



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

June 2, 2022

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

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 5, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at Wayne State University. According to the information provided, OLAW understands that there were two separate but similar incidents involving protocol expiration. Per IACUC procedures, two principal investigators (PIs) were notified that their protocols were expiring. The PIs were directed to immediately submit a transfer form to move mice to the institution's holding protocol. When the animals were not transferred to the holding protocol by the PIs, the IACUC transferred the animals to the holding protocol within 5 days of protocol expiration. One protocol involved in these incidents was supported by PHS funds.

Corrective and preventive measures included several changes implemented by the IACUC. If a protocol is not renewed prior to its expiration date, the IACUC will transfer the animals to the holding protocol prior to or on the expiration date. Protocol expiration notice reminders now inform the PI one week before expiration that animals will be transferred to the holding protocol by the IACUC office if the protocol is not renewed. In addition, the Associate Director for Responsible Conduct for Research (ADRCR) will be copied on all expiration reminders. The ADRCR will notify the PI, the Attending Veterinarian, and building leader the day before the protocol expires that the animals will be transferred to the IACUC holding protocol if a renewal protocol is not approved and/or the PI does not have an appropriate existing protocol to which the animals can be transferred. Finally, an SOP has been developed with explicit instructions for the transfer of animals to the IACUC holding protocol.

OLAW appreciates the consideration of this matter by Wayne State University, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M.
Engel -S
Date: 2022.06.02 11:30:17 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact



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

A3310-26

(b) (6)
philc@wayne.edu

Animal Welfare Assurance Number: D16-00198

May 5, 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 Serious Non-compliance

Dear Dr. Morse:

I am writing to report two incidents of serious non-compliance. The IACUC 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 incidents occurred on two different protocols, one of which is PHS-funded. In particular, protocol 19-01-0916 was funded by a National Cancer Institute grant number R01CA222359A.

Incident(s):

Per IACUC procedures, a PI was notified that his NIH-funded protocol expired on March 03, 2022, and to immediately submit a transfer form to move animals to the Holding Protocol. When animals were not transferred to the WSU IACUC Holding Protocol, the IACUC transferred the animals to the Holding Protocol on March 07, 2022. No federal grant funds were spent during the period of time mice were on the expired protocol. On April 16, 2022, a second PI was notified that a protocol had expired and she must immediately submit a transfer form to transfer animals to the Holding Protocol. When the transfer form was not submitted, mice were transferred to the WSU IACUC Holding Protocol by the IACUC on April 21, 2022. This second protocol was not funded by NIH.

IACUC Corrective Actions:

If a protocol is not renewed prior to its expiration date, the IACUC will transfer the protocol to the Holding Protocol prior to or on the expiration date. Protocol expiration notice reminders now include an additional reminder one week before expiration that informs the PI that if a renewal protocol is not approved all animals will be transferred to the Holding Protocol by the IACUC Office (not the PI) at the day of expiration (or previous business day if expiration is on weekend/holiday). In addition, the Associate Director, Responsible Conduct for Research (ADRCR), will be copied on all expiration notice reminders (90-day, 60-day, 1-week, and final notice). The ADRCR will copy the Attending Veterinarian and Division of Laboratory Animal Resources building leader the day before the protocol expiration date notifying that if a renewal protocol is not approved, and/or the PI does not have an appropriate existing protocol to which the animals can be transferred, that the animals must be transferred to the IACUC

Holding Protocol. Finally, the ADRCR has developed an "Expiring Protocols" SOP with explicit instructions for the transfer of animals to the Holding Protocol.

IACUC Finding:

During the IACUC meeting convened on April 27, 2022 the IACUC voted that delays in transferring mice to the IACUC Holding Protocol after protocol expiration represent serious noncompliance and voted to approve the corrective actions listed above.

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

(b) (6)

Elizabeth Snyderwine, Ph.D., Elizabeth_Snyderwine@nih.gov

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 6, 2022 7:55 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: Thursday, May 5, 2022 4:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Snyderwine, Elizabeth (NIH/NCI) [E] <snyderwe@dc37a.nci.nih.gov>; AAALac International <accredit@aaalac.org>;
(b) (6)

(b) (6)

Subject: [EXTERNAL] Noncompliance 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)
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