



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

September 1, 2021

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

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 August 20, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Baylor College of Medicine (BCM). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the BCM Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: unauthorized personnel participating in animal-related activities, failure to adhere to the IACUC-approved protocol and institutional policies/procedures. The final report states on June 28, 2021, a veterinary technician observed two post-operative mice with wound dehiscence. The wounds were repaired under the direction of a clinical veterinarian. Also, the animals were observed during the weekend by laboratory staff, but they did not observe the wound dehiscence. It is further stated that documentation related to surgery was not completed for June 27, 2021.

Per the report, it was determined that while the mice received a non-steroidal anti-inflammatory drug on the day of surgery, they did not receive a pre-operative opioid as described in the protocol. The clinical veterinarian noted that the research staff did not initially use proper aseptic technique during wound repair. This action was corrected in real time. Two additional lab members were observed performing a head-post repair in one mouse and intracranial dye injection in another mouse while not wearing appropriate laboratory surgical attire. Also, it was determined that the lab member performing the terminal dye injection had not yet been added to the approved protocol and had not completed the required surgery training.

In response to these findings, the IACUC required the following corrective actions:

- The Attending Veterinarian halted all surgeries until the IACUC reviewed the findings and approved an appropriate oversight plan for surgery by the research staff.
- All laboratory staff members who are performing surgeries must be retrained in aseptic technique, wound closure, and analgesic administration. In addition, all staff members performing satellite oversight and monitoring duties must be appropriately trained in wound evaluation, recognition of pain and rodent pain condition scores.
- The Principal Investigator held a laboratory meeting to review the approved protocol and submitted an amendment to add the new laboratory member to the animal protocol.

- An amendment to the protocol must be submitted to add procedures related to head post repair, if needed, on anesthetized mice.
- The IACUC Chair will conduct a mandatory meeting with the Principal Investigator and laboratory personnel to discuss the determination letter, required corrective actions, and plans for ensuring compliance.
- Two comprehensive Post-Approval Monitoring (PAM) reviews focused on surgery will be conducted within the next six months.
- The next scheduled oviduct surgery must be completed with observation by a clinical veterinarian.
- All laboratory members have completed the interactive "Top 10 Pitfalls in Animal Research and how to Avoid Them" training.
- The Principal Investigator 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.
- If compliance with the IACUC approved surgical 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.

It is noted that this project is supported by PHS and non-PHS funding. Based on its assessment of this explanation, OLAW understands that the Baylor College of Medicine 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.

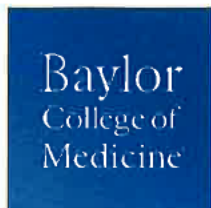
Sincerely,

Jacquelyn  
T. Tubbs -S

Digitally signed by Jacquelyn T.  
Tubbs -S  
Date: 2021.09.01 10:11:00 -0400

Jacquelyn Tubbs, DVM, DACLAM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



A3823-9U

OFFICE OF RESEARCH

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mdickins@bcm.edu

**CONFIDENTIAL**

August 20, 2021

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-5596: Monitoring Neuronal Circuits in the Mammalian CNS

**Species:** Mice

**Funding Sources:** National Institutes of Health (NIH): (b) (4) and non-PHS Funding

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

**Postoperative Monitoring<sup>ii</sup> and Analgesia<sup>iii</sup>**

1. On June 28, 2021, a veterinary technician performing a satellite inspection observed two post-operative mice with dehiscd wounds. The animals otherwise appeared well and the wounds were repaired under the direction of a clinical veterinarian. It was determined that the mice were observed over the weekend by laboratory staff performing weekend satellite inspection duties. These staff did not note wound dehiscence. However, surgery related documentation in writing was not completed for Sunday, June 27, 2021.

<sup>i</sup> 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;"

<sup>ii</sup> IACUC Policy: "Rodent Anesthesia, Surgery, and Post-Operative Monitoring: "The frequency and length of post-operative monitoring is dependent on the invasiveness of the surgical procedure, veterinary recommendations, and the individual response of the animal. At a minimum, animal observations and analgesic administration must be documented daily for 3 days after surgery. The Green Surgery Card must be completely filled out and posted on the cage to fulfill this requirement. All animals must be monitored daily and the Green Surgery Card maintained on the cage until external sutures or staples are removed."

<sup>iii</sup> 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."

<sup>iv</sup> The GUIDE, 8<sup>th</sup> 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."

<sup>v</sup> The GUIDE, 8<sup>th</sup> Ed. p115: "Researchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced – that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns."

<sup>vi</sup> PHS Policy IV.C.1.f: "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures"

2. During an interview with research staff, it was learned that the same two mice did not receive a pre-operative opioid as described in the IACUC-approved protocol. They did receive an NSAID on the day of surgery but not on subsequent days for the full duration described in the approved protocol.

#### **Aseptic Technique<sup>iv, v</sup>**

3. While advising the research staff on the wound repair of the two mice described above, the clinical veterinarian noted that the research staff did not initially use proper aseptic technique. This was corrected in real time. Two other laboratory members were observed conducting a head-post repair in one mouse and an intracranial dye injection in another mouse without wearing appropriate laboratory surgical attire.

#### **Researcher Approval<sup>vi</sup>**

4. During the assessment, it was discovered that the laboratory member who was performing the terminal dye injection was not yet added to the currently approved animal protocol and had not yet completed the required surgery training.

*8/10/2021 – 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 Attending Veterinarian halted all surgeries until the IACUC reviewed the findings and approved an appropriate oversight plan for surgery by the research staff.
2. All laboratory staff members who are performing surgeries must be retrained in aseptic technique, wound closure, and analgesic administration. In addition, all staff members performing satellite oversight and monitoring duties must be appropriately trained in wound evaluation, recognition of pain and rodent pain condition scores.
3. The Principal Investigator held a laboratory meeting to review the approved protocol and submitted an amendment to add the new laboratory member to the animal protocol.
4. An amendment to the protocol must be submitted to add procedures related to headpost repair, if needed, on anesthetized mice.
5. The IACUC Chair will conduct a mandatory meeting with the Principal Investigator and laboratory personnel to discuss the determination letter, required corrective actions, and plans for ensuring compliance.
6. Two comprehensive Post-Approval Monitoring (PAM) reviews focused on surgery will be conducted within the next six months.
7. The next scheduled oviduct surgery must be completed with observation by a clinical veterinarian.
8. All laboratory members have completed the interactive "Top 10 Pitfalls in Animal Research and how to Avoid Them" training.
9. The Principal Investigator 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.
10. If compliance with the IACUC approved surgical 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.

These findings of non-compliance do 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, the National Institutes of Health 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]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, August 23, 2021 6:58 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:** Friday, August 20, 2021 5:13 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** OLAW Report- Assurance D16-00475

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)

