



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 20, 2022

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

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 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, the State University of New York. According to the information provided, OLAW understands that laboratory personnel performed survival cannula implant surgery, followed by non-survival microdialysis surgery one week later, on twenty mice without prior IACUC approval on a PHS supported study.

The corrective actions consisted of the IACUC approving the Principal Investigator's (PI's) corrective action plan that included submission of a protocol amendment to add survival cannulation and non-survival microdialysis surgeries. In addition, the IACUC also mandated that the PI submit a memo describing the oversight procedures to prevent recurrence of similar incidents of noncompliance.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee -

S

Digitally signed by Neera V.
Gopee -S
Date: 2022.05.20 11:22:44 -04'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

cc: IACUC Chair



Division of Compliance Oversight

Record of Call for Case # A3354-2E

Date & Time	Message	Initials
5/20/22 at 9:43 am	Called Dr. Rosemary Dziak to confirm species involved in the noncompliance (b) (6) She will call back with the requested information.	NVG
5/20/22 at 9:55 am	Dr Dziak returned call to confirm that the species involved in the noncompliance were mice	NVG



University at Buffalo

Research and Economic Development

The State University of New York

May 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 where cannulation and microdialysis procedures were performed under PMY41040Y, but not listed on the protocol. The incident was self-reported by the PI on March 7, 2022. Per the PI, the protocol was not amended appropriately to incorporate the cannula implantation component as part of the survival stereotactic surgery procedure. The lab performed the cannula implant surgeries from November 22, 2021, to November 26, 2021. The animals underwent a non-survival microdialysis surgery one week later. Twenty animals were involved in the non-compliance incident. The PI submitted a corrective action plan that included adding a cannulation survival surgery and microdialysis non-survival surgery amendment to the protocol. On March 21, 2022, during a fully convened IACUC meeting, the committee determined that the PI must submit a letter stating how they will ensure oversight of the lab to prevent this non-compliance from reoccurring. This study is supported by PHS funding.

On April 18, 2022, at a fully convened IACUC meeting, the committee reviewed the PI's response to the additional corrective action request. The committee reviewed the letter stating how they will oversee their laboratory staff to ensure the non-compliance does not occur again. The committee accepted the corrective action plan and determined that no further corrective action is needed.

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: Wednesday, May 18, 2022 9:50 AM
To: Stanley Halvorsen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: U.Buffalo-initial noncompliance report-PMY41040Y

Thank you. We will respond soon.
Axel Wolff

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Wednesday, May 18, 2022 9:17 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>
Subject: [EXTERNAL] Re: U.Buffalo-initial noncompliance report-PMY41040Y

Dear Dr. Wolff,

Please find attached correspondence providing a noncompliance final report for IACUC protocol - PMY41040Y - 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)



On Apr 13, 2022, at 7:23 AM, OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> wrote:

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

From: Stanley Halvorsen <stanh@buffalo.edu>
Sent: Tuesday, April 12, 2022 2:12 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> (b) (6)
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Buffalo, NY 14260

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e-mail: stanh@buffalo.edu

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University at Buffalo

Research and Economic
Development

The State University of New York

April 12, 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

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On March 21, 2022, at a fully convened IACUC meeting, the committee reviewed the PI's response. PI's response detailing the non-compliance incident and the PI's corrective action. The IACUC committee has determined that the PI must submit a letter stating how they will ensure appropriate oversight to ensure the non-compliance does not occur again.

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
The University at Buffalo

Cc:

(b) (6)

Rosemary Dziak, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

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Axel Wolff

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