



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
A3205-01 [OLAW Case O]

Ms. Sheila Garrity
Executive Director
Research Integrity and Compliance
George Washington University
2121 Eye Street, N.W., (b) (4)
Washington, DC 20052

Dear Ms. Garrity,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 27, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at George Washington University, following up on an initial report on February 15, 2022. According to the information provided, OLAW understands that a cohort of post-surgical mice failed to receive the full regimen of analgesia and were not monitored following the procedure which contributed to clinical signs of pain/distress and one death. In addition, the mice had been subjected to two consecutive unapproved anesthetic inductions.

The corrective actions consisted of retraining the Principal Investigator (PI) and staff on animal welfare regulations, aseptic surgery, anesthesia/analgesia, post-operative monitoring, recordkeeping, and humane endpoints. The laboratory was placed on enhanced post-approval monitoring.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. OLAW recommends consideration by the Attending Veterinarian and PI as to whether long acting/sustained release analgesics would be advisable for this type of study. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

May 27, 2022

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

The George Washington University (GW), in accordance with Assurance D16-00128 (formerly A3205-01) and the Public Health Service (PHS) Policy IV.F.3., provides this report of non-compliance regarding an incident in which analgesics were not provided in accordance with the protocol following a surgical event.

The animals involved in the non-compliance event were funded by the National Heart, Lung, and Blood Institute (NHLBI). The grant number is **1K08HL129072-05**.

At 5pm on January 26, 2022, the veterinary staff identified a dead mouse and several more mice that were displaying symptoms of pain and distress (e.g. severely hunched postures, depression, etc.). The veterinary staff immediately called the PI to inquire about these mice. During the phone call, the PI stated that these mice underwent surgery the day prior, at which time they received one dose of buprenorphine. The mice did not receive any further doses of analgesia, nor were they monitored since the time of surgery. According to the IACUC protocol, mice were to be given buprenorphine at 0.2mg/kg SC BID x 48 hours post-surgery. However, the lab did not follow this analgesic plan.

The PI also noted that the mice underwent two anesthetic inductions. The first induction was for the surgery. The mice were allowed to recover, and then were induced for a second time to allow the PI to take a picture of the surgical wound. This was not approved in the IACUC protocol.

The IACUC discussed this matter at a convened meeting with a quorum on February 14, 2022. The Committee determined that the following corrective actions be taken:

1. The PI and personnel on the protocol must undergo a hands-on training on the following topics:
 - a. Animal Welfare Regulations
 - b. Aseptic Surgery
 - c. Anesthesia/Analgesia
 - d. Post-operative Monitoring

- e. Recordkeeping
- f. Humane Endpoints
- 2. A post-approval monitoring (PAM) visit must be performed during the next set of surgeries.

The PI and the personnel listed on the protocol completed the hands-on training on February 22, 2022.

A PAM visit was performed on May 10th, 2022. The PAM monitor observed a minor survival surgery and no significant deficiencies were noted.

The George Washington University is committed to protecting the welfare of animals used in research, as well as the individuals that work directly with these animals, and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact (b) (6)

Thank you for your consideration of this matter.

Sincerely,

Sheila R. Garrity

Digitally signed by Sheila R. Garrity
DN: cn=Sheila R. Garrity, o=The George Washington
University, ou=Office of the Vice President for
Research, email=srgarrity@gwu.edu, c=US
Date: 2022.05.31 15:59:58 -04'00'

Sheila Garrity, JD, MPH, MBA
Institutional Official
Associate Vice President for Research Integrity
The George Washington University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 1, 2022 11:09 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Final Report - D16-00128 (A3205-01)

Thank you for this corrected report, (b) (6) I will switch this out with the other letter and shred it. I'll send a response to the IO shortly.

Axel Wolff

From: (b) (6) On Behalf Of IACUC
Sent: Wednesday, June 1, 2022 11:05 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Re: [EXTERNAL] Final Report - D16-00128 (A3205-01)

This is the correct final report.

