



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

March 9, 2022

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

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 February 22, 2022 letter reporting an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Michigan. According to the information provided, OLAW understands that expired xylazine was used to premedicate one pig for a non-recovery procedure. The noncompliance was identified during a USDA-APHIS inspection. The pig involved in this incident was not supported by NIH funding.

Corrective and preventive measures included: 1) Retraining of responsible staff on the regulations and policies governing the use of drugs, including analgesia and anesthesia, 2) counseling responsible staff regarding the potential animal welfare impact of using expired substances, 3) review of methods for ensuring that expired drugs are identified and not used, and 4) review of methods for labeling and storing expired substances. In addition, the principal investigator will be required to submit a corrective action plan to the IACUC (within 6 months), as well as a report detailing the success of the implemented plan.

OLAW appreciates the consideration of this matter by the University of Michigan 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: 2022.03.10 08:02:16 -05'00'

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

cc: IACUC contact

Dr. Robert M. Gibbens, USDA, APHIS, Animal Care



INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

UNIVERSITY OF MICHIGAN

February 22, 2022

A3114-45

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 (U-M), in accordance with Assurance D16-00072 and PHS Policy IV.F.3., provides this report of non-compliance. During a USDA-APHIS inspection, the VMO identified [and a non-critical citation (2.33 - b.5) was given to the University] that expired Xylazine was used to pre-medicate an animal (one pig) for a non-recovery procedure. The associated animal study is not funded by an NIH grant, however, this report is submitted to ensure full transparency to OLAW regarding this incident for which a USDA citation was issued.

This incident was discussed by the IACUC on January 24, 2022. Prior to the IACUC meeting, the PI and all lab personnel met with a ULAM facility veterinarian and an Animal Care and Use Office Quality Assurance (QA) team member to develop a corrective action plan. The topics and actions of this meeting included:

1. Re-training on the regulations and policies governing the use of substances (inclusive of anesthesia and analgesia);
2. A discussion on the potential impact on animal welfare if expired substances are used;
3. A review of potential methods for ensuring that drugs are identified as expired and not used beyond their expiration date; and
4. A review of the methods for labeling and storing expired substances.

The IACUC determined that above noted re-training was appropriate and required the PI to submit a report (within six months) detailing the corrective action plan employed to prevent future occurrences of the non-compliance and a summary of the success of the implemented corrective action plan.

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
ACUO Associate Director

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 23, 2022 8:37 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Report for D16-00072[WARNING: UNSCANNABLE EXTRACTION FAILED]

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Tuesday, February 22, 2022 6:02 PM
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[WARNING: UNSCANNABLE EXTRACTION FAILED]

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)