



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

January 5, 2022

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

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 the November 18, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at Baylor College of Medicine (BCM). According to the information provided, OLAW understands that an unapproved surgical procedure was performed on one mouse. At the time of the procedure, a protocol amendment to add surgery had been submitted to the IACUC but had not yet been approved. Further, the procedure was performed by a researcher who was not yet deemed proficient by the BCM surgery training program. The mouse was euthanized at the request of the veterinarian. The animal involved in this incident was not supported by PHS funding.

Corrective and preventive measures included requiring all research personnel to complete an interactive training module regarding how to avoid common pitfalls in animal research. Second, two comprehensive post-approval monitoring reviews will be conducted by May 2022. Last, the researcher who will perform the surgeries must retake all related surgery training courses and be deemed proficient to conduct surgery.

OLAW appreciates the consideration of this matter by BCM which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel  
-S

Digitally signed by Robyn M.  
Engel -S  
Date: 2022.01.10 10:59:44  
-05'00'

Robyn M. Engel, DVM  
Animal Welfare Program Specialist  
Office of Laboratory Animal Welfare

cc: IACUC contact



A3823 - 9V

One Baylor Plaza, BCM310  
Houston, Texas 77030-3411

(713) 798 - 2104  
(713) 798 - 2721 FAX  
mdickins@bcm.edu

OFFICE OF RESEARCH

**CONFIDENTIAL**

November 19, 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 finding in animal research after an assessment of the following protocol:

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

**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*<sup>i</sup> with the federal regulations:

**Unapproved Procedure<sup>ii</sup> and Incomplete Surgical Training<sup>iii</sup>**

*9/24/2021 – Unapproved Procedure and Training*

One mouse with a cranial incision was observed in a recovery cage within a laboratory by a Clinical Veterinarian. The mouse was given pre-operative analgesics, prepared and anesthetized appropriately. The mouse was appropriately euthanized at the request of the Clinical Veterinarian. At the time of the procedure, a protocol amendment had been submitted to the IACUC to add surgery but had not yet been approved.

This procedure was performed by a researcher who was not yet deemed proficient, as required in our surgery training program. The researcher had completed the on-line and hands-on courses, but had not yet completed the final proficiency assessment.

*11/9/2021 – Determination at a fully convened IACUC meeting*

<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"

<sup>iii</sup>: PHS Policy IV.B.6: "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 those components of PHS-conducted or supported activities related to the care and use of animals as specified in IV.C. of this Policy"

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

1. All research personnel are required to complete the interactive "Top 10 Pitfalls in Animal Research and How to Avoid Them" training.
2. Two comprehensive Post-Approval Monitoring (PAM) reviews will be conducted within the next six months.
3. The researcher who will perform surgery must retake all related surgery training courses and be deemed proficient to conduct surgery.

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:** Monday, November 22, 2021 7:30 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 soon.

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

**From:** (b) (6)  
**Sent:** Friday, November 19, 2021 7:13 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)