



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

May 6, 2021

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

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

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 28, 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 between March 17, 2021 and March 24, 2021, seven mice were fed a tamoxifen special diet that was not approved in the IACUC protocol. The studies were funded by PHS.

As a corrective measure, the principal investigator (PI) will require all lab members to review the current approval IACUC protocols and a monthly lab meeting will be planned to review updates to protocols and pending revisions. In addition, the IACUC sent a letter of reprimand to the PI and the PI's supervisor. The PI was reminded that data collected from studies involved in off-protocol work cannot be used in public presentations or publications without disclosing lack of IACUC approval and off-protocol work cannot be paid with NIH funding therefore charges will be removed.

OLAW appreciates the prompt consideration of this matter by the University of Pittsburgh which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole L. Lukovsky-
akhsanov -S

Digitally signed by Nicole L.
Lukovsky-akhsanov -S
Date: 2021.05.06 13:59:40 -04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



University of
Pittsburgh

Office of
Research Protections

A3187-9I

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

Suite 401, Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
Phone: 412-647-9614
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April 28, 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 incident¹.

Two boxes containing a total of seven mice were fed a tamoxifen special diet from March 17 to March 24. During that period, the use of this special diet was not described in the investigator's approved IACUC protocols.

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

1. The investigator will require all lab members to review the current portfolio of all IACUC protocols.
2. The investigator will plan a regular monthly meeting with all lab members to review updates to protocols and pending revisions.

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

5R01HL124021-06	Defining the Complex Biology of the miR-130/301 Family in Pulmonary Hypertension
4UH3TR002073-03	Computational repurposing of chemotherapies for pulmonary hypertension
5R01HL122596-06	Iron-Sulfur Deficiency as a Critical Pathogenic Cause of Pulmonary Hypertension
5F30HL139017-04	Fratxin loss induces endothelial dysfunction to promote pulmonary hypertension

¹ PHS Policy IV.B.7

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. Any such charges will be removed.
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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 30, 2021 7:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notices

Thank you for these reports, (b) (6) We will send responses soon.

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

From: (b) (6)
Sent: Wednesday, April 28, 2021 1:27 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable Event Notices

Please review the attached correspondence forwarded on behalf of Bill J. Yates, PhD, Vice Chancellor for Research Protections. Thank you!

(b) (6)

