



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 18, 2020

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

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 Mr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 8, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Pittsburgh Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states 37 mice were found dead in their cages. The animals had been inoculated with B16 tumor cells that likely metastasized and caused the animals' deaths per the final report. The protocol stipulated daily monitoring of animals and euthanasia of mice if "unusual or severe toxicity" developed. The technician responsible for monitoring was unavailable, and the principal investigator (PI) did not have an alternative monitoring strategy. As a result, animals were not euthanized in accordance with the endpoints described in the protocol. The IACUC reviewed the incident at the April 20, 2020 meeting. The committee reviewed and accepted the PI's corrective action plan, which included the following:

- The PI discussed the incident on March 30th at the weekly lab meeting.
- The PI will consult with DLAR if personnel are unable to enter the animal facility for any reason.

The report also states the IACUC sent a letter of reprimand to the animal facility director, the investigator and their supervisors regarding the event. It is noted that these animals were involved in PHS supported animal-activities.

Based on its assessment of this explanation, OLAW understands that the University of Pittsburgh has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

May 18, 2020
OLAW Case A3187-9A

Sincerely,

Jacquelyn T. Tubbs -S
Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2020.05.27
07:56:08 -04'00'

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



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

Office of Research Protections

Suite 401, Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
412-624-2202
ghuber@pitt.edu
orp.pitt.edu

May 8, 2020

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 that was reviewed by the University's Institutional Animal Care and Use Committee (IACUC) at its April 20, 2020 meeting.

Thirty-seven mice assigned to the investigator's protocol were found dead in their cages. They had been inoculated with B16 tumor cells and likely died due to metastasis. The protocol stated that mice with solid tumors will be monitored daily and sacrificed if "unusual or severe toxicity" developed, in consultation with a veterinarian. The technician responsible for monitoring the animals was unavailable, and the principal investigator did not formulate an alternate monitoring strategy. Consequently, the animals were not euthanized in accordance with endpoints stipulated in the protocol.

The University of Pittsburgh IACUC reviewed and accepted the investigator's corrective action plan, which consisted of the following items:

1. The investigator discussed the event on March 30 at a weekly lab meeting.
2. The investigator will consult with the DLAR if personnel are unable to enter the animal facility for any reason.

¹ PHS Policy IV.B.7

Brent Morse, DVM, DACLAM

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May 6, 2020

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

5R01CA219399-03	IMMUNOSTIMULATORY NANOCARRIER FOR BREAST CANCER IMMUNOCHEMOTHERAPY
5R01CA216410-04	DEVELOPING NANO TECHNOLOGY FOR HER2 DIRECTED THERAPY
5R01CA223788-03	NANOTHERAPEUTICS FOR SYNERGISTIC TARGETING OF MYC IN PROSTATE CANCER

The IACUC has levied the following sanctions:

1. A letter of reprimand was sent to the animal facility director, the investigator, and their supervisors regarding this event. These letters have been placed in our files.

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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 13, 2020 7:32 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notice

Thank you for these reports. A response to the 2nd one will be sent soon.
Axel Wolff

From: (b) (6)
Sent: Monday, May 11, 2020 12:25 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 George A. Huber, Vice Chancellor for Research Protections. Thank you.

(b) (6)

