

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

August 28, 2023

Re: Animal Welfare Assurance #A3187-01 [OLAW Case 10N]

Bill Yates, Ph.D. 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 August 11, 2023, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory at the University of Pittsburgh. According to the information provided, OLAW understands that an investigator accidentally administered tamoxifen in hydrogel, instead of diet gel, resulting in the demise of four mice on a PHS-supported study.

The corrective action consisted of submitting a letter regarding the noncompliance to both the investigator and supervisor and the IACUC approving the investigator's action plan to deliver tamoxifen via Diet Gel Boost.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the adverse. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee -S Digitally signed by Neera V. Gopee -S Date: 2023.08.28 11:24:46 -04'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT Associate Director, Animal Welfare Policy Office of Laboratory Animal Welfare National Institutes of Health

cc: IACUC Chair

Bill J. Yates, PhD Vice Chancellor for Research Protections Professor of Otolaryngology & Neuroscience & Clinical and Translational Science (b) (4) Hieber Building 3500 Fifth Avenue Pittsburgh, PA 15213 (b) (6)

Email: vcorp@pitt.edu

August 11, 2023

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.

During a pilot study, four mice were lost due to the investigator accidentally delivering tamoxifen via hydrogel instead of diet gel.

The IACUC approved the corrective action plan submitted by the investigator for the incident, which included the following item:

• The investigator's team will deliver tamoxifen via Diet Gel Boost.

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

R21-AI166697

FSTL-1 Regulated Pathways in Hematopoietic Stem Cell

Homeostasis and Transplantation

R01-HL144556

The Role of AMP-activated Protein Kinase in GVHD-

causing T Cells

The IACUC levied the following sanction:

A letter was sent to the investigator and their supervisor regarding these events.

¹ PHS Policy IV.C.1.d.

Brent Morse, DVM, DACLAM August 11, 2023 Page 2

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

Sincerely,
(b) (6)

Bill J. Yates, PhD

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)

Sent: Friday, August 11, 2023 2:11 PM

To: (b) (6)

Cc: OLAW Division of Compliance Oversight (NIH/OD)

Subject: RE: University of Pittsburgh

Good afternoon (b) (6)

Thank you for sending us these two reports and we will send official responses soon.

Best, Devora

Devora McCoy, BS, MBA (pronunciation)
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390

Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Friday, August 11, 2023 7:44 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: [EXTERNAL] University of Pittsburgh

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