IACUC Office

The George Washington University

(b) (4)

2300 I Street NW

Washington D.C. 20052

(b) (6)

E-mail: iacuc@gwu.edu • **Website:** [GWU IACUC](http://www.gwu.edu/~iacuc)

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On Wed, Jun 1, 2022 at 10:20 AM OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> wrote:

Hello (b) (6)

OLAW will accept this submission as a preliminary report as it only identifies a serious noncompliance, but does not offer the corrective actions. If you have a response from the Institutional Official outlining how the requirements of the Assurance and *Guide for the Care and Use of Laboratory Animals* are being met, please submit this to OLAW for evaluation.

Axel Wolff, M.S., D.V.M.

Deputy Director, OLAW

From: [REDACTED] (b) (6) On Behalf Of IACUC
Sent: Wednesday, June 1, 2022 9:48 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Sheila Garrity <sgarrity@gwu.edu>; [REDACTED] (b) (6)
Subject: [EXTERNAL] Final Report - D16-00128 (A3205-01)

To Whom It May Concern:

This is a final report of a non-compliance that occurred at The George Washington University, assurance # D16-00128 (A3205-01) on January 26, 2022.

The animals involved in the non-compliance situation were funded by HHS/NIH/National Heart, Lung, and Blood Institute. The grant number is 1K08HL129072-01A1. The funding coordinator has not yet been notified of this situation.

Please find the attached memo regarding details of the incident and all corrective action measures being completed.

Thank you,

[REDACTED] (b) (6)

Wolff, Axel (NIH/OD) [E]

A3205-0

From: IACUC <iacuc@email.gwu.edu>
Sent: Tuesday, February 15, 2022 1:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: Re: [EXTERNAL] Preliminary Report - D16-00128 (A3205-01)

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.

Hello Dr. Wolff,

We kept missing each other on the phone! 😊 I will be sure to schedule a time to call you in the future.

Thank you so much!

IACUC Office

The George Washington University

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2300 I Street NW

Washington D.C. 20052

(b) (6)

E-mail: iacuc@gwu.edu • **Website:** GWU IACUC

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On Tue, Feb 15, 2022 at 12:40 PM OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> wrote:

Thank you for this comprehensive preliminary report, (b) (6) We will open a new case file and look forward to receiving the final report from the IO.

You are always welcome to call us however it is best to set up a phone appointment to ensure contact.

Axel Wolff, M.S., D.V.M.

Deputy Director, OLAW

From: IACUC <iacuc@email.gwu.edu>
Sent: Tuesday, February 15, 2022 10:11 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Sheila Garrity <sgarrity@gwu.edu>
Subject: [EXTERNAL] Preliminary Report - D16-00128 (A3205-01)

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.

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At 5pm on January 26, 2022, the veterinary staff identified a dead mouse and several more mice that were displaying symptoms of pain and distress (e.g. severely hunched postures, depression, etc.). The veterinary staff immediately called the PI to inquire about these mice. During the phone call, the PI stated that these mice underwent surgery the day prior, at which time they received one dose of buprenorphine. The mice did not receive any further doses of analgesia, nor were they monitored since the time of surgery. According to the IACUC protocol, mice are to be given buprenorphine at 0.2mg/kg SC BID x 48 hours post-surgery. However, this analgesic protocol was not being followed.

The PI also noted that the mice underwent two anesthetic inductions. The first induction was for the surgery. The mice were allowed to recover, and then were induced for a second time to allow the PI to take a picture of the surgical wound. This was not approved in the IACUC protocol.

The IACUC discussed this matter at the most recent full committee meeting. The IACUC determined that the following corrective actions be implemented:

- A noncompliance letter will be sent to the PI. The letter will indicate that continued noncompliance will result in a protocol suspension.
- PI and animal user training

- Animal Welfare Regulations
- Aseptic Surgery
- Anesthesia/Analgesia
- Post-operative Monitoring
- Recordkeeping
- Humane Endpoints

- Post-Approval Monitoring visits

A final report will be sent to OLAW from the IO no later than May 20, 2022.

This preliminary report has been submitted by:

(b) (6)

(b) (6)

IACUC Office

The George Washington University

(b) (4)

2300 I Street NW

Washington D.C. 20052

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