



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

October 12, 2022

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

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 October 3, 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 two cages of mice were found in a satellite room, with one cage containing four dead mice and the other containing three dead and one live mouse. The animals had been used for training in an ultrasound system but had not been monitored and the cages had not been returned to the vivarium following the training.

The corrective actions consisted of placing the area under enhanced post-approval monitoring and having the Principal Investigator ensure that all laboratory staff conduct daily health checks appropriately and know how to store and return cages.

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 institution 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

A3823-10K



OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

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

CONFIDENTIAL

October 3, 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-4101: Whole Animal and Organ System Phenotyping of Rodents in the Mouse Phenotyping Core Facility
Species: Mice and Rats
Funding Source: Non-PHS Funding

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

7/6/2022 – Inadequate Monitoringⁱⁱ and Improper Housing in a Sattelite Facility^{iii-iv}

During a routine satellite inspection performed by a Clinical Veterinarian, two cages of mice were found on a counter top. One cage contained 4 dead mice and the other contained 3 dead mice and 1 live mouse. It was not clear when the animals died or the exact cause. The animals had been recently utilized for training in an ultrasound system. These cages should have been returned to the animal housing facility after use and were likely not monitored as required.

9/13/2022 – Determination at a fully convened IACUC meeting

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

1. One comprehensive Post-Approval Monitoring (PAM) review will be conducted within the next three months.

ⁱ 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;"

ⁱⁱ 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."

ⁱⁱⁱ PHS Policy IV.C.1.d The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

^{iv} The GUIDE pp. 50-51: All animals should be housed under conditions that provide sufficient space as well as supplementary structures and resources required to meet physical, physiologic, and behavioral needs.

2. The PI has provided a comprehensive plan detailing how to ensure that all core laboratory members are informed on how to store and return cages, monitor animals, and complete health checks appropriately.

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

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 3, 2022 1:40 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 two 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: Monday, October 3, 2022 1:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
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)

