



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 12, 2023

Re: Animal Welfare Assurance  
A3195-01 [OLAW Case 5J]

Dr. Mary Klotman  
Dean, School of Medicine and  
Vice Chancellor for Health Affairs  
Duke University Medical Center  
Duke South Clinic – 200 Trent Drive  
(b) (4) Davidson Building  
Durham, NC 27710

Dear Dr. Klotman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 11, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Duke University following up on an initial March 31, 2023 notification by telephone.

According to the information provided, this office understands that the Duke University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to use of drugs beyond the post-puncture discard date. The final report states buprenorphine-SR was administered as pre- and post-surgical analgesia to ~225 mice after the manufacture labeled post-puncture discard-date. It is stated the buprenorphine SR was within the labeled expiration date, and all animals associated with the incident exhibited no signs of post-surgical pain/distress during monitoring. In response to the incident, the following corrective action plan was developed:

- The Principal Investigator received a post-approval monitoring visit and a comprehensive audit of their anesthesia and analgesia drug storage and monitoring process by the Duke Office of Animal Welfare Assurance (e.g., Duke IACUC administrative office) to ensure compliance.
- Refinements to the laboratory's drug monitoring process were made to ensure drugs are removed from use prior to their expiration or discard-date.
- Re-education of laboratory members on the refined drug monitoring process occurred.

Per the report, Duke IACUC reviewed the matter at the March 23, 2023 meeting and determined it to be reportable to OLAW. The committee found the corrective actions to be appropriate and no further actions were required.

It is noted that this research is associated with PHS-funding and/or other funding sources with OLAW oversight. Based on its assessment of this explanation, OLAW understands that the Duke University 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.

Page 2 – Dr. Klotman  
May 12, 2023  
OLAW Case A3195-5J

Sincerely,

Jacquelyn T.

Tubbs -S

Digitally signed by Jacquelyn T.  
Tubbs -S  
Date: 2023.05.12 08:09:05  
-0400

Jacquelyn Tubbs, DVM, DACLAM

Senior Animal Welfare Program Specialist

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC Contact



Duke University  
Durham, North Carolina 27705



Office of Animal Welfare Assurance  
Campus Mail: Hock Plaza Box 2724  
US Mail: 2424 Erwin Road; Suite 606; Durham, NC 27705

Voice: 919.668.6720  
Fax: 919.668.6725

<https://myresearchpath.duke.edu/topics/conduct-research-animals>

April 11, 2023

Duke University; Animal Welfare Assurance # D16-00123 (A3195-01)

Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

Duke University, in accordance with PHS Policy IV.F.3., provides this report of an incident, which involved an animal activity conducted or supported with PHS-funds or other funds with OLAW oversight. This incident was reviewed and determined to be reportable by the Duke Institutional Animal Care & Use Committee (IACUC).

**Reportable requirement:** Serious deviation from the provisions of the *Guide*.

**Preliminary report:** A preliminary, verbal report was provided to Dr. Jacquelyn Tubbs by Anna Hampton (Duke University Office of Animal Welfare Assurance Director and IACUC Chair) on March 31, 2023.

**Number of animals affected:** Approximately 225 mice

**Date:** Identified February 2, 2023

**Description, outcome, and actions taken:** Buprenorphine SR was administered for pre- and post-surgical analgesia to approximately 225 mice after the manufacture labeled 28 post-puncture discard-date. The buprenorphine SR was within the labeled expiration date. All animals reached a surgical plane of anesthesia for the procedure and no signs of post-surgical pain or distress was identified in these animals during monitoring.

Corrective actions to prevent reoccurrence included:

- The Principal Investigator received a post-approval monitoring visit and a comprehensive audit of their anesthesia and analgesia drug storage and monitoring process by the Duke Office of Animal Welfare Assurance (e.g., the Duke IACUC administrative office) to ensure compliance.
- Refinements to the laboratory's drug monitoring process were made to ensure drugs are removed from use prior to their expiration or discard-date.
- Re-education of laboratory members on the refined drug monitoring process occurred.

**Conclusion:** The Duke IACUC completed its investigation and performed final review of the issue at the March 23, 2023 IACUC meeting. The Duke IACUC determined that the incident was reportable to regulatory, granting, and oversight bodies, where applicable. In addition, the IACUC determined that the corrective actions were appropriate and no further actions were necessary. The Duke IACUC considers this incident closed.

This item was reported to Duke grants management to ensure compliance with the terms and conditions of the grant or award.

The Duke University 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 contact Anna Hampton, DVM, IACUC Chair at [Anna.Hampton@Duke.edu](mailto:Anna.Hampton@Duke.edu) or (b) (6)



Duke University  
Durham, North Carolina 27705



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Voice: 919.668.6720  
Fax: 919.668.6725  
<https://myresearchpath.duke.edu/topics/conduct-research-animals>

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dr. Mary E. Klotman  
Duke University  
Dean, School of Medicine  
Vice Chancellor for Health Affairs  
Institutional Official

**McCoy, Devora (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, April 18, 2023 9:21 AM  
**To:** Anna Hampton  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Duke OLAW Report (Assurance # A3195-01 / D16-00123)

Good morning Dr. Hampton,

Thank you for sending us this final report for case A3195-5J and we will send an official response soon.

Best,  
Devora

Devora McCoy, BS, MBA ([pronunciation](#))  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

**From:** Anna Hampton <[anna.hampton@duke.edu](mailto:anna.hampton@duke.edu)>  
**Sent:** Monday, April 17, 2023 8:01 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Subject:** [EXTERNAL] Duke OLAW Report (Assurance # A3195-01 / D16-00123)

Dear OLAW,

Please see the attached final report for Duke University (Assurance # A3195-01 / D16-00123).

Please do not hesitate to contact me if you have any questions or need additional information.

Anna

Anna Hampton, DVM, DACLAM, DACAW, CPIA  
Director, Office of Animal Welfare Assurance  
Chair, Institutional Animal Care and Use Committee  
Duke University  
2424 Erwin Road, (b) (4)  
Durham, NC 27705  
(b) (6)

[Duke Animal Program Website](#)

A3195-5J



## Initial Report of Noncompliance

By: J. Tubbs

Date: 03-31-2023

Time: 3:06pm

Name of Person reporting: Anna Hampton  
Telephone #:  
Fax #:  
Email: Anna.Hampton@duke.edu

Name of Institution: Duke University  
Assurance number: A3195-01

Did incident involve PHS funded activity? TBD  
Funding component:  
Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

PI used buprenorphine SR after 28d puncture date, it was still unexpired but used after the puncture date. No observed pain and/distress.

Species involved: Mice  
Personnel involved:  
Dates and times: Feb 2022  
Animal deaths: None

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Projected submission to OLAW of final report from Institutional Official:  
60-90d

OFFICE USE ONLY  
Case # \_\_\_\_\_