



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

June 10, 2021

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

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 May 27, 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. 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: failure to adhere to institutional policies/procedures. The final report states on April 1, 2021, one cage of mice containing 40 euthanized animals was found in a central animal facility euthanasia room. In response, the Attending Veterinarian ceased all euthanasia procedures for the laboratory until euthanasia retraining could be accomplished. On May 11, 2021 the IACUC required the following corrective actions:

- All research personnel completed a hands-on retraining session with central animal facility personnel on using the Euthanex chamber automated euthanasia system.
- All research personnel completed a workshop on common noncompliance problems and how to avoid them (Top 10 pitfalls).
- A Post-Approval Monitoring (PAM) session will be conducted within the next six months.

It is noted that this project is not supported by PHS funds. 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
Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.06.10 14:32:42
+0400'

cc: IACUC Contact



OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

(713) 798 – 2104
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mdickins@bcm.edu

CONFIDENTIAL

A3823-95

May 27, 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-6660: The Roles of Prolyl Hydroxylase Domain Proteins in Cardiac Function

Species: Mice

Funding Source: Non-PHS Funding

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

Euthanasia Conditions¹¹

4/1/21 – Cage found in an overcrowded condition

One cage of mice containing approximately 40 euthanized animals was observed in a central animal facility euthanasia room. No animals were observed with any injuries or other indications of problems relating to overcrowding. The Attending Veterinarian halted all euthanasia procedures for the laboratory until euthanasia re-training could be completed.

5/11/21 – 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 completed a hands-on re-training session with central animal facility personnel on using the Euthanex chamber automated euthanasia system.
2. All research personnel completed a workshop on common non-compliance problems and how to avoid them (Top 10 pitfalls).
3. A Post-Approval Monitoring (PAM) session will be conducted within the next six months.

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 taken with respect to: a. any serious or continuing noncompliance with this Policy;"

¹¹ 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"

This notification will also be sent to AAALAC International 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, May 28, 2021 7:19 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: Thursday, May 27, 2021 12:43 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.

(b) (6)

