



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

April 5, 2022

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

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 March 8, 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 following up on an initial February 2, 2022 notification by email.

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: the conduct of animal activities without prior IACUC review and approval. The final report states 9 mice underwent a tail snipping procedure, which was not an approved procedure on the protocol.

The IACUC reviewed the Principal Investigator's (PI) description of how many animals underwent the procedure and how the PI will provide laboratory personnel with appropriate oversight. It is understood the PI also submitted an amendment to add the procedure to the protocol. The committee accepted the PI's corrective action plan to prevent future recurrence of this incident.

It is noted that this research is supported by NIH 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: 2022.04.05 10:53:39 -04'00'

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

cc: IACUC Contact



University at Buffalo

Research and Economic
Development

The State University of New York

February 2, 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, is providing this initial report of a noncompliance incident where the Principal Investigator (PI) performed activities under PROTO201900078, in which mice underwent a tail snipping procedure which is not approved on the protocol. This study is supported by PHS funding.

The IACUC opened an investigation of the noncompliance incident. The incidents occurred on more than one occasion during December of 2021. The CMLAF staff reported to the Clinical Veterinarian that mice more than 21 days old, had undergone a tail snipping procedure and the laboratory staff did not submit post-operative paperwork. The protocol is not currently approved for tail snipping. The Clinical Veterinarian reported the incident to the CMLAF Director and the CMLAF Director subsequently reported the incident to the IACUC on January 13, 2022. Since the initial report of tail snipping, no further incidents of noncompliance have been reported by the CMLAF staff. The total number of mice that had undergone this procedure is unknown.

The IACUC committee discussed the noncompliance issue on January 18, 2022, during a fully convened meeting with a quorum of members. The committee requested of the PI the following regarding this incident:

1. How many mice underwent the tail snipping procedure?
2. Describe the tail snipping procedure used.
3. The tail snipping procedure must be added to protocol by amendment.
4. The PI must provide the IACUC with a step-by-step outline for all genotyping or identification procedures listed under PROTO201900078 and use these outlines to train laboratory staff.
5. The PI must submit a letter stating how they will provide laboratory staff with appropriate oversight to ensure the issue does not occur again.

The PI has been notified of the committee requirements. Based on the PI's response, additional actions could be requested. A final report will be forthcoming pending the completion of the investigation and final determination by the IACUC committee.

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 Halvorsen, PhD
Executive Director, Regulatory Support

Cc:

(b) (6)

Rosemary Dziak, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 4, 2022 6:56 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-initial noncompliance report-PROTO201900078

Thank you for this report, Dr. Halvorsen. We will send a response soon.

Axel Wolff

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Wednesday, February 2, 2022 1:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <iacuc@research.buffalo.edu>; Rosemary Dziak <rdziak@buffalo.edu>; Vice President for Research and Economic Development <VPR@research.buffalo.edu>; (b) (6)
Subject: Buffalo-initial noncompliance report-PROTO201900078

Dear Dr. Wolff,

Please find attached correspondence providing a noncompliance initial report for IACUC protocol - PROTO201900078
- from the Institutional Official at the University at Buffalo.

Thank you,

Stanley W. Halvorsen, PhD
Assoc. Prof. of Pharmacology & Toxicology

Executive Director, Regulatory Support
Research & Economic Development
(b) (4) Capen Hall
Buffalo, NY 14260

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