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

January 20, 2022

Re: Animal Welfare Assurance
#A3354-01 (OLAW Case 1Z)

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 January 7, 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 adhere to the IACUC-approved protocol. The final report states that rabbits underwent stereotaxic surgery and post-operative (post-op) analgesia doses were not administered. The Principal Investigator (PI) stated the incident occurred due to staff illness, a missing animal room key and locked animal room. As a result, 4 animals did not receive post-op analgesia as described in the protocol. Following self-report by the PI, a clinical veterinarian assessed the animals. In response, additional treatment under veterinary care was provided to one rabbit, as the other animals did not present post-op issues from the missed analgesic. Per the report, the rabbit is doing well following additional veterinary care.

The PI's report to the IACUC included a corrective action plan which included the following:

- The lab has established a new working procedure for post-operative care following rabbit surgery.
- The responsible members of the lab will contact the Laboratory Animal Facilities (LAF) vet staff to outline a post-operative plan to ensure analgesics are administered as outlined in the protocol.
- The lab received a new animal room key, and it is available to all protocol team members.
- Two protocol team members will be specifically assigned to the administration of post-operative medication.
- The lab will use Slack messaging software to confirm that post-operative medications have been given.
- The PI will review these messages and will contact protocol team members as needed to ensure medication has been administered.

The IACUC reviewed the incident and corrective action plan on December 20, 2021. The committee accepted plan and determined no additional actions were necessary. It is noted that the study is supported by NIH funding.

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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: 2022.01.20 13:34:40 -05'00'

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

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A3354-1C

University at Buffalo
Research and Economic Development
The State University of New York

January 7, 2022
~~December XX, 2021~~

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 noncompliance report that occurred under PMY22117Y, in which rabbits that underwent stereotaxic surgery missed doses of postoperative analgesia. The PI stated the issue arose from staff illness, a missing animal room key, and locked animal room. In total, four animals did not receive analgesic dosages as outlined in the protocol. The incident was self-reported by the PI. A clinical veterinarian ~~veterinary~~ assessed the animals; three of the four rabbits did not present any postoperative issues from the missed analgesic. However, the fourth rabbit did show signs of possible distress. The rabbit in question was prescribed Baytril and received two additional days of carprofen. It was reported that the rabbit is now doing well following veterinary care.

In the PI's report to the IACUC, they present the IACUC with a corrective action plan and have instituted the following changes to prevent further noncompliance incidents. The lab has established a new working procedure for postoperative care following rabbit surgery. The PI stated that the responsible members of the lab will contact the Laboratory Animal Facilities (LAF) vet staff to outline a postoperative plan to ensure analgesics are administered~~dration~~ as outlined in the protocol. The lab received a new animal room key, and it is available to all protocol team members. Two protocol team members will be specifically assigned to the administration of postoperative medication. The lab will use Slack messaging software to confirm that postoperative medications have been given. The PI will review these messages and will contact protocol team members as needed to ensure medication has been administered. This study is supported by NIH funding.

On December 20, 2021, the committee reviewed the noncompliance and the PI's corrective action plan. The IACUC committee has accepted the corrective action plan and determined that no further corrective action is needed.

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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,

[redacted] (b) (6)

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

Cc: [redacted] (b) (6)

Rosemary Dziak, IACUC Chair
[redacted] (b) (6)

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 10, 2022 7:33 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-noncompliance-PMY22117Y

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

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Friday, January 7, 2022 2:10 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>; [redacted] (b) (6)
Subject: [EXTERNAL] Buffalo-noncompliance-PMY22117Y

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Wolff,

Please find attached correspondence providing a noncompliance report for IACUC protocol PMY22117Y 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

Phone: [redacted] (b) (6)
e-mail: stanh@buffalo.edu

University at Buffalo
The State University of New York

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A3354 — 17

University at Buffalo
Research and Economic Development
The State University of New York

September 01, 2021

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 suspension and subsequent protocol closure report due to the Principal investigator's (PI) lack of response and oversight of the protocol, Proto201900160. On January 10, 2020 the IACUC approved a breeding only protocol that enable the PI to transfer their small mouse colony from Dartmouth College to the University at Buffalo. In March 2020, the colony exceeded the allotted animal numbers by 10 animals, an amendment was submitted to account for this increase and approved by designated member review. In April 2020, the PI again exceeded the allotted animal numbers. During this time the PI was asked to provide a more robust justification for the increase in animal numbers and add an intended experimental plan to the protocol. While the amendment was being worked on, breeding pairs were separated as to not further exceed that allotted animal numbers.

April 2020-April 2021, the PI made a few attempts to justify the animal numbers and add experiments to the protocol. The PI cited COVID 19 as a reason for the delay in completing the amendment. During this time the PI's mice had aged out and were no longer of optimal breeding age.

On May 4, 2021, the PI was sent an official IACUC correspondence stating that he needed to complete the amendment. The letter stated that the PI must contact the IACUC chair no later than May 14, 2021. The committee felt this was necessary due to past difficulties and misunderstandings that may have contributed to the delay in moving forward with the amendment. It was noted that failure to do so could result in the suspension of the protocol. The PI did not contact the IACUC Chair in the allotted time. The issue was discussed on May 17, 2021 at a fully convened IACUC meeting. The committee unanimously voted to suspend the protocol with the understanding that the protocol will be administratively closed if the PI continued to ignore all attempts at communication and does not complete the amendment. The remaining 29 mice were transferred to a holding protocol.

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www.buffalo.edu/research

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On June 14, 2021, the PI was sent an official IACUC correspondence stating that the PI had 30 days to contact the IACUC Chair to discuss the protocol. It was stated that after this 30 day period the PI's protocol would be closed and the remaining mice euthanized. On July 14, 2021, the PI was sent a final letter stating that the protocol will be administratively closed and the remaining 29 mice will be euthanized. This protocol is not supported by PHS funding.

A final modification request was sent to the PI on April 27, 2021 however the IACUC Chair and Administrative office were unable to reach the PI. Attempts at contact were made by email and phone, including calling the PI's cell phone. Overall, the PI has been recalcitrant and uncommunicative regarding justifying a continuation of this protocol. Additionally, the PI had not paid any per diem charges since July 2020.

On August 20, 2021, the IACUC Chair, Institutional Official (IO), Director of Research Compliance and IACUC Administrator met via Zoom to review the reasons for the suspension and closure of the protocol.

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)

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OLAW Division of Compliance Oversight (NIH/OD)

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, September 2, 2021 10:58 AM
To: Stanley Halvorsen
Cc: IACUC; Rosemary Dziak; (b) (6) Vice President for Research and Economic Development; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-noncompliance-Proto201900160_Initial

Thank you for providing this initial report. We will open a case file and await further information.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Wednesday, September 1, 2021 3:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <iacuc@research.buffalo.edu>; Rosemary Dziak <rdziak@buffalo.edu>; (b) (6) (b) (6) Vice President for Research and Economic Development <VPR@research.buffalo.edu>
Subject: Buffalo-noncompliance-Proto201900160_Initial

Dear Dr. Wolff,

Please find attached correspondence providing the initial report on IACUC protocol Proto201900160 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
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Phone: (b) (6)
e-mail: stanh@buffalo.edu

University at Buffalo
The State University of New York

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