



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

June 5, 2023

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

Dr. Bill Yates
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 May 23, 2023 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 ten mice were administered a therapeutic drug, carvedilol, which had not been approved for use on the protocol. A protocol modification had been submitted requesting approval for the administration of the drug, but it was not approved by the IACUC when the drug was administered. The investigator's research is supported by NIH grants.

The investigator submitted a corrective action plan for the incident, which included the investigator discussing the incident with their staff and establishing a new preapproval process that is now required for all animal modeling experiments. Specifically, the investigator must physically sign-off on all work prior to ordering animals and at the time of initiating any animal experiment.

The following actions were taken by the IACUC:

1. A letter was sent to the investigator and their supervisor regarding these events.
2. The investigator was reminded that no animal-related charges associated with off-protocol work can be paid with NIH funds.
3. The investigator was also reminded that any data collected from off-protocol work cannot be used in publications or presentations without disclosing that the data were not obtained with IACUC approval.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Brent C.
Morse -S
Date: 2023.06.05 09:36:59 -04'00'

cc: IACUC contact



University of
Pittsburgh

Office of
Research Protections

A3187-10K

*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

May 23, 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.

Ten mice assigned to an investigator's protocol were treated with the therapeutic drug carvedilol, an agent not approved for use on the protocol. A protocol modification had been submitted requesting approval for the administration of carvedilol, but it was not approved by the IACUC when the drug was administered.

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

- The investigator discussed the incident with their staff, and established a new pre-approval process that is now required for all animal modeling experiments. Specifically, the investigator must physically sign-off on all work prior to ordering animals and at the time of initiating any animal experiment.

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

5R01CA204419-02	Induction of Therapeutic Immunity in the Tumor Microenvironment
1P01CA234212-01A1	Targeting the Chemokine System to Sensitize Tumors to Immunotherapy

¹ PHS Policy IV.B.7

Brent Morse, DVM, DACLAM
May 23, 2023
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The IACUC levied the following sanctions:

1. A letter was sent to the investigator and their supervisor regarding these events.
2. The investigator was reminded that no animal-related charges associated with off-protocol work can be paid with NIH funds.
3. The investigator was also reminded that any data collected from off-protocol work cannot be used in publications or presentations without disclosing that the data were not obtained with IACUC approval.

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

Sincerely,

 (b) (6)

Bill J. Yates, PhD

From: OLAW Division of Compliance Oversight (NIH/OD)
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notices
Date: Friday, May 26, 2023 1:18:25 PM

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: Tuesday, May 23, 2023 2:57 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] 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)