



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

April 28, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Z]

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 April 24, 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: an incident that resulted in suspension of an investigator's protocols. The suspension was determined at an IACUC meeting held on April 20, 2020. The final report states on March 6, 2020 a member of the investigator's laboratory was discovered by animal care staff to be using another lab member's ID badge to enter an animal facility area that she did not have access to, which is prohibited by the animal facility's biosecurity policy. It is stated the IACUC suspended the investigator's protocols because this incident was a repeat offense by the same lab member. It is noted the same individual entered the animal facility using another lab member's ID badge during the previous protocol suspension. During that time, the incident was discussed between the Principal Investigator (PI) and lab personnel during a training session conducted by IACUC Compliance Office staff on December 17, 2019. As a result of the repeat noncompliance, the following corrective actions were taken by the IACUC:

- All the investigator's protocols have been suspended for a one-month period.
- A letter of reprimand was sent to the investigator and his supervisor regarding this event.
- The investigator and lab staff will undergo mandatory training on security access policies and why they are important for biosecurity.
- Once the suspension has been lifted, the investigator's animal-related activities will continue to be subject to enhanced monitoring by the Compliance Officer.
- The investigator was warned that further noncompliance by his lab may result in permanent loss of animal use privileges at the university.

Page 2 – Mr. Huber
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OLAW Case A3187-8Z

It is noted that these protocols are supported by PHS funds. 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.

Sincerely,

**Jacquelyn T.
Tubbs -S**
Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2020.04.28 11:27:03
-04'00'
Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



University of
Pittsburgh

Office of
Research Protections

A 3187

Office of Research Protections

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

April 24, 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 an incident that was considered by the University's Institutional Animal Care and Use Committee (IACUC) at its April 20, 2020 meeting, resulting in a suspension of an investigator's protocols.

On March 6th, 2020, a member of the investigator's laboratory was discovered by animal care staff to be using another lab member's ID badge to enter an animal facility area that she did not have access to, which is disallowed by our animal facility's biosecurity policy.

The IACUC suspended the investigator's protocols because this incident was a repeat offense by the same lab member. This individual entered the animal facility using another lab member's ID badge during the previous protocol suspension. The incident was discussed with the PI and lab personnel during a training session conducted by IACUC Compliance Office staff on December 17, 2019.

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

5R56CA229262-02

GENOME TARGETING OF LIVER CANCER

The IACUC has levied the following sanctions:

1. All of the investigator's protocols have been suspended for a one-month period.
2. A letter of reprimand was sent to the investigator and his supervisor regarding this event. The letter has been placed in our files.
3. The investigator and lab staff will undergo mandatory further training on security access policies and why they are important for biosecurity.

Brent Morse, DVM, DACLAM

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April 24, 2020

4. Once the suspension has been lifted, the investigator's animal-related activities will continue to be subject to enhanced monitoring by the Compliance Officer.
5. The investigator was warned that further noncompliance by his lab may result in permanent loss of animal use privileges at the university.

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: Friday, April 24, 2020 9:57 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notice

Thank you for this report, (b) (6) We will respond soon.
Axel Wolff

From: (b) (6)
Sent: Friday, April 24, 2020 9:42 AM
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)

A large rectangular area of the document is completely redacted with a solid grey fill. The text "(b) (6)" is visible in the top right corner of this redacted area.

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, April 24, 2020 8:58 AM
To: (b) (6)
Subject: RE: protocol suspension

Thank you for this report, (b) (6) We will start a new case file.
Axel Wolff

From: (b) (6)
Sent: Friday, April 24, 2020 8:40 AM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Subject: protocol suspension

Good morning, Dr. Wolff,
I am writing to inform you that the University of Pittsburgh's IACUC voted to suspend a protocol due to continued non-compliance from a PI/lab group to follow an important IACUC policy regarding biosecurity of our animal facilities. You will receive (or maybe already have) the reporting letter from our Institutional Official, George Huber.

Institute: University of Pittsburgh
Assurance number: A3287-01 (legacy assurance number) and D16-00118 (current number)

Funding Component: NIH 5R56CA229262-02 GENOME TARGETING OF LIVER CANCER

Incident: Lab member entered an animal facility using an access card/ID from another lab member. While she did have access privileges to another animal facility, she did not have access to this particular facility since we try to prevent cross-trafficking. While this may not be considered an event that could rise to the protocol suspension level, the lab had been trained on this issue a few months before because of a similar infraction.

The reporting letter details the IACUC's decision.

Please let me know if you need any other information at this time.

Best,
(b) (6)

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(b) (6)

(b) (6)

