



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

May 4, 2022

Re: Animal Welfare Assurance
#A3354-01 (OLAW Case 2F)

Dr. Stanley Halvorsen
Executive Director of Regulatory Support
Institutional Official
State University of New York - University of Buffalo
(b) (4) Capen Hall
Buffalo, NY 14260

Dear Dr. Halvorsen,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 18, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University at Buffalo, State University of New York. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University at Buffalo, State University of New York Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to euthanize animals based humane endpoints as described in the protocol. The final report states two mice reached humane endpoints based on weight loss. The noncompliance was identified during a Post-Approval Monitoring chart review. On December 16, 2021, two mice exhibited weight loss greater than 30% and animals are to be euthanized when 20% weight loss occurs. Both animals were found dead the following day.

The IACUC requested the Principal Investigator (PI) explain why the animals were allowed to exceed 20% weight loss. The committee stated the protocol must be amended to increase the weight loss threshold to 25% and the PI must submit a letter detailing how they will ensure appropriate oversight. Ultimately, the IACUC accepted the PI's corrective action plan to prevent recurrence of this incident. It is noted that this research is supported by PHS funding.

Based on its assessment of this explanation, OLAW understands that the University at Buffalo, State University of New York has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn
T. Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.05.04
07:17:23 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3354-2F



University at Buffalo

Research and Economic
Development

The State University of New York

April 18, 2022

Axel Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff,

The University at Buffalo, the State University of New York, in accordance with A3354-01 and PHS Policy IV.F.3, provides a report of non-compliance that occurred under PROTO202000086. The lab failed to euthanize two mice that reached humane endpoints as outlined in the protocol. The Laboratory Animal Facilities Director discovered the non-compliance incident during a PAM chart review. Once a mouse reaches 20% weight loss, the animal must be euthanized per the protocol. On 12/16/2021, one mouse reached 34.5% weight loss, and the other mouse reached a 33.2% weight loss. The mice were subsequently found dead on 12/17/2021. This study is supported by PHS funding.

On February 21, 2022, at a fully convened IACUC meeting, the committee determined the following actions must be completed to resolve the non-compliance incident. The committee requested the PI explain why the mice were allowed to exceed a 20% weight loss. The protocol must be amended to increase the weight loss threshold to 25%, and the PI must submit a letter stating how they will ensure appropriate oversight.

On March 21, 2022, at a fully convened IACUC meeting, the committee reviewed the PI's response. PI's response detailed why the mice were allowed to exceed the 20% weight loss threshold and how they will provide laboratory personnel with appropriate oversight. The PI has also submitted an amendment to the IACUC, increasing the weight loss endpoint to 25%. The IACUC committee has accepted the PI's corrective action plan to prevent future instances of non-compliance.

The University at Buffalo, State University of New York, 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 do not hesitate to contact myself or Rosemary Dziak, PhD, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Stanley W. Halvorsen, PhD
Executive Director, Regulatory Support
Institutional Official
The University at Buffalo

Cc:

(b) (6)

Rosemary Dziak, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, April 20, 2022 7:13 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: submitted noncompliance reports

Thank you for sending 4 reports, Dr. Halvorsen. We will send responses soon.

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