



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 40]

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 24, 2021 letter reporting a 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 a cage of three mice that were administered *Toxoplasma gondii* were maintained under ABSL-1 rather than ABSL-2 conditions. The associated animal study is funded by the PHS.

Corrective and preventive actions included: the PI indicated upon discovery of the error that the cage was immediately relocated to ABLS2, and refresher training was provided to the laboratory staff members. In addition, the U-M Biosafety Officer performed a risk assessment and determined that there was negligible risk to personnel since the animal model was rodents and the only known definitive host is felines. The IACUC also asked that members of the quality assurance team provide additional education, guidance, and oversight to ensure the expectations are understood and adherence is confirmed.

OLAW believes that the corrective and preventive measure put in place by the University of Michigan was consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2021.09.01 15:33:02 -04'00'

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

cc: IACUC contact



INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

UNIVERSITY OF MICHIGAN

August 24, 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 (U-M), in accordance with Assurance D16-00072 and PHS Policy IV.F.3., provides this report of non-compliance. A lab member failed to house animals appropriately; specifically, a cage of three mice that were administered *Toxoplasma gondii* were maintained under ABSL-1 rather than ABSL-2 conditions. The associated animal study is funded by four different NIH grants. However, the expenses associated with a single cage of mice were negligible, and consequently, the NIH funding component was not notified of the situation.

The IACUC and PI discussed this incident on June 21, 2021. The IACUC determined that the PI was aware of the containment requirements, but in this particular case failed to satisfy the expectation. The PI indicated upon discovery of the error that the cage was immediately relocated to ABLS2, and refresher training was provided to the laboratory staff members. In addition, the U-M Biosafety Officer performed a risk assessment and determined that there was negligible risk to personnel since the animal model was rodents and the only known definitive host is felines.

Considering the steps taken by the PI, the IACUC asked that members of the quality assurance team provide additional education, guidance, and oversight to ensure the expectations are understood and adherence is confirmed. The immediate concern has been resolved, and the potential for future reoccurrences has been mitigated.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, August 25, 2021 7:26 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report for D16-00072

Thank you for this report. We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Tuesday, August 24, 2021 5:32 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)