



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

August 29, 2022

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

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 August 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 three anesthetized mice were perfused, although this activity had not been described in the approved protocol.

The corrective action consisted of amending the protocol to include perfusion, retraining the laboratory staff, counseling the Principal Investigator to ensure that personnel are appropriately supervised and conduct only approved procedures, counseling the PI and staff on maintaining compliance, and warning the laboratory of the consequences of additional noncompliance.

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 Institutional Animal Care and Use Committee 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  
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**CONFIDENTIAL**

August 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 findings in animal research after an assessment of the following protocol:

**Protocol:** AN-8015: Opto-Induced Protein Aggregation in Animal Models

**Species:** Mice

**Funding Sources:** Non-PHS Funding

For this investigator's second incident of this nature, the IACUC determined that the following finding constituted a *serious and continuing noncompliance*<sup>i</sup> with the federal regulations:

*6/6/2022 – Unapproved Procedure Performed<sup>ii</sup>*

During a semi-annual laboratory inspection, a laboratory member stated that they have performed perfusions on mice under anesthesia, a procedure that is not described in the IACUC approved protocol. During this time, a total of three mice were perfused without incident. An amendment was submitted to the IACUC to include perfusions, which was subsequently approved.

*8/9/2022 – Determination at a fully convened IACUC meeting*

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

1. All research personnel are required to retake the following AALAS Learning Library tracks: BCM Mice: General Care and Husbandry (containing 5 courses) and BCM IACUC Course: Working with the IACUC.
2. The PI must ensure compliance and appropriate oversight through a robust and comprehensive oversight plan, which includes a description of how they will ensure compliance with the protocol, a description of monitoring for compliance of procedures and research personnel to ensure no procedures, experiments or surgeries are completed unless they are described in the protocol and approved by the IACUC.

<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>: PHS Policy IV.B.7: "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"

3. As a result of this serious and continuing non-compliance, the IACUC Chair and Director of Research Compliance will conduct a mandatory meeting with the PI and their laboratory personnel to discuss this determination letter, required corrective actions, and plans for ensuring compliance.
4. Escalating required corrective actions including, but not limited to suspension of animal research privileges will occur if they are compliant with the compliance oversight plan or compliance is not achieved moving forward.

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 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

**McCoy, Devora (NIH/OD) [E]**

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**From:** (b) (6)  
**Sent:** Friday, August 26, 2022 4:47 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] OLAW Reports- Assurance D16-00475  
**Attachments:** OLAW Notification D16-00475 AN-6102 signedMD.pdf; OLAW Notification D16-00475 CCM signedMD.pdf; OLAW Notification D16-00475 AN-8015 signedMD.pdf; OLAW Notification D16-00475 AN-5896 signedMD.pdf; OLAW Notification D16-00475 AN-8678 signedMD.pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

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)

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