



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

January 21, 2022

Re: Animal Welfare Assurance
A3114-01 [OLAW Case 4R]

Dr. Rebecca Cunningham
Vice President for Research and
Institutional Official
University of Michigan
(b) (4) Victor Vaughan Building
1111 Catherine Street
Ann Arbor, MI 48109-2054

Dear Dr. Cunningham,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 9, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Michigan. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Michigan Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal activities without prior IACUC review and approval; lack of appropriate veterinary oversight; failure to adhere to approved humane endpoints; and failure to follow veterinary directives. The final report states the IACUC was notified that animal activities were performed involving 6 mice, and these procedures were approved on a different investigator's IACUC protocol. The animals were kept in the investigator's lab space >24h without IACUC approval and were not provided adequate veterinary care. It is stated a separate group of 5 mice were not provided topical ointment for the entire duration of the veterinary orders.

In response, the IACUC voted to suspend the Principal Investigator's protocol and the matter was discussed on December 6, 2021. It is noted the protocol is supported by NIH funding and the University of Michigan. The committee determined the incident was not a programmatic failure and requires the following actions from the Principal Investigator (PI):

- A complete re-review of the protocol by the PI and a Faculty Veterinarian.
- A meeting with the PI, the lab staff, the IACUC Chair, and the Attending Veterinarian.
- The development of a corrective action plan (to be presented by the PI to the IACUC) to include the training and mentoring of new and current staff, a plan for the PI's oversight of all animal activities, and procedures for ensuring compliance with applicable IACUC policies, guidelines, and SOPs, adherence to the IACUC-approved protocol.
- When the IACUC protocol is reinstated and animal activities commence, the investigator's program will remain on probation until further notice, during which time the PI is required to submit bi-monthly reports to the IACUC on the status of their research program (e.g., what animal activities were conducted, the clinical status of the animals, veterinary communications).

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Based on its assessment of this explanation, OLAW understands that the University of Michigan 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: 2022.01.21
08:34:12 -05'00'

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

cc: IACUC Contact

A3114-4R



INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

UNIVERSITY OF MICHIGAN

December 9, 2021

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Morse:

The University of Michigan, in accordance with Assurance D16-00072 and PHS Policy IV.F.3., provides this report of non-compliance associated with a Principal Investigator's (PI) animal study protocol, titled "*Inflammation, the gut microbiome, and colon carcinogenesis*." Animal activities involving approximately six (6) mice were conducted (a) without appropriate IACUC approval (the procedures conducted were approved on a different PI's IACUC protocol); (b) without appropriate veterinary oversight (the animals were kept in the PI's lab space for more than 24 hours, without IACUC approval, and were not provided adequate veterinary care); and (c) without adhering to approved humane endpoints. Additionally, in a separate group of approximately five (5) mice, animals were not provided a topical ointment for the entire duration of the veterinary orders.

The IACUC considered this matter in accordance with the IACUC's *Policy on Investigating Noncompliance and Animal Welfare Concerns* and voted to suspend the Principal Investigator's (PIs) IACUC protocol. This matter was discussed by the IACUC on December 6, 2021.

The suspended protocol involves research funding provided through the National Institutes of Health (grant number R01 DK122812-01) and the University of Michigan. NIH funding used to support activities that were not approved by the IACUC were negligible and, once suspended, no funds are being spent on animal activities. Accordingly, the NIH funding component was not notified of the situation.

The IACUC determined the concerns to be isolated to this laboratory and not a programmatic failure. In addition to the protocol suspension, the IACUC requires:

- A complete re-review of the protocol by the PI and a Faculty Veterinarian;
- A meeting with the PI, the lab staff, the IACUC Chair, and the Attending Veterinarian;
- The development of a corrective action plan (to be presented by the PI to the IACUC) to include the training and mentoring of new and current staff, a plan for the PI's oversight of all animal activities, and procedures for ensuring compliance with applicable IACUC policies, guidelines, and SOPs, adherence to the IACUC approved protocol; and
- When the IACUC protocol is reinstated and animal activities commence, the PI's program will remain on probation until further notice, during which time the PI is required to submit bimonthly reports to the IACUC on the status of their research program (e.g., what animal activities were conducted, the clinical status of the animals, veterinary communications).

The PI's protocol suspension will not be lifted until the IACUC is satisfied with the corrective action measures.

The University of Michigan is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact (b) (6)

Sincerely,

(b) (6)

Rebecca Cunningham, IO and Vice President for Research

(b) (6)

Cc: AAALAC International
IACUC Chair
Attending Veterinarian
ACUO Associate Director

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 15, 2021 7:25 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report for D16-00072

Thank you (b) (6) We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Friday, December 10, 2021 11:57 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: accredit@aaalac.org; (b) (6)
Subject: [EXTERNAL] Report for D16-00072
Importance: High

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.

Dear Dr. Morse,

Attached please find a report from The University of Michigan's IACUC, assurance # D16-00072.

Please let me know if you have any problems accessing the attachment.

Thank you,

(b) (6)