



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 12, 2019

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

Mr. George A. Huber
Vice Chancellor for
Research Conduct and Compliance
University of Pittsburgh
3500 Fifth Avenue
Suite (b) (4) Hieber Building
Pittsburgh, PA 15260

Dear Mr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 31, 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 on June 5, 2019 two unattended boxes of anesthetized mice were found by animal care staff on a rack in the housing room following corneal wounding procedures. No mice died but three required veterinary intervention. This activity was funded by the PHS.

The corrective action plan submitted by the investigator included the investigator meeting with lab personnel to discuss details of the protocol and implications of non-compliance. Future lab members will have read and understand the protocol. Two individuals will sign off on the readiness of animals to be returned to the housing room. The IACUC also sent a letter of reprimand to the PI and his supervisor. In addition, the investigator and laboratory personnel will undergo training on post-surgical monitoring requirements. The animal research activities of the investigator and laboratory staff will be subject to enhanced monitoring by the Compliance Officer for three months.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



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: 412-648-4010
ghuber@pitt.edu

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

July 31, 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, Requiring that "the IACUC shall confirm that the research project...is consistent with the *Guide* unless acceptable justification for a departure is presented."

The violation was discovered by animal care staff on June 5, 2019, and was as follows:

Two boxes of anesthetized mice assigned to the investigators IACUC protocol were found unattended in their cages on the rack in the housing room following corneal wounding procedures. None of the mice died, though three required veterinary intervention, which included manual stimulation and warming with a heat lamp.

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

1. The investigator held a meeting with the lab personnel actively involved in the wounding procedures where the details of the protocol were read aloud and implications of non-compliance discussed.
2. The investigator will ensure that future lab members have read and understand the protocol.

Brent Morse, DVM, DACLAM
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3. The investigator has instructed personnel to document that animals have recovered from anesthesia before being returned to housing. This will be done in the notebook already used by the lab to record procedural details, and will require that two individuals sign off on the readiness of each box to be returned to the housing room.

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

5R01EY016415-12

STEM CELLS FOR CORNEAL ENGINEERING

The IACUC has levied the following sanctions:

1. A letter of reprimand was sent to the Principal Investigator and his supervisor regarding this violation. The letter has been placed in our files as evidence of a violation.
2. The investigator and laboratory staff will undergo training on post-surgical monitoring requirements.
3. For a three-month period, the animal research activities of the investigator and laboratory staff will be subject to enhanced monitoring by the Compliance Officer.

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

Sincerely,

(b) (6)

George A. Huber

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 5, 2019 9:32 AM
To: (b) (6)
Subject: RE: Reportable Event Notice

Thank you for this report (b) (6) Dr. Morse will respond soon.

Regards,
Joan

From: (b) (6)
Sent: Thursday, August 1, 2019 8:12 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable Event Notice

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

(b) (6)

