



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 25, 2021

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

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 May 14, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Wayne State University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Wayne State University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of procedures without prior veterinary consultation, failure to adhere to an institutional policy and the IACUC-approved protocol. The final report states 3 rats underwent survival surgery without the minimum 2-day acclimation period required by the institutional policy. Two rats underwent surgery on the day of arrival and the third animal underwent surgery the day after arrival. It is stated one animal chewed open an area of skin near the incision and was treated topically by the veterinarians. Instructions were recorded in the medical record for researchers to continue topical treatment, however, researchers performed an unapproved surgical repair of the wound. The report also details that researchers failed to document the administration of buprenorphine HCL as approved in the protocol. It is understood that animals did not appear in pain in the opinion of the veterinarians.

The principal investigator (PI) was contacted by research compliance and stated he was unaware of the policy on acclimatization of animals. He assured the IACUC he will adhere to the policy moving forward. The PI acknowledged that a research staff member performed the wound repair because veterinarians had approved repair in the past. Per the report, it is now understood by the PI that any treatment or procedure not approved in the protocol must be performed under veterinary consultation. The PI confirmed that buprenorphine was administered as per the protocol, but lab staff did not document the administration in the medical records. In response, the lab will ensure that all treatment is recorded properly in treatment records.

On April 28, 2021, the IACUC voted the matter as a serious noncompliance and accepted the PI's corrective actions. Also, the research compliance specialist will conduct Post-Approval Monitoring of the protocol and meet with the PI and lab staff to review the results. It is noted that this study is supported by PHS funds. In the future, please include the source of funding and provide grant numbers for all PHS, NSF or NASA supported work.

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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: 2021.05.25 15:18:05
-04'00'

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

cc: IACUC Contact



A 3310-20

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

May 14, 2021

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 Serious Non-compliance

Dear Dr. Borkowski:

I am writing to report an incident of serious non-compliance. A researcher at Wayne State University (WSU) failed to follow WSU policy and Federal regulations which led to serious deviation from the provisions of the *Guide* with respect to the proper care and use of animals in research. The study is funded by PHS.

Incident:

Three rats received during the week of March 15, 2021 underwent survival surgery without a minimum 2-day acclimation period required by the WSU *Acclimation of Animals* policy. Two rats had surgery on the day of arrival, and a third undergoing surgery the day after arrival.

One of the rats chewed open an area of skin near the incision which veterinarians treated topically and recorded the instructions on the animal's medical record for the researchers to continue topical treatment. The researchers performed an unapproved surgical repair of the wound.

The researchers also failed to document the administration of buprenorphine HCL twice per day as approved in the protocol. The rats did not present with pain, so it was the opinion of the veterinarians that the administration of the drug did occur, but it was not properly recorded in the records.

PI Response:

When contacted by research compliance, the PI admitted that he was unaware of the WSU *Acclimation of Animals* policy and assured the IACUC that he will follow the policy moving forward. He stated that one of his research staff noticed that the wound size had increased and repaired the wound surgically because veterinarians had approved repair in the past. It is now understood that any treatment or procedure that is not approved in the protocol must be performed under veterinary consultation. The PI also confirmed that the buprenorphine was being administered per the approved protocol, but lab staff failed to document the administration in the animals' post-op medical records. In the future, the lab will ensure that all treatment is recorded properly in the treatment records.

IACUC Finding:

During a convened meeting on April 28, 2021 the IACUC voted that performing a surgical procedure that was not approved in the protocol, and failing to document the administration of buprenorphine to represent serious non-compliance. The IACUC accepted the investigator's remedial actions and did not request any additional information. As is our standard procedure, the research compliance specialist will conduct Post Approval Monitoring of the protocol and meet with the PI and lab staff to go over the results.

Please contact me if you would like additional information.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.
Institutional Official

c.c. Gary L. Borkowski, D.V.M., M.S., AAALAC International, accredit@aaalac.org
Moh Malek, Ph.D., IACUC Chair, en7488@wayne.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 17, 2021 7:23 AM
To: Philip Cunningham
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: 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 <philc@wayne.edu>
Sent: Friday, May 14, 2021 12:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALac International <accredit@aaalac.org>; Moh Malek <en7488@wayne.edu>; (b) (6)
(b) (6)
Subject: Report

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

Regards,
Phil

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

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