



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) 480-3387

July 12, 2021

Re: Animal Welfare Assurance  
#A3187-01 [OLAW Case 9K]

Dr. Bill Yates  
Interim Vice Chancellor for Research Protections  
University of Pittsburgh  
(b) (4) Hieber Building  
3500 Fifth Avenue  
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 29, 2021 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 mice were given tamoxifen in drinking water for six months although this activity had not been approved by the Institutional Animal Care and Use Committee (IACUC).

The corrective actions consisted of keeping an electronic version of the protocol to allow access by laboratory staff, issuing a letter of reprimand to the investigator and supervisor, ensuring that the grant was not charged for any unauthorized animal activities, and informing the investigator about the ramifications of using unapproved data in publications/presentations.

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



University of  
Pittsburgh

Office of  
Research Protections

Bill J. Yates, PhD  
Vice Chancellor for Research Protections  
Professor of Otolaryngology & Neuroscience &  
Clinical and Translational Science

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June 29, 2021

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 advise your office of a reportable incident<sup>1</sup>.

For a six-month period, mice assigned to an investigator's protocol were treated with tamoxifen in their drinking water, although the use of this drug was not described in the approved protocol.

The IACUC accepted the investigator's corrective action plan (CAP), which consisted of the following items:

1. The investigator will maintain a current version of the protocol in an online folder so that all lab personnel can access it to ensure that all procedures to be performed have been approved by the IACUC.

The investigator's research is funded by the following NIH grant:

5-R01-AI148356-02      IL-17 regulates LN stromal cell metabolism and function

The IACUC levied the following sanctions

1. A letter of reprimand was sent to the investigator, and his/her supervisor regarding this event. This letter has been placed in our files.
2. The investigator was reminded that studies involving off-protocol work cannot be paid for with NIH funds. Such charges will be removed.

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<sup>1</sup> PHS Policy IV.B.7

Brent Morse, DVM, DACLAM

June 29, 2021

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3. The investigator was reminded that data collected from studies involving off-protocol work represents work not approved by the IACUC and cannot be used in public presentations or publications without disclosing the lack of IACUC approval.

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

Sincerely,

(b) (6)

Bill J. Yates, PhD

**Walker, Keri (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, June 30, 2021 8:15 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reportable Event Notice

Good morning,

Thank you for these reports. We will send a response soon.

Best,  
Keri

*Keri Walker  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Dr., Suite 2500  
Bethesda, MD 20892  
301-435-2390  
[keri.walker@nih.gov](mailto:keri.walker@nih.gov)*

**From:** (b) (6)  
**Sent:** Tuesday, June 29, 2021 12:33 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 Bill J. Yates, PhD, Vice Chancellor for Research Protections. Thank you.

(b) (6)

