



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

February 26, 2019

Re: Animal Welfare Assurance
A3261-01 [OLAW Case 2G]

Dr. Jan M. Weisenberger
Senior Associate Vice President
for Research
Ohio State University-Columbus
(b) (4) Bricker Hall, 190 North Oval Mall
Columbus, OH 43210-1321

Dear Dr. Weisenberger,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 19, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The Ohio State University. According to the information provided, OLAW understands that mice were identified with swollen feet after being injected with Freund's complete adjuvant. The investigator had been directed to update the humane endpoint early removal criteria before injecting additional animals but this was not done and additional mice with swollen feet were found.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) reviewing a protocol amendment addressing early removal criteria, disapproving the amendment, and terminating the protocol. The investigator will submit new protocols for IACUC review. The NIH funding component was notified about the protocol termination.

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
Associate Director IACUC/IBC



February 19, 2019

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge One, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892

Janet M. Weisenberger
Senior Associate
Vice President for Research
614-247-4764 Phone

RE: Animal Welfare Assurance #A3261-01, D16-00168

Dear Dr. Morse:

This letter reports an incident of noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at The Ohio State University. The incident involved the conduct of a procedure that resulted in adverse effects to the feet of mice after the investigator had been told to submit an amendment to update the early removal criteria before injecting any additional animals. The Institutional Animal Care and Use Committee (IACUC) reviewed this issue at its convened monthly meeting on February 15.

The PI had been requested in March 2018 to update his early removal criteria (ERC) before injecting any additional animals due to the observation of swollen feet in mice injected with Freund's complete adjuvant, and was reminded of this requirement again in September 2018. The PI created an amendment to clarify the ERC, however it had not been reviewed or approved by the IACUC. The PI proceeded to inject mice in January 2019 that again exhibited the adverse effects. The amendment and incident was reviewed by the IACUC and the IACUC voted to disapprove the amendment and terminate the protocol. The PI is in the process of submitting new protocols for the work to be conducted. Some of the work in the protocol is funded by the National Institute of Neurological Disorders and Stroke (R01NS093073).

The Ohio State University remains committed to ensuring the proper care and treatment of animals used in research and teaching at the Institution. Funding agencies will be notified as needed. Please contact me at (b) (6) or weisenberger.21@osu.edu if you require any further information.

Sincerely,

(b) (6)

Janet M. Weisenberger, PhD
Senior Associate Vice President for Research

cc: Valerie Bergdall, OSU Attending Veterinarian
Peter Reiser, OSU IACUC Chair

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, February 25, 2019 10:13 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: report on a termination of an activity by the IACUC from D16-00168

Thank you for providing this report. 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

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From: (b) (6)
Sent: Friday, February 22, 2019 2:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: report on a termination of an activity by the IACUC from D16-00168

Attached is a letter from our Institutional Official regarding a termination of an activity by the IACUC at The Ohio State University. Please let me know if you have any questions.

(b) (6)



(b) (6)