



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

February 23, 2022

Re: Animal Welfare Assurance
A3823-01 [OLAW Case 9X]

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 February 15, 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 33 mice received expired pre-operative analgesic and did not receive the post-operative analgesic described in the approved protocol. No adverse effects were reported due to receipt of the expired agent or missing one.

The corrective actions consisted of the Principal Investigator counseling the laboratory staff on following the protocol as approved, labeling and separating the expired drugs, developing a monthly drug inventory system to track expiration dates, and having staff undergo retraining. The PI and staff were counseled and the laboratory was placed on enhanced post-approval monitoring.

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 institution 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



A3823-9X

OFFICE OF RESEARCH

One Baylor Plaza, BCM310
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CONFIDENTIAL

February 15, 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 findings in animal research after an assessment of the following protocol:

Protocol: AN-8400: Inflammation Modulating Polymer Scaffold for Wound Healing

Species: Mice

Funding Source: non-PHS Funding

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

Expired Analgesic^{ii, iii} and Post-operative Analgesia^{iv}

1/13/2022 – While conducting a routine post approval monitoring (PAM) visit, it was found that expired Buprenorphine SR was administered as a pre-procedure analgesic to 33 mice. All mice were monitored following the dorsal wound procedure as described in the approved protocol and none of the mice had any adverse effects.

During the same PAM visit, it was found that the same 33 mice did not receive post-operative meloxicam SR as described in the IACUC-approved protocol. All of the mice were monitored and euthanized at set experimental endpoints and showed no signs of unusual pain or distress.

ⁱ 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 taken with respect to: a. any serious or continuing noncompliance with this Policy;"

ⁱⁱ BCM IACUC "Guidelines for the Use of Expired Drugs, Substances, and Medical Material: "For survival procedures, the use of expired drugs and medical material such as fluids, catheters, or suture material is not acceptable veterinary practice and does not constitute adequate veterinary care."

ⁱⁱⁱ 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."

^{iv} 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."

2/08/2022 – Determination, review and approval of the surgical oversight plan at a fully convened IACUC meeting

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

1. The Principal Investigator (PI) held a laboratory meeting with the research staff, reviewed and discussed the approved protocol procedures and reminded everyone about their responsibility to know which procedures are approved on the protocol.
2. The PI and research staff labeled the expired drugs as expired and placed them into a separated expired drug section within their locked controlled drugs box.
3. The PI developed a monthly drug inventory monitoring system to monitor all the drugs in their possession to ensure that everything is in-date and appropriately labeled.
4. The IACUC Chair will conduct a mandatory meeting with the PI and laboratory personnel to discuss the determination letter, required corrective actions, and plans for ensuring compliance.
5. Two comprehensive PAM reviews focused on surgery, will be conducted within the next six months.
6. All research personnel are required to complete the interactive "Top 10 Pitfalls in Animal Research and how to Avoid Them" training.
7. 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.

This notification will also be sent to AAALAC International and the non-PHS funding source according to the terms and conditions of the award.

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

Sincerely,

(b) (6)

Mary Dickinson, PhD
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: Friday, February 18, 2022 7:45 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Report- Assurance D16-00475

Thank you for this report. We will send a response soon.

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

From: (b) (6)
Sent: Tuesday, February 15, 2022 4:29 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] OLAW Report- Assurance D16-00475

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.

Dear Dr. Morse,

Please find the attached notification 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)

