels until the rats succumbed. Ten rats were lost.

The University of Pittsburgh IACUC reviewed and accepted the investigator's corrective action plan (CAP), which consisted of the following item:

1. All individuals (animal care, lab personnel and personnel of labs sharing the housing room) were trained that the alarm should never be turned off and, instead, DLAR personnel should be notified.

Brent Morse, DVM, DACLAM

Page 2

August 23, 2019

2. A box that covers the alarm to prevent tampering has been manufactured. This will prevent unauthorized personnel from tampering with the alarm thus allowing the chamber to respond properly to altered oxygen levels.
3. DLAR and the investigators are examining the feasibility of linking the alarm system to a Sensaphone calling system to alert the investigators to a problem with the system.
4. The investigator will ensure that future lab members have read and understand the protocol.

The investigator's research is supported by the following NIH grants:

5R01EY016415-12	COMPUTATIONAL REPURPOSING OF CHEMOTHERAPIES FOR PULMONARY HYPERTENSION
5R01HL124021-06	DEFINING THE COMPLEX BIOLOGY OF THE MIR-130/301 FAMILY IN PULMONARY HYPERTENSION
5R01HL122596-06	IRON-SULFUR DEFICIENCY AS A CRITICAL PATHOGENIC CAUSE OF PULMONARY HYPERTENSION
5F30HL139017-02	FRATAXIN LOSS INDUCES ENDOTHELIAL DYSFUNCTION TO PROMOTE PULMONARY HYPERTENSION

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

(b) (6)

George A. Huber

Na, Jane (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 23, 2019 4:18 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of Pittsburgh Reportable Event Notice

Dear (b) (6)

Thank you for providing these reports. We will send official responses soon.

Jane

Jane Na, DVM, CPIA
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
Phone (301) 402-1922
E-fax (301) 451-5609

Disclaimer: 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: (b) (6)
Sent: Friday, August 23, 2019 3:34 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: University of Pittsburgh Reportable Event Notice

Please review the attached documents forwarded on behalf of George A. Huber, Vice Chancellor for Research Conduct and Compliance. Thank you.

(b) (6)



3187-8L

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Thursday, July 18, 2019 6:09 AM
To: Chapman, Deborah L
Subject: RE: reportable event

Thank you for this preliminary report, Dr. Chapman. I will start a new case file.
Axel Wolff

From: Chapman, Deborah L <dlc7@pitt.edu>
Sent: Wednesday, July 17, 2019 3:42 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Subject: reportable event

Dear Dr. Wolff,

As per our conversation on July 17, 2019. We had of a loss of 10 rats in a hypoxia chamber on May 21, 2019. Below are the details.

Institute: University of Pittsburgh
Assurance number: A3287-01 (legacy assurance number) and D16-00118 (current number)

Funding Component: NIH grant numbers: 1UH2TR002073, HL124021, HL 122596, HL139017; AHA 18EIA33900027

Incident: An audible alarm sounded for an hypoxia unit (+/- 0.5% O2 levels will trigger an audible alarm). An unidentified individual shut off the alarm but did not report the alarm to DLAR personnel. Turning off the causes the system to not be able to regulate the nitrogen levels, therefore nitrogen continued to flow in to the chamber, reducing oxygen levels until the rats succumbed. Ten rats were lost.

CAP: All individuals (DLAR and lab personnel) were trained that the alarm should never be turned off and, instead, DLAR personnel should be notified. A box that covers the alarm to prevent tampering has been manufactured. This will prevent unauthorized personnel from tampering with the alarm thus allowing the chamber to respond properly to altered oxygen levels. DLAR and the investigators are examining the feasibility of linking the alarm system to a sensaphone calling system to alert the investigators to a problem with the system.

A letter from the Institutional Official will be sent with finalized details following the IACUC full committee meeting in August.

Please let me know if you need any additional information.
Debbie

--
Deborah L. Chapman, Ph.D.
Associate Professor
Department of Biological Sciences

Chair, Institutional Animal Care and Use Committee

University of Pittsburgh
(b) (4) Life Sciences Annex
Fifth & Ruskin Avenues

Pittsburgh, PA 15260

tel (office): (b) (6)



Initial Report of Noncompliance

By: *aw*

Date: *7/17/19*

Time: *12:40*

Name of Person reporting: *Debbie Chapman*

Telephone #: *(b) (6)*

Fax #:

Email:

Name of Institution: *U of Pittsburgh*

Assurance number: *A3187*

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

10 rats died in hypoxia chamber. Alarm off

Species involved: *Rat*

Personnel involved:

Dates and times:

Animal deaths: *10*

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

Retrain staff

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____