



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

June 6, 2022

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

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 May 19, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University at Buffalo, the State University of New York following up on an initial April 18, 2022 notification by email.

According to the information provided, this Office understands that the University at Buffalo 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 that cannulation procedures were performed on animals, but the procedure was not described in the protocol. The incident was self-reported by the Principal Investigator (PI), and the PI stated the cannulation procedure was not transferred into the protocol during the triennial submission. In response to the incident, the PI stated they would review the entire protocol to ensure all procedures were present and outlined in the protocol.

On March 21, 2022, the IACUC reviewed the incident and the PI's corrective action plan and required the following additional corrective actions:

- The PI must submit a letter detailing how they will ensure appropriate oversight to ensure the noncompliance does not occur again.
- The PI must determine the number of animals that underwent the unapproved procedure.

On April 18, 2022, the IACUC reviewed the PI's revised plan and noted that 45 rats underwent the cannulation procedure. Per the report, the committee accepted the PI's corrective action plan and explanation of events and required no additional measures to be taken.

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, the 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: 2022.06.06 10:30:23 -04'00'

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

cc: IACUC Contact



A3354-2H



University at Buffalo

Research and Economic  
Development

*The State University of New York*

May 19, 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 noncompliance report where cannulation procedures were performed under PROTO201900203. The cannulation procedure was not outlined in the protocol. The incident was self-reported by the PI. Per the PI, the incident occurred when entering the triennial into Click the protocol form. During the entry the cannulation procedure from the previous approved protocol was not transferred into Click. The PI stated that they would be reviewing the entire protocol to ensure all procedures were present and outlined in the protocol. On March 21, 2022, at a fully convened IACUC meeting, the committee reviewed the PI's response detailing the noncompliance incident and the PI's corrective action plan. Upon reviewing the documents, the committee determined that the PI must also submit a letter stating how they will ensure appropriate oversight to ensure the noncompliance does not occur again. The PI also needed to determine the number of animals that underwent the unapproved procedure. This study is supported by NIH funding.

On April 18, 2021, at a fully convened IACUC meeting, the committee reviewed PI's corrective action plan. The PI also stated that 45 rats underwent cannulation surgery. The committee accepted the corrective action plan and explanation of events. The committee determined that no further corrective action is needed, and the PI is sincere in ensuring the noncompliance does not reoccur.

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:** Friday, May 20, 2022 7:53 AM  
**To:** Stanley Halvorsen  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Buffalo-Final noncompliance report-PROTO201900203

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

Axel Wolff

**From:** Stanley Halvorsen <stanh@buffalo.edu>  
**Sent:** Thursday, May 19, 2022 8:47 AM  
**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:** [EXTERNAL] Buffalo-Final noncompliance report-PROTO201900203

Dear Dr. Wolff,

Please find attached correspondence providing the final noncompliance report for IACUC protocol  
- PROTO201900203 - 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

(b) (6)

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







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 an initial report of non-compliance where cannulation procedures were performed under PROTO201900203, but the procedure is not outlined in the protocol. The incident was self-reported by the PI. Per the PI, the incident occurred when entering the triennial into Click from the old paper protocol form. During the switch, the cannulation procedure was not transferred into Click. The PI stated that they would be reviewing the entire protocol to ensure all procedures were present and outlined in the protocol. This study is supported by NIH funding.

On March 21, 2022, at a fully convened IACUC meeting, the committee reviewed the PI's response detailing the non-compliance incident and the PI's corrective action plan. Upon reviewing the documents, the committee has started an investigation into this non-compliance issue. The IACUC committee has determined that the PI must also submit a letter stating how they will ensure appropriate oversight to ensure the non-compliance does not occur again and the number of animals that underwent the procedure. Based on the PI's response, more corrective actions could be requested.

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:** Stanley Halvorsen <stanh@buffalo.edu>  
**Sent:** Monday, April 18, 2022 2:25 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** IACUC; Rosemary Dziak; Vice President for Research and Economic Development;  
(b) (6)  
**Subject:** U.Buffalo - noncompliance report-PROTO202000086  
**Attachments:** 2line\_color-small.jpg; Untitled attachment 00081.html;  
Wolff\_Noncompliance\_PROTO202000086.docx; Untitled attachment 00084.html

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Dear Dr. Wolff,

Please find attached correspondence providing a noncompliance report for IACUC protocol - PROTO202000086 - 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

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



**Wolff, Axel (NIH/OD) [E]**

---

**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Wednesday, April 20, 2022 7:13 AM  
**To:** Stanley Halvorsen  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** submitted noncompliance reports

Thank you for sending 4 reports, Dr. Halvorsen. We will send responses soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW