



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

January 6, 2020

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

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

Dear Dr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 19, 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, this Office understands that the University of Pittsburgh Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: two boxes of mice that were not administered the same post-operative analgesic as specified in the protocol. This finding was discovered during semiannual review of facilities and use areas. The mice received a regimen of ketamine instead of buprenorphine as approved in the protocol. It is noted that this research is supported by NIH grants. The incident was reviewed at the IACUC meeting held on November 18, 2019. The committee has reviewed and accepted the investigator's corrective action plan, which consisted of pausing the study until buprenorphine was obtained. The IACUC also imposed the following sanctions:

- 1) A letter of reprimand was sent to the PI and his/her supervisor regarding this violation.
- 2) The investigator and laboratory staff will undergo training on protocol adherence.

Based on its assessment of this explanation, OLAW understands that the University of Pittsburgh 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 Contact



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

Office of Research Protections

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Pittsburgh, PA 15213
412-624-2202
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December 19, 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 an incident of non-compliance¹ that was reviewed by the University's Institutional Animal Care and Use Committee (IACUC) at its November 18, 2019 meeting.

The incident was discovered by the IACUC during the semi-annual review of animal facilities and use areas and was as follows:

Two boxes of mice covered by the investigator's IACUC approved protocol were not administered the same post-operative analgesic specified in the protocol, after an October 2019 procedure. The protocol-approved analgesic was buprenorphine; the investigator instead provided a regimen of ketamine.

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

1. The investigator has paused the study until buprenorphine is obtained.

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

- NOVEL ROLE OF SMOOTH MUSCLE B5 REDUCTASE IN SICKLE CELL DISEASE
- VASCULAR SMOOTH MUSCLE AND BLOOD PRESSURE REGULATION BY CYB5R3²

¹ PHS Policy IV.C.1.d

Brent Morse, DVM, DACLAM
Page 2
December 19, 2019

The IACUC has levied the following sanctions:

1. A letter of reprimand was sent to the Principal Investigator and his/her supervisor regarding this violation. The letter has been placed in our files as evidence of the incident.
2. The investigator and laboratory staff will undergo training on protocol adherence.

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

Sincerely,

 (b) (6)

George A. Huber

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 19, 2019 3:50 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notice

Thank you for providing these final reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
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: (b) (6)
Sent: Thursday, December 19, 2019 2:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable Event Notice

Please review the attached correspondence forwarded on behalf of George A. Huber, Vice Chancellor for Research Protections. Thank you.

(b) (6)

