



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 30, 2020

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

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 March 26, 2020 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 110 mice on a dental pulp exposure study failed to receive post-operative analgesia as stated in the approved protocol. The investigator stated that provision of analgesia would interfere with the study. No adverse clinical signs were noted in the mice because the procedure destroys the nerve and interrupts the pain pathway.

The corrective action consisted of the Principal Investigator working with the veterinarian to develop a protocol amendment to remove provision of analgesia. The amendment was subsequently approved by the Institutional Animal Care and Use Committee (IACUC).

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 IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Assistant VP for Research, Animal Welfare



INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

UNIVERSITY OF MICHIGAN

March 26, 2020

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, in accordance with Assurance D16-00072 and PHS Policy IV.F.3., provides this report of noncompliance regarding the involvement of 110 mice used in activities that were not consistent with the IACUC approved protocol. Specifically, animals that underwent pulp exposure experiments did not receive post-operative analgesia as required in the protocol. The PI indicated the analgesia was not provided because its use would confound the research. It should be noted that the pulp-exposure procedure includes destruction of the nerve and no adverse consequences have been noticed in these animals, compared to their naïve counterparts. The activities were associated with a PI's animal study protocol, titled "Role of Serum Amyloid A in Oral Inflammation." This incident was discussed by the IACUC on March 16, 2020.

The research funding is provided through the University of Michigan and the National Institutes of Health R01DE024796. NIH funding used to support activities that were not approved by the IACUC were negligible. Accordingly, the NIH funding component was not notified of the situation.

To resolve the situation, the area veterinarian and the PI met to prepare a protocol amendment after discussing the need to conduct the procedure in the absence of analgesia and potential alternatives. Consequently, a protocol amendment was made and subsequently approved by the IACUC. The IACUC determined that this was an isolated incident and not a programmatic failure.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 27, 2020 9:55 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report for D16-00072

Thanks (b) (6) We'll send a response soon.
Axel Wolff

From: (b) (6)
Sent: Friday, March 27, 2020 9:49 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b) (6) Cunningham, Rebecca <stroh@med.umich.edu>; (b) (6) (b) (6) accredit@aaalac.org
Subject: Report for D16-00072
Importance: High

To whom it may concern at OLAW,

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)



Electronic Mail is not secure, may not be read every day, and should not be used for urgent or sensitive issues