



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 2C)

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 following up on an initial February 7, 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: administration of an unapproved analgesic to animals and failure to adhere to the IACUC-approved protocol. The final report states the noncompliance was revealed during a review of medical records. On December 14, 2021, two animals (swine) received the incorrect analgesic. The animals were scheduled to undergo a terminal procedure that required the placement of a fentanyl patch pre-operatively on December 13th. The animals instead received buprenorphine pre-operatively, which was not approved for use on the protocol. It was determined a second incident occurred on October 19, 2021 and involved an animal (swine) that underwent a survival procedure. The protocol stated animals were to receive gabapentin for 5 days every 12h post-operatively. However, the animal only received gabapentin for 3 days. No adverse effects were identified, and the animal did well throughout the study, per the report.

The IACUC reviewed the Principal Investigator's (PI) response and determined the PI did not include steps for pre- and post-operative care, and noted the protocol was not reviewed and amended. The committee sent a second letter to the PI requesting the missing information to resolve the noncompliance. The PI responded and requested the IACUC administratively close the protocol. The IACUC was notified of the protocol's closure on March 21, 2022 and the committee did not require any additional corrective actions.

It is noted that this research is not 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.

Page 2 – Dr. Halvorsen
May 4, 2022
OLAW Case A3354-2C

Sincerely,

Jacquelyn T.

Tubbs -S

Digitally signed by Jacquelyn
T. Tubbs -S

Date: 2022.05.04 07:25:38
+0400

Jacquelyn Tubbs, DVM, DACLAM

Senior Animal Welfare Program Specialist

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC Contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations



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, is providing a final report of a non-compliance incident where the Principal Investigator (PI) performed activities under PROTO201900198, swine did not receive the correct analgesic and, post-operative medication. A total of three swine were involved in the non-compliance incident. This study is not supported by PHS funding.

The IACUC opened an investigation of the non-compliance incident that took place in October 2021 and December 2021. The non-compliance incident was discovered during a review of medical records and was reported to the IACUC on January 12, 2022, by the CMLAF Director. On 12/14/2021, two swine received the incorrect analgesic. The animals were scheduled to undergo a terminal procedure that would have necessitated the placement of a fentanyl patch pre-operatively on 12/13/2021. Instead, buprenorphine was administered pre-operatively. The Clinical Veterinarian reviewed the buprenorphine dosage and determined that the laboratory staff provided adequate analgesia for this terminal procedure. However, the use of buprenorphine was not approved for the terminal procedure. The second incident occurred on 10/19/2021. The swine had undergone a survival trochlear replacement, and per the protocol, the swine was to receive five days of gabapentin every 12 hours post-operatively. The animal received gabapentin as per the protocol for three days but never received doses on the fourth and fifth days. There were no reports of adverse effects due to the missed gabapentin, and the swine continued to do well through the rest of the study.

A fully convened IACUC committee met on February 21, 2022, to discuss the PI's response to the non-compliance incident. The committee determined that the PI did not provide step-by-step operating procedures for pre and post-operative care, and the protocol was not reviewed and amended. A letter indicating how the PI will provide the laboratory staff with appropriate oversight was not submitted.

The IACUC committee sent the PI a second letter requesting the missing materials to resolve the non-compliance issue. On March 1, 2022, the PI requested the IACUC administratively

close PROTO201900198. The committee was informed of the protocol's closure at a fully convened meeting on March 21, 2022. The committee determined that no further corrective actions were required.

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
Institutional Official
The University at Buffalo

Cc:

(b) (6)

Rosemary Dziak, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-initial noncompliance report-PROTO201900198

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

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Monday, April 18, 2022 2:03 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <iacuc@research.buffalo.edu>; Vice President for Research and Economic Development <VPR@research.buffalo.edu>; Rosemary Dziak <rdziak@buffalo.edu>; (b) (6)
Subject: Buffalo-initial noncompliance report-PROTO201900198

Dear Dr. Wolff,

Please find attached correspondence providing a final report of noncompliance occurring under IACUC protocol PROTO201900198 from the Institutional Official at the University at Buffalo. Please note that in the initial report of this incident the letter incorrectly identified PROTO201900078 as the offending protocol.

Thank you,

Stanley W. Halvorsen, PhD
Assoc. Prof. of Pharmacology & Toxicology
Institutional Official for animal & human subject research

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

(b) (6)

[e-mail: stanh@buffalo.edu](mailto:stanh@buffalo.edu)



University at Buffalo

Research and Economic
Development

The State University of New York

February 7, 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 non-compliance incident where the Principal Investigator (PI) performed activities under PROTO201900078, swine did not receive the correct analgesic and, post-operative medication. A total of three swine were involved in the non-compliance incident. This study is not supported by PHS funding.

The IACUC opened an investigation of the non-compliance incident that took place in October 2021 and December 2021. The non-compliance incident was discovered during a review of medical records and was reported to the IACUC on January 12, 2022, by the CMLAF Director. On 12/14/2021, two swine received the incorrect analgesic. The animals were scheduled to undergo a terminal procedure that would have necessitated the placement of a fentanyl patch pre-operatively on 12/13/2021. Instead, buprenorphine was administered pre-operatively. The Clinical Veterinarian reviewed the buprenorphine dosage and determined that the laboratory staff provided adequate analgesia for this terminal procedure. However, the use of buprenorphine was not approved for the terminal procedure. The second incident occurred on 10/19/2021. The swine had undergone a survival trochlear replacement, and per the protocol, the swine was to receive five days of gabapentin every 12 hours post-operatively. The animal received gabapentin as per the protocol for three days but never received doses on the fourth and fifth days. There were no reports of adverse effects due to the missed gabapentin, and the swine continued to do well through the rest of the study.

The IACUC has noted that some amendments were not appropriately integrated into the Click system for this protocol. The issue was addressed with Click's parent company Huron.

A fully convened IACUC committee met on January 18, 2022, to discuss the non-compliance. The committee has determined that the following action must be completed to correct the non-compliance.

516 Capen Hall, Buffalo, NY 14260-1611
716.645.3321 (F) 716.645.6792
www.buffalo.edu/research

1. The PI must provide the IACUC with the step-by-step operating procedures on pre and post-operative care. This document must include medications, dosages, and dosage frequency for each medication.
2. The PI must review each experiment in the protocol to ensure that the final version of the protocol is correct.
3. The PI must submit a letter stating how they will provide laboratory staff with appropriate oversight to ensure the non-compliance issue does not occur again.

Based on the PIs response, additional corrective actions may be required.

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

Cc:

(b) (6)

Rosemary Dziak, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 9, 2022 7:21 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-initial noncompliance report-PROTO201900198

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

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Monday, February 7, 2022 12:25 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <iacuc@research.buffalo.edu>; Vice President for Research and Economic Development <VPR@research.buffalo.edu>; Rosemary Dziak <rdziak@buffalo.edu>; (b) (6)
Subject: Buffalo-initial noncompliance report-PROTO201900198

Dear Dr. Wolff,

Please find attached correspondence providing an initial noncompliance report for IACUC protocol
- PROTO201900198 - from the Institutional Official at the University at Buffalo.

Thank you,

Stanley W. Halvorsen, PhD
Assoc. Prof. of Pharmacology & Toxicology
Institutional Official for animal & human subject research

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

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e-mail: stanh@buffalo.edu