



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 4, 2022

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

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 April 26, 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 29 mice involved in a bone fracture study failed to receive the second analgesic specified in the approved protocol. The animals had received the initial analgesic which was a long acting drug and were reported to be in good condition.

The corrective actions consisted of having the mice evaluated by a veterinarian and providing the second analgesic for three consecutive days. The mice recovered without incident. The Principal Investigator (PI) was directed to discuss the content of the protocol with the laboratory staff, a senior laboratory member must now document appropriate conduct of surgery and provision of analgesia, the Institutional Animal Care and Use Committee (IACUC) chair counseled the PI and staff, the PI will review animal activities with staff during laboratory meetings, and the IACUC will monitor the surgical records. The laboratory staff was retrained and the laboratory was placed under 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 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



2A3823-10A

OFFICE OF RESEARCH

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CONFIDENTIAL

April 26, 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-6721: Role of Skeletal Stem Cells in Bone Regeneration and Repair In Vivo

Species: Mice

Funding Sources: National Institute of Arthritis and Musculoskeletal and Skin Disease (NIAMS) R61-AR078073, R01-AR072018; National Institute on Aging (NIA) R21-AG064345; and Non-PHS funding

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

Preoperative analgesicsⁱⁱ

01/18/2022 – Mice did not receive the IACUC approved secondary NSAID analgesic

During a routine facility health evaluation and review of surgery cage cards, it was discovered that twenty-nine mice had undergone a tibia fracture procedure several days prior and received the primary analgesic Buprenorphine (Sustained-Release) as described in the IACUC approved protocol. However, the mice did not receive the secondary analgesic, Meloxicam, following the procedure as approved. The mice were observed daily by the researcher and were noted to be in good condition. After evaluation by a clinical veterinarian, all the mice were given Meloxicam for the next three days and recovered without incident.

4/12/2022 – Determination and review of the surgical oversight plan at a fully convened IACUC meeting

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

1. The Attending Veterinarian instructed the PI to review the protocol with all personnel performing surgery and submit documentation to the IACUC office.

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 PHS Policy IV.B.7: "As an agent of the institution, the IACUC shall with respect to PHS-conducted or supported activities review and approve, require modifications in (to secure approval or withhold approval) of proposed significant changes regarding the use of animals in ongoing activities"

2. A comprehensive plan from the Principal Investigator (PI) was reviewed and accepted to ensure appropriate oversight of compliance by all personnel involved in surgery.
 - o The oversight plan includes a process of accounting of all surgeries conducted, substances delivered to an animal during the perioperative periods, including anesthetic and analgesic drugs (pre- & post-surgery), and a verification process that such activities were performed by the surgeon, e.g. review and sign-off by a lab manager or another lab surgeon (i.e. a "buddy system").
 - o The IACUC Chair will convene a mandatory meeting with the PI and laboratory personnel to review and discuss the determination, the required corrective actions, and the plans for ensuring compliance.
 - o The PI will review records, procedures, and compliance (e.g. any checklists, discussion at lab meetings, and description of material reviewed).
 - o The PI will document in writing their review of the surgical records and notify the IACUC of any deviations from approved procedures.
3. All research personnel are required to complete the interactive training session "Top 10 Pitfalls and How to Avoid Them."
4. For the next six months, a monthly review of all surgery and analgesia records will be conducted.
5. 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, National Institute of Arthritis and Musculoskeletal and Skin Disease (NIAMS); National Institute on Aging (NIA) and non-PHS funding sources 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, April 29, 2022 10:08 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Report- Assurance D16-00475

Thank you for this report, (b) (6) We will send a response shortly.
Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Friday, April 29, 2022 9:43 AM
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)

A large rectangular area of the document is completely redacted with a solid grey fill, covering approximately the bottom third of the page content.