



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 24, 2022

Re: Animal Welfare Assurance
A3823-01 [OLAW Case 10D]

Dr. Mary Dickinson
Vice President and Dean of Research
Baylor College of Medicine
One Baylor Plaza, BCM335
Houston, TX 77030

Dear Dr. Dickinson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 20, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Baylor College of Medicine. According to the information provided, OLAW understands that five mice failed to receive the complete analgesic regimen outlined in the protocol following an aortic constriction surgery. The pre-surgical analgesics had been given but not the post-operative drug. One mouse died and two of five in the cohort appeared sickly.

The corrective actions consisted of the veterinarian examining and monitoring the mice and giving the necessary analgesics. The mice were doing well following treatment, the Principal Investigator (PI) consulted with the Attending Veterinarian regarding continuing care, and the PI counseled the laboratory staff to follow the protocol and to administer analgesics as approved therein. Preventive measures include the use of surgical checklists, enhanced oversight of post-operative care, closer monitoring of the project by the PI, and the placement of the laboratory on enhanced post-approval monitoring. The Institutional Animal Care and Use Committee (IACUC) chair counseled the PI and staff, the staff members were retrained, and future noncompliance will result in escalating sanctions.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Contact



A3823-100

OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

(713) 798 – 2104
(713) 798 – 2721 FAX
mdickins@bcm.edu

CONFIDENTIAL

May 20, 2022

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
olawdco@mail.nih.gov

RE: Assurance #D16-00475

Dear Dr. Morse,

As Institutional Official for Baylor College of Medicine (BCM), I have the duty to inform you of our Institutional Animal Care and Use Committee's (IACUC) recent finding in animal research after an assessment of the following protocol:

Protocol: AN-7226: Genetic and epigenetic regulation of cardiovascular and metabolic diseases

Species: Mice

Funding Sources: National Institutes of Health (NIH) R01-HL143067 and R43-HL160236

For this investigator's first incident of this nature, the IACUC determined that the following finding constituted *serious noncompliance*¹ with the federal regulations:

3/18/22 - Post-operative Analgesic²

During a routine facility health evaluation, a cage of five adult mice was found with two mice with ruffled fur and one mouse expired. not alive. Upon inquiry, the five mice had undergone a transverse aortic constriction surgery two days before and received the primary analgesic Buprenorphine (sustained-release) and Meloxicam pre-operatively, as described in the IACUC approved protocol. However, the mice did not receive a dose of Meloxicam the day after surgery. The remaining four mice were evaluated by a clinical veterinarian, monitored daily and given the post-operative analgesic regimen, which included additional Buprenorphine and daily Meloxicam, as described in the IACUC-approved protocol. All mice were in good health and are expected to complete the study regimen.

5/10/2022 – Determination, review and approval of the surgical oversight plan at a fully convened IACUC meeting

¹ PHS Policy IV.F.3.a: "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions

² PHS Policy IV.C.1.b: "Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator."

To protect the welfare of animals and prevent future recurrence, the IACUC required the following corrective actions:

1. The Principal Investigator (PI) consulted with the Attending Veterinarian on the best approach to be followed for continuing care for these animals.
2. The PI held a laboratory meeting with all research staff performing surgeries, and reviewed and discussed the required analgesic regimen and emphasized the need to monitor animals after surgery and administer analgesics as described in the approved protocol.
3. To prevent future recurrence of this issue, the PI implemented a plan that requires the surgeon to set active alarms for all post-operative care.
4. The PI will confirm in writing monthly compliance (checklist, lab meeting summary, or description of material reviewed) through oversight and review of records for procedures for the next six months, and that documentation will be reviewed when the records are reviewed.
5. Two comprehensive PAM reviews focused on surgery, will be conducted within the next six months.
6. The IACUC Chair has conducted a mandatory meeting with the PI and all laboratory personnel to discuss the determination letter, required corrective actions, and plans for ensuring compliance.
7. All research personnel have completed the interactive training session "Top 10 Pitfalls and How to Avoid Them."
8. If compliance with the IACUC approved plan or the increased oversight is not maintained, there will be escalating punitive corrective actions including, but not limited to suspension of all surgical privileges.

This finding of non-compliance does not appear to pose any potential or actual effect on costs related to this PHS-supported research.

This notification will also be sent to AAALAC International and the National Institutes of Health.

Please do not hesitate to contact me if you have any questions.

Sincerely,

(b) (6)

Mary E. Dickinson, Ph.D.
Sr. Vice President and Dean of Research
Institutional Official
Baylor College of Medicine

cc: Principal Investigator
Department Chair
Research Compliance Services files

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 23, 2022 7:05 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Reports- Assurance D16-00475

Thank you for these reports (b) (6) We will send responses soon.

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

From: (b) (6)
Sent: Friday, May 20, 2022 5:41 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] OLAW Reports- Assurance D16-00475

Dear Dr. Morse,

Please find the attached notifications of research non-compliance as determined by our IACUC, and sent on behalf of Dr. Mary Dickinson, Institutional Official.

Please feel free to contact me if you have any questions.

Thank you,

(b) (6)