



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 4, 2022

Re: Animal Welfare Assurance  
A3310-01 [OLAW Case 2F]

Dr. Phillip Cunningham  
Associate Vice President for Research  
Wayne State University  
5700 Cass Ave., (b) (4)  
Detroit, MI 48202

Dear Dr. Cunningham,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 15, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Wayne State University (WSU). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the WSU Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: temperatures in an animal room that exceeded the acceptable range. The final report states in February of this year, a laboratory that housed mice outside of the Division of Laboratory Animal Resources (DLAR) experienced temperatures outside of the acceptable range. From November 22, 2021 through February 4, 2022, the average temperatures in the room were between 80°F and slightly above 90°F. It is understood the animals present during this time frame produced abnormal scientific results and the data generated during this time frame was discarded. Also, the remaining 21 mice were euthanized due to scientific concerns.

Per the report, the husbandry duties are shared between the laboratory and DLAR. The deviation in temperature was reported to WSU Facilities Planning and Management (FP&M) by laboratory staff in December 2021. It was determined that high temperatures had been reported to FP&M a total of six times by laboratory staff beginning November 24, 2021. While the room had a remote temperature monitor in place, due to miscommunication this monitor was believed to be in a room that did not have animals housed. As a result, the sustained high temperatures were dismissed by veterinary staff when noticed on the temperature monitoring software.

In response to these findings, the following corrective actions were implemented:

- The room temperature was brought into range within 24 hours after discovery by the Attending Veterinarian (AV) and the Principal Investigator (PI).
- The PI purchased a temperature-controlled incubator to replace the non-temperature-controlled incubator that previously housed the dams and pups.

- DLAR placed an air conditioner in the basement of the building to be used as needed.
- The WSU Outside Housing agreement form will be amended to denote that the following process should be followed immediately when the temperature exceeds the appropriate range for that species as listed in The Guide:
  - The FP&M Service center is notified.
  - The DLAR Leader, a Veterinarian and the PI are notified.
- The IACUC SOP on outside housing is being updated to clearly delineate the responsibilities for when a temperature/humidity excursion occurs. All DLAR staff have been reminded to immediately inform veterinary staff if temperature/humidity excursions occur in any animal housing location.

The report states the Institutional Official and the AV met with FP&M regarding how to better triage phone calls received by the service center and to better address environmental events that place animals at risk. It is understood that this plan is under development and will be implemented when finalized. The IACUC determined the incident was not a noncompliance on the part of the PI and voted the matter to be reportable. It is stated that once renovations have been completed in the largest section of the vivarium, it will likely reduce the arrangements for housing outside the vivarium.

It is noted that the final report did not include the funding source involving the incident. In the future, please include the source of funding and provide grant numbers for all PHS, NSF or NASA supported work.

Based on its assessment of this explanation, OLAW understands that the Wayne State University 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: 2022.04.04  
08:51:11 -04'00'

Jacquelyn Tubbs, DVM, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



Philip R Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
5057 Woodward, Suite 2317  
Detroit, MI 48202

(b) (6)

[philc@wayne.edu](mailto:philc@wayne.edu)

**Animal Welfare Assurance Number: D16-00198**

March 15, 2022

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892  
[olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

RE: Reportable Non-compliance

Dear Dr. Morse:

I am writing to report an incident of minor non-compliance. The Division of Laboratory Animal Resources (DLAR) at Wayne State University (WSU) failed to follow WSU policy and Federal regulations which led to a deviation from the provisions of the *Guide* with respect to the proper care and use of animals in research.

**Incident:**

In February of 2022 it was discovered that a laboratory which housed mice outside of the DLAR vivarium experienced temperatures outside of the acceptable range. From November 22, 2021 through February 4, 2022, the average temperatures in the room were sustained between 80 °F and slightly above 90 °F. The animals present during this time period produced abnormal scientific results and all of the data generated during this time period was discarded. Additionally, the remaining 21 animals were euthanized for scientific concerns.

In this room, husbandry duties were shared between the laboratory personnel and DLAR. The temperature excursion was reported to Wayne State University Facilities Planning and Management (FP&M) in December of 2021 by laboratory staff via e-mail. Additionally, a review of room records revealed that high temperatures were reported to FP&M a total of six times by laboratory staff beginning November 24, 2021.

This room did have a remote temperature monitor in place, however, due to a miscommunication this monitor was believed to be in a room that did not have animals present. As such, the sustained high temperatures were dismissed by veterinary staff when noticed on the temperature monitoring software.

**Corrective Actions:**

The room temperature was brought into range within 24 hours after discovery by the Attending Veterinarian (AV), and the Principal Investigator (PI). The PI has purchased a temperature-controlled

incubator to replace the non-temperature-controlled incubator that previously housed the dams and pups. DLAR has placed an air conditioner in the basement of the building to be used as needed.

The AV also implemented a number of corrective actions. The WSU Outside Housing agreement form will be amended to denote that the following process should be followed immediately when the temperature exceeds the appropriate range for that species as listed in The Guide:

1. The FP&M Service center is notified,
2. The DLAR Leader, a Veterinarian and the PI are notified.

Additionally, the IACUC SOP on outside housing is being updated to clearly delineate the responsibilities when a temperature/humidity excursion occurs. All DLAR staff have been reminded to immediately inform veterinary staff if temperature/humidity excursions occur in any animal housing location.

The IO and the AV also met with FP&M management on how to better triage phone calls that come into the service center and to better address environmental events that place animals at risk. That plan is under development and will be implemented once finalized.

Finally, the AV noted that as we approach the completion of significant renovations for our largest vivarium on campus, we anticipate greatly reducing our arrangements for housing outside of the vivarium that were initiated during this process. As such, there will be a minimal amount of outside housing after the renovation is completed in Summer 2022.

**IACUC Finding:**

During a convened meeting on February 23, 2022, the IACUC voted that the event did not constitute non-compliance on the part of the PI. The IACUC voted that the incident constitutes minor non-compliance on the part of DLAR but determined that it should be reported.

Please contact me if you would like additional information.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.  
Institutional Official

c.c. Moh Malek, Ph.D., IACUC Chair, [en7488@wayne.edu](mailto:en7488@wayne.edu)

(b) (6)

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, March 16, 2022 7:32 AM  
**To:** Philip Cunningham  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Noncompliance report

Thank you for this report, Dr. Cunningham. We will send a response soon.

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

**From:** Philip Cunningham <ad4487@wayne.edu>  
**Sent:** Tuesday, March 15, 2022 1:23 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** AAALac International <accredit@aaalac.org>; (b) (6)

**Subject:** [EXTERNAL] Noncompliance report

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Please see the attached report of minor noncompliance. Please contact me if you would like additional information.

Best regards,  
Phil

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Philip R. Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
Wayne State University  
5057 Woodward Avenue, (b) (4)  
Detroit, MI 48202

Phone: (b) (6)  
FAX: (b) (6)  
Email: [philc@wayne.edu](mailto:philc@wayne.edu)

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