



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

December 9, 2022

Re: Animal Welfare Assurance
A3823-01 [OLAW Case 100]

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

Dear Dr. Dickinson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 28, 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 20 mice in several cages were found unattended in a procedure room. Some of the mice were anesthetized while others were recovering from anesthesia following surgery.

The immediate action taken upon discovery consisted of animal care staff monitoring the mice until recovered and seeking the surgeon. The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) chair counseling the Principal Investigator (PI) and staff and requiring a plan for oversight of surgeries and post-operative monitoring. The laboratory staff was required to undertake retraining, the laboratory was placed on enhanced post-approval monitoring, and the IACUC will review monthly compliance reports submitted by the PI.

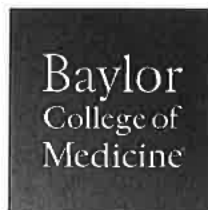
Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair



OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

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CONFIDENTIAL

November 28, 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-7089: Efficacy of Novel Targeted Therapies Using Transgenic and Xenograft Neuroblastoma Models

Species: Mice

Funding Source: National Cancer Institute (NCI) R01-CA222224

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

9/21/2022 – Monitoring^{ii, iii, iv}

Central animal care facility staff found several unattended cages of mice containing a total of 20 mice that had recently undergone an orthotopic tumor implantation surgery in a procedure room. Some were awake and moving and others were still partially anesthetized. The mice were monitored until the surgeon returned to the room and they recovered without incident.

11/8/2022 – Determination 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
ⁱⁱ The Guide for the Care and Use of Laboratory Animals p.119, "An important component of postsurgical care is observation of the animal and intervention as necessary during recovery from anesthesia and surgery (Haskin and Eisele 1997). The intensity of monitoring will vary with the species and the procedure and may be greater during the intermediate anesthetic recovery period. During this period, animals should be in a clean, dry, comfortable area where they can be observed frequently by trained personnel. Particular attention should be given to the thermoregulation, cardiovascular and respiratory function, electrolyte and fluid balance, and management of postoperative pain or discomfort. Additional care may be warranted, including long-term administration of parental fluids, analgesics, and other drugs, as well as care of surgical incisions. Appropriate medical records should also be maintained. After recovery from the anesthesia, monitoring is often less intense but should include attention to basic biological functions of the intake and elimination and to the behavioral signs of postoperative pain, monitoring for postsurgical infections, monitoring for the surgical incision site dehiscence as appropriate, and timely removal of skin sutures, clips or staples (UFAW 1989)."

^{iv} The GUIDE, 8th Ed. p115: "Successful surgical outcomes require appropriate attention to presurgical planning, personnel training, anesthesia, aseptic and surgical technique, assessment of animal well-being, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and postoperative care."

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

1. The IACUC Chair will conduct a mandatory meeting with the PI and her laboratory personnel to discuss the determination letter, required corrective actions, and plans for ensuring compliance.
2. The PI must provide a robust and comprehensive plan to ensure compliance and appropriate oversight for surgical processes:
 - o This surgical oversight plan must include a description of the process of oversight of surgeries, description of monitoring of substances including analgesia that will be provided at each surgery and a verification process that such activities were performed by the surgeon, e.g. review and sign-off by you as the PI, lab manager, or another trained lab surgeon (i.e. "buddy system"). The plan must be submitted within 2 weeks of the determination letter.
3. All research personnel are required to complete the interactive "Top 10 Pitfalls in Animal Research and how to Avoid Them" training.
4. Two comprehensive Post-Approval Monitoring (PAM) reviews focused on surgery, will be conducted within the next six months.
5. 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 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 Cancer Institute 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

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 29, 2022 12:49 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Reports- Assurance D16-00475

Good afternoon (b) (6)

Thank you for sending us these three reports and we will send official responses soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: (b) (6)
Sent: Tuesday, November 29, 2022 10:38 AM
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)

