



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 8N]

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 three mice were subjected to unapproved intracerebral injections with an unapproved strain of virus.

The corrective actions consisted of euthanizing the mice and not collecting data. The laboratory staff was counseled on following the protocol and on contacting the veterinary staff before working with recombinant viruses. A letter of reprimand was issued to the Principal Investigator and their supervisor.

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, Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
Phone: 412-624-2202
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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 August 19, 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.B.7, requiring that the IACUC "review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities."

The incident was as follows:

Three mice covered by the investigator's IACUC protocol underwent intracerebral injection of AAV. While IV and IP injections of BSL2 AAV were described in the protocol, intracerebral injections and this strain of virus were not. Upon discovery of the noncompliance, the three mice were sacrificed, and no data were collected.

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 instructed his/her team to be fully familiar with the protocol and what procedures the lab is approved to perform.
2. The investigator has also instructed his/her team to seek consultation with veterinary staff before initiating any procedure involving recombinant viruses.

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

Brent Morse, DVM, DACLAM
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5R01DK112844-03

REGULATION OF PPAR ALPHA BY PACS-2 IN
RESPONSE TO NUTRIENT STRESS

5R01DK114855-03

ALLOSTERIC REGULATION OF SIRT1 BY A
PACS-2 AND DBC1 REGULATORY HUB

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 a violation.

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

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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)

