



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

August 2, 2023

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

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 June 29, 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 May 11, 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 administration of an analgesic beyond the post-puncture discard date. The final report states an incident identified on April 13, 2023 involved the administration of buprenorphine SR for pre- and post-surgical analgesia to 6 mice after the manufacture labeled 28 post-puncture discard-date. It is also stated the buprenorphine SR was not expired and all animals reached a surgical plane of anesthesia for the procedure. Per the report, no signs of post-surgical pain or distress were identified in the mice during monitoring.

In response to the incident, the following corrective actions were implemented:

- The Principal Investigator met with animal program leadership to review the concern.
- Refinements to the laboratory's drug monitoring processes 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.

Additionally, the following actions occurred program wide by the Duke Animal Care and Use Protocol:

- Enhanced outreach to Principal Investigators reminding them of the established requirement of monitoring expiration dates and discarding analgesics and anesthetic agents at the time of expiration.
- Provided and will continue to provide monthly notifications to the entire research community reminding them to check for expired analgesics and anesthetics.
- Increased animal program efforts to disseminate the animal program template for "Monthly Monitoring for Drug/Substance Expiration" to the entire research community.

The IACUC determined these corrective actions were appropriate and no further actions were required. It is noted the activity was conducted or supported with PHS-funds or other funds with OLAW oversight. However, the funding source is not specified in the report. In the future, please note the source of funding and provide grant numbers for all PHS, HHS, BARDA, NSF, or NASA supported work.

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.

Sincerely,
Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn
T. Tubbs -S
Date: 2023.08.02 15:12:53
-04'00'

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>

June 29, 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 Dr. Anna Hampton (Duke University Office of Animal Welfare Assurance Director and IACUC Chair) on May 11, 2023.

Number of animals affected: 6 mice

Date: Identified April 13, 2023

Description, outcome, and actions taken: Buprenorphine SR was administered for pre- and post-surgical analgesia to 6 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 met with animal program leadership (i.e., the Attending Veterinarian, the IACUC Chair, and/or their designees) to review the concern.
- Refinements to the laboratory's drug monitoring processes 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.

In addition the Duke Animal Care and Use Protocol has performed the following items program wide:

- Enhanced outreach to Principal Investigators reminding them of the established requirement of monitoring expiration dates and discarding analgesics and anesthetic agents at the time of expiration.
- Provided and will continue to provide monthly notifications to the entire research community reminding them to check for expired analgesics and anesthetics.
- Increased animal program efforts to disseminate the animal program template for "Monthly Monitoring for Drug/Substance Expiration" to the entire research community.

Conclusion: The Duke IACUC completed its investigation and performed final review of the issue at the June 22, 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.



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>

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 or (b) (6)

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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, July 13, 2023 9:01 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 A3195-5K 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

From: Anna Hampton <anna.hampton@duke.edu>
Sent: Wednesday, July 12, 2023 3:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <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](#)



A3195-5K

Initial Report of Noncompliance

By: J. Tubbs

Date: 05-11-2023

Time: 850A

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?

6 rats supported with DHHs funds, given Bup-SR beyond discard date, no signs pain/distress.

Species involved:

Personnel involved:

Dates and times: April 2023 identified event

Animal deaths:

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 # _____