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

September 1, 2021

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

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 August 23, 2021 letter reporting three incidents of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Michigan. According to the information provided it is understood that, concerning the first incident, a five-week-old male white New Zealand rabbit was observed to have an approximately ½-1 inch triangular shape portion of his right ear missing at the tip. This was the result of the lab having performed an unauthorized method for tissue sampling. For the second incident, which also occurred in the same lab as incident one above, it is understood that expired controlled substances were used, albeit successfully, to euthanize approximately 275 mice. The research is funded through the PHS.

Corrective and preventive actions included requiring the PI to submit monthly reports to the IACUC for a period of six months. The reports were to include: 1) a summary of the animal activities that were conducted during the reporting period; 2) the outcome of the activities; and 3) if applicable, a brief description of any unanticipated outcomes. In addition, four of the PI's staff's privileges to perform animal activities were suspended, pending, at minimum, all four individuals attending an IACUC meeting to present and discuss on the ethical considerations applicable to animal research; the users' responsibility for ensuring animal welfare; and the reason for the IACUC protocol and subsequent adherence.

Regarding the third incident, it was discovered that expired controlled substances were used, albeit successfully, to euthanize nine rabbits. The research is funded through the PHS.

Corrective and preventive actions included requiring the PI to submit a report to the IACUC (due in February 2022) detailing the following information:

a) Describe the corrective action plan employed to prevent future occurrences of the non-compliance and
b) Provide a summary report of the success of the implemented corrective action plan.

OLAW believes that the corrective and preventive measures put in place by the University of Michigan were consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. **Please note:** for incident number three, OLAW assumes that the IACUC has already reviewed and accepted the PI's corrective action plan and is not waiting until February 2022 to do so. If this is not correct, please explain. We appreciate being informed of this matter and find no cause for further action by this office, at this time.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse -S
Date: 2021.09.01 15:34:00 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact
Dr. Robert M. Gibbens, USDA, APHIS, AC

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A3114-4P

# INSTITUTIONAL ANIMAL CARE & USE COMMITTEE
UNIVERSITY OF MICHIGAN

August 23, 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. All of the below incidents occurred within a relatively short time span. The details of each incident are provided below:

**Incident 1**

The below finding was reported by the USDA VMO during a recent inspection:

2.31(e)(3) Critical - Institutional Animal Care and Use Committee (IACUC)

- A 5-week-old male white New Zealand rabbit was observed to have an approximately ½-1 inch triangular shape portion of his right ear missing at the tip. The edge of the wound was scabbed. The skin of the front portion of the ear, adjacent to the wound edge, was reddened.
- The lab performed an unauthorized method for the approved tissue sampling procedure that led to this complication. At the time of the inspection, the veterinary staff had already notified the lab to discontinue use of that procedure.
- A significant change was made to the protocol without veterinary authorization. This failure does not give the IACUC and veterinary staff a complete understand of the animal's use as well as the opportunity to identify any potential for animal pain or distress. It is essential that a complete description of all animal procedures used in the protocol be discussed and approved to ensure humane and judicious use of these animals.

The research is funded through NIH, but the funding used to support this activity was negligible. Accordingly, the NIH funding component was not notified of the situation.

1. The IACUC discussed this matter on July 29, 2021 in concert with an additional allegation (refer to Incident #2, below) for this PI.

2. Based on the IACUC discussion, and to mitigate the potential for future reoccurrences, the IACUC required the following:

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Ann Arbor, MI 48109-2054
T: 734-763-8028 F: 734-936-3234
acuoffice@umich.edu 15,16,18-2021

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a. The PI was required to submit monthly reports to the IACUC for a period of six months. The reports were to include: 1) a summary of the animal activities that were conducted during the reporting period; 2) the outcome of the activities; and 3) if applicable, a brief description of any unanticipated outcomes.

b. Four of the PIs staff's privileges to perform animal activities were suspended, pending at minimum, all four individuals attend an IACUC meeting to present and discuss on the ethical considerations applicable to animal research; the users' responsibility for ensuring animal welfare; and the reason for the IACUC protocol and subsequent adherence.

**Incident 2**

During an audit performed by the U-M Controlled Substance Monitoring program, it was discovered that expired controlled substances were used, albeit successfully, to euthanize naïve animals (~275 mice). The research is funded through NIH, but the funds used to support this activity were negligible. Accordingly, the NIH funding component was not notified of the situation.

1. The IACUC discussed this matter on July 29, 2021 in concert with an additional allegation (refer to Incident #1, above) for this PI.

3. As noted above, based on the IACUC discussion, and to mitigate the potential for future reoccurrences, the IACUC required the following:

    a. The PI was required to submit monthly reports to the IACUC for a period of six months. The reports were to include: 1) a summary of the animal activities that were conducted during the reporting period; 2) the outcome of the activities; and 3) if applicable, a brief description of any unanticipated outcomes.

    b. Four of the PIs staff's privileges to perform animal activities were suspended, pending at minimum, all four individuals attend an IACUC meeting to present and discuss on the ethical considerations applicable to animal research; the users' responsibility for ensuring animal welfare; and the reason for the IACUC protocol and subsequent adherence.

**Incident 3**

During an audit performed by the U-M Controlled Substance Monitoring program, it was discovered that expired controlled substances were used, albeit successfully, to euthanize naïve animals (9 rabbits). The research is funded through NIH, but the funds used to support this activity were negligible. Accordingly, the NIH funding component was not notified of the situation.

1. This matter was discussed by the IACUC on August 2, 2021.

2. As noted above, based on the IACUC discussion, and to mitigate the potential for future reoccurrences, the IACUC requires the PI to submit a report to the IACUC (due in February 2022) detailing the following information:

    a. Describe the corrective action plan employed to prevent future occurrences of the non-compliance and
    b. Provide a summary report of the success of the implemented corrective action plan.



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The IACUC determined that these were isolated incidents and/or potentially related to the complexities of the pandemic and reduced operations, and not programmatic in nature. The corrective action plans and IACUC imposed sanctions, as detailed above, are also supplemented by the involvement of the Animal Care and Use Office's PI Advocacy and Quality Assurance team members, who provide additional guidance, education, and oversight of the labs animal activities to facilitate compliance. Collectively, these approaches have resolved the root causes of the non-compliances and strengthened the relationships between the PIs, animal users, veterinary and husbandry staff, and the compliance office staff.

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 William G. Greer (wggreer@med.umich.edu).

Sincerely,

(b) (6)

Rebecca Cunningham, IO and Vice President for Research

(b) (6)

William Greer, Assistant Vice President for Research, and Director of the Animal Care and Use Office

Cc: AAALAC International
IACUC Chair
Attending Veterinarian



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

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

Thank you for these reports, (b) (6) We will send responses soon.

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

**From:** (b) (6)
**Sent:** Tuesday, August 24, 2021 5:26 PM
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
**Cc:** Greer, Bill <wggreer@med.umich.edu>; accredit@aaalac.org; (b) (6) (b) (6)
**Subject:** Report for D16-00072
**Importance:** High

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)

(b) (6)



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(b) (6)





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