



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 10, 2022

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

Dr. Philip R. Cunningham
Associate Vice President for Research
Wayne State University
5057 Woodward Avenue, (b) (4)
Detroit, MI 48201

Dear Dr. Cunningham,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 8, 2022 letter reporting a deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Wayne State University, following up on an initial report on January 12, 2022. According to the information provided, OLAW understands that the daily health check was not conducted for one weekend day in a mouse satellite facility. The individual responsible was filling in during the pandemic staff shortage and was not familiar with the building. No adverse animal impacts occurred due to the missed room check.

The corrective actions consisted of posting weekend staff instructions in a designated location to ensure that husbandry staff knows which tasks to complete.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



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

(b) (6)
philc@wayne.edu

Animal Welfare Assurance Number: D16-00198

June 8, 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

RE: Report of Minor Non-compliance

Dear Dr. Morse:

I am writing to inform you of 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 reportable deviation from the provisions of the *Guide* with respect to the proper care and use of animals in research.

Incident:

On Sunday January 2, 2022 DLAR employees failed to perform a daily check on a satellite room outside of the vivarium proper that contained 40 mice. Subsequent observation on the following day revealed an absence of adverse outcomes associated with the failure.

Attending Veterinarian (AV) Response:

Investigation of the incident revealed that a staff member that was unfamiliar with the building performed duties that day due to staff shortages related to the COVID-19 pandemic. The AV added that DLAR staff will be reminded to place the weekend directions for staff in a designated location so that any DLAR staff member can find the sheet and perform weekend duties in a proper manner.

IACUC Finding:

During a convened meeting on January 26, 2022, the IACUC voted that the incident constitutes minor non-compliance and to accepted the AV's corrective actions, but felt that the incident should none-the-less 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
Gary L. Borkowski, D.V.M., M.S., AAALAC International, accredit@aaaalac.org

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Wednesday, June 8, 2022 7:55 AM
To: Michael Bradley
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary report of non-compliance

Good morning Dr. Bradley,

After reviewing the letter sent, it looks like the only information we are still waiting for to be addressed in a final report is the failure to perform daily room checks by the DLAR employees in January of this year. Please also have the species that were involved included with the final report.

Thank you,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 6, 2022 12:22 PM
To: Michael Bradley <Michael-Bradley@wayne.edu>
Subject: RE: preliminary report of non-compliance

Hi Dr. Bradley,

Perfect, thank you for sending this information.

Best,
Devora

From: Michael Bradley <Michael-Bradley@wayne.edu>
Sent: Monday, June 6, 2022 12:09 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] RE: preliminary report of non-compliance

Hi Devora,

Thanks for reaching out. We sent a formal report to OLAW in March of this year. Please find it attached!

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 6, 2022 11:55 AM
To: Michael Bradley
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary report of non-compliance

Good morning Dr. Bradley,

I'm reaching out to you to see if there are any recent updates on this case?

Thank you,

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Friday, January 14, 2022 7:29 AM
To: Michael Bradley <Michael-Bradley@wayne.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: preliminary report of non-compliance

Thank you for this preliminary report, Dr. Bradley. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation. Make sure to tell us what species were involved.

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

From: Michael Bradley <Michael-Bradley@wayne.edu>
Sent: Wednesday, January 12, 2022 2:31 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] preliminary report of non-compliance

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.

OLAW,

I am writing to send along a preliminary report of Non-compliance at Wayne State University (Assurance # D16-00198). Below are the details of the incident that we are reporting, along with the plan for correction:

Wolff, Axel (NIH/OD) [E]

A3310-2E

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, January 14, 2022 7:29 AM
To: Michael Bradley
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary report of non-compliance

Thank you for this preliminary report, Dr. Bradley. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation. Make sure to tell us what species were involved.

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

From: Michael Bradley <Michael-Bradley@wayne.edu>
Sent: Wednesday, January 12, 2022 2:31 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] preliminary report of non-compliance

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.

OLAW,

I am writing to send along a preliminary report of Non-compliance at Wayne State University (Assurance # D16-00198). Below are the details of the incident that we are reporting, along with the plan for correction:

On Sunday 1/2/2022, DLAR employees failed to perform a daily room check on animals that were being housed in an IACUC approved satellite room outside of the vivarium proper. Subsequent observation on the following day revealed an absence of adverse outcomes associated with the failure to observe on 1/2/2022. Investigation of the incident revealed that a staff member that was unfamiliar with the building performed duties that day due to staff shortages related to the COVID-19 pandemic. DLAR staff will be reminded to place the weekend directions for staff in a predictable location so that any DLAR staff member can find the sheet and perform weekend duties in a proper manner.

This item will be discussed with the IACUC at the next meeting on 1/26/21 and a formal and final report from the IO will follow.

Please let me know if any additional details are needed at this time.

Regards,
Mike

Michael Bradley, DVM, DACLAM
Attending Veterinarian
Division of Laboratory Animal Resources
Wayne State University
(b) (6)

Michael-Bradley@wayne.edu