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 2A)

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 perform aseptic technique. The final report states a laboratory was identified not using aseptic technique during a cannulation procedure. The incident was reported by a Department of Health Inspector. The individuals were noted performing surgery using non-sterile gloves. Also, the surgical field and surgical instruments were compromised, and non-sterile items were located within the surgical field. It is understood 32 mice underwent the procedure, and no complications were observed in the animals due to lack of aseptic technique.

On December 20, 2021, the IACUC reviewed the Principal Investigator's letter describing how they will provide laboratory personnel with appropriate oversight and ensure aseptic technique is adhered to. The individuals associated with the event completed their retraining requirements. It is understood the committee accepted the retraining of personnel and the investigator's corrective action plan.

It is noted the study 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: 2022.01.20 13:42:57 -05'00'

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

cc: IACUC Contact

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A3354-

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

January 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 a final report of non-compliance report that occurred under PMY09073N, in which individuals from the lab were observed not using aseptic technique during a cannulation procedure. The incident was reported by a Department of Health (DOH) Inspector. During the DOH inspection, two individuals were observed performing surgery using non-sterile gloves, and the sterile field was compromised, including some surgical instruments. A cellphone and laptop were also located within the sterile field. The individuals worked on a total of 32 mice. Neither the veterinary staff nor PI reported any complications due to the lack of aseptic technique. This study is supported by NIH funding.

On December 20, 2021, the committee reviewed the PI's letter outlining how they will provide laboratory personnel with appropriate oversight and ensure aseptic technique is followed. The staff members in question completed their retraining requirements. The IACUC committee has accepted the personnel retraining and 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 Halvorsen, PhD

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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 7:49 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-noncompliance-PMY09073N _Final

Thank you. We will send a response soon.
Axel Wolff

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Friday, January 7, 2022 4:26 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] Re: Buffalo-noncompliance-PMY09073N _Final

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Dear Dr. Wolff,

Please find attached correspondence providing the final report on IACUC protocol PMY09073N from the Institutional Official at the University at Buffalo.

Regards,

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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3354-2A

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

December 21, 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 an initial non-compliance report that occurred under PMY09073N, in which individuals from the lab were observed not using aseptic technique during a cannulation procedure. The incident was reported by a Department of Health (DOH) Inspector. During the DOH inspection, two individuals were observed performing surgery using not sterile gloves, and the sterile field was compromised, including the surgical instruments. A cellphone and laptop were also located in the sterile field. The individuals worked on a total of 32 mice. Neither the Veterinary staff nor PI reported any complications with these animals due to this incident. This study is supported by NIH funding.

On November 29, 2021, the committee reviewed the DOH report and noncompliance incident during a fully convened meeting with a quorum of members. The committee determined that the following steps must be completed:

1. The PI must submit a letter stating how they will provide laboratory staff with appropriate oversight and ensure aseptic technique is followed for all surgical procedures as outlined in the protocol and according to LAF SOP 2.A.3 (*Rodent Surgery*).

2. The staff members in question need to retake *Introduction to Surgery*, both the UBlearns on-line and the in-person components of the course, within 30 days of receiving this letter.

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.

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Thank you for your consideration of this matter.

Sincerely,

[redacted] (b) (6)

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

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: Wednesday, December 22, 2021 8:04 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-noncompliance-PMY09073N _Initial

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

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Tuesday, December 21, 2021 10:56 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <iacuc@research.buffalo.edu>; Rosemary Dziak <rdziak@buffalo.edu>; [redacted] (b) (6)
Vice President for Research and Economic Development <VPR@research.buffalo.edu>
Subject: [EXTERNAL] Buffalo-noncompliance-PMY09073N _Initial

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Dear Dr. Wolff,

Please find attached correspondence providing the initial report on IACUC protocol PMY09073N 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
Amherst, NY 14260

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

University at Buffalo
The State University of New York

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