



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

October 16, 2019

Re: Animal Welfare Assurance  
#A3187-01 [OLAW Case 80]

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 October 14, 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 five mice received injections of an experimental drug which was not described in the approved protocol.

The corrective actions consisted of counseling the laboratory staff to follow Institutional Animal Care and Use Committee (IACUC) policies and to not give drugs which are not listed in the protocol. The protocol was amended, a letter of reprimand was issued to the Principal Investigator (PI) and supervisor, and the PI was counseled on not using data acquired under unapproved conditions.

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 IACUC 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



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

A3187-80

Office of Research Protections

Suite 401, Hiebert Building  
3500 Fifth Avenue  
Pittsburgh, PA 15213  
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October 14, 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 September 23, 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 violation was self-reported by the investigator and was as follows:

Five mice covered by the investigator's IACUC protocol underwent Tamoxifen injections, a procedure that is not described in the protocol.

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 lab personnel to clarify that drugs or chemicals not listed on the animal protocol can never be used in the animals.
2. The investigator held a lab meeting to reinforce IACUC policies.
3. The lab submitted a modification to the IACUC protocol to add Tamoxifen administration.

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

5R37DA023206-13	COCAINE-INDUCED ADAPTATION IN NMDA RECEPTORS
5F31DA043940-02	FAST-SPIKING INTERNEURONS IN THE NUCLEUS ACCUMBENS AND CUE-INDUCED COCAINE SEEKING
5R01DA040620-04	GLIAL-MEDIATED SYNAPTIC REMODELING IN DRUG ADDICTION

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 was reminded that any data collected from studies involving off-protocol work represents work not approved by the IACUC. Consequently, data resulting from the unapproved use of animals may not be used in any public presentations or publications unless it is also disclosed that the data was not collected under an approved IACUC protocol.

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

Sincerely,

(b) (6)

George A. Huber

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, October 15, 2019 9:00 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reportable Event

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

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**From:** (b) (6)  
**Sent:** Monday, October 14, 2019 2:30 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Reportable Event

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

