



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 2B)

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 use aseptic technique during a surgical procedure. The final report states an individual was identified not using aseptic technique when performing an IACUC-approved surgical procedure. The Department of Health Inspector observed the incident and noted the individual's cell phone was within the sterile field and touched while wearing sterile gloves. The surgery was performed on a total of 3 rats. Per the report, the veterinary staff nor the Principal Investigator (PI) reported any complications due to the lack of aseptic technique.

The IACUC reviewed the PI's letter describing how laboratory personnel will be provided with appropriate oversight and ensured aseptic technique will be followed. The individual responsible for the incident has completed their retraining requirements. The committee accepted the retraining of personnel and the corrective action plan. It is noted that this 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

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

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2022.01.20 13:47:48
-05'00'

cc: IACUC Contact



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 that occurred under PROTO202100165 in which an individual from the lab was observed not using aseptic technique during a surgical procedure as described in the protocol. The incident was reported by a Department of Health (DOH) Inspector. During the DOH inspection, the individual's cell phone was within the sterile field, and they touched the phone several times while wearing sterile gloves. The individual had performed surgery on a total of three rats. 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 member 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
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)
Sent: Monday, January 10, 2022 7:50 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-noncompliance-PROTO202100165_Final

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

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Friday, January 7, 2022 4:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <iacuc@research.buffalo.edu>; (b) (6) Vice President for Research and Economic Development <VPR@research.buffalo.edu>; Rosemary Dziak <rdziak@buffalo.edu>
Subject: [EXTERNAL] Re: Buffalo-noncompliance-PROTO202100165_Final

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 the final report on IACUC protocol PROTO202100165 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: (b) (6)
e-mail: stanh@buffalo.edu

 **University at Buffalo**
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 PROTO202100165 in which an individual from the lab was observed not using aseptic technique during a surgical procedure as described in their approved protocol. The incident was reported by a Department of Health (DOH) Inspector. During the DOH inspection, the individual's cell phone was within the sterile field, and they touched the phone several times while wearing sterile gloves. The individual had performed surgery on a total of three rats. Neither the Veterinary staff nor the 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 non-compliance 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 during surgical procedures as outlined in the protocol and according to LAF SOP 2.A.3 (*Rodent Surgery*).
1. The staff members in question need to retake the institution's course, *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.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

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

Cc:

(b) (6)

Rosemary Dziak, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 22, 2021 8:02 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Buffalo-noncompliance-PROTO202100165 _Initial

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

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Tuesday, December 21, 2021 10:54 AM
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)
Vice President for Research and Economic Development <VPR@research.buffalo.edu>
Subject: [EXTERNAL] Buffalo-noncompliance-PROTO202100165 _Initial

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 the initial report on IACUC protocol PROTO202100165 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: (b) (6)
e-mail: stanh@buffalo.edu

