



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) 402-7065

December 2, 2019

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

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 November 21, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Michigan. According to the information provided, OLAW understands that a non-pharmaceutical mixture of two anesthetics had been used on rodents. No adverse effects were observed in the animals.

The corrective actions consisted of counseling the investigator to use a pharmaceutical grade anesthetic agent in the animals. The incident was reported to the Food and Drug Administration.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. In future reports please specifically identify the species involved. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair  
Director Animal Care and Use Office



**INSTITUTIONAL ANIMAL CARE  
AND USE COMMITTEE**  
UNIVERSITY OF MICHIGAN

A3114-4J

Date: November 21, 2019

Axel Wolff, M.S., D.V.M.  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Dear Dr. Wolff:

The University of Michigan (U-M), in accordance with Assurance D16-00072 and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) provides this report to OLAW. This matter was discussed by the U-M IACUC on Monday, October 21, 2019.

A Principal Investigator requested a veterinary consultation after switching from isoflurane to Ketamine and Xylazine. During this consultation, it was discovered that a solution of Ketamine hydrochloride and Xylazine hydrochloride was commercially available for use in laboratory rodents. However, the veterinarian discovered the product was not pharmaceutical grade. Based on the conversation, a dilution of the product performed as expected in animal studies. The concern was immediately resolved by the IACUC.

In accordance with the expectation, the IACUC investigated the finding as an allegation of noncompliance. The committee agreed that given the circumstances the following actions would appropriately mitigate the problem.

1. The veterinary team, on behalf of the IACUC, notified the rodent researcher community that a non-pharmaceutical Ketamine/Xylazine solution was commercially available, but reminded the researchers that since the product is a non-pharmaceutical grade that it could not be used in animal activities; and
2. The U-M Deputy Attending Veterinarian communicated the concern to the Office of Minor Use and Minor Species, Animal Drug Development of the Food and Drug Administration (FDA). The FDA referred the report to the Office of Surveillance and Compliance for further investigation.

Sincerely, /

(b) (6)

Rebecca Cunningham, IO and  
Interim Vice President for Research

(b) (6)

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

cc: AAALAC International  
(b) (6)

## Morse, Brent (NIH/OD) [E]

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, November 26, 2019 3:48 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Greer, William; (b) (6) Cunningham, Rebecca  
**Subject:** RE: Report from #D16-00072

Thank you for supplying this report (b) (6) We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

---

**From:** (b) (6)  
**Sent:** Monday, November 25, 2019 1:39 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** accredit@aaalac.org; Greer, William <wgreer@med.umich.edu>; (b) (6)  
(b) (6) Cunningham, Rebecca <stroh@med.umich.edu>  
**Subject:** Report from #D16-00072  
**Importance:** High

Dear Dr. Wolff,

As a follow-up to your conversation with Bill Greer, attached please find a final report from the University of Michigan.

Please let me know if there are any questions or problems accessing the attachment.

Thank you,  
(b) (6)

(b) (6)