



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

March 28, 2022

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

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 March 22, 2022 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Baylor College of Medicine. According to the information provided, OLAW understands that for a six month period, the wire bar lids and cage tops in the immunocompetent mouse rooms of the Transgenic Mouse Facility had not been changed at the interval stipulated in the standard operating procedure (SOP). No health problems have been reported due to this deviation. The lids and cage tops had been changed at the proper interval in the immunodeficient rooms.

The corrective actions consisted of counseling the facility manager and husbandry staff on the relevant SOP, having the veterinary staff create and present a training module for the facility supervisors and managers on husbandry procedures, temporarily relocating husbandry staff to the affected area to change all wire bar lids and cage tops, monitoring cage change logs, and hiring additional staff to ensure that cages are changed as required. Cages are currently being changed at the correct intervals.

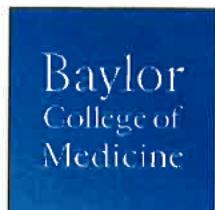
Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Contact



A3823-92

OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

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CONFIDENTIAL

March 22, 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 finding in animal housing after an assessment conducted at one of our central animal facilities.

The IACUC determined that the following finding constituted *a serious deviation from the requirements set forth in The Guide for the Care and Use of Animals*ⁱ:

Sanitation of Cages^{ii, iii}

1/13/2022 – From July 2021 until January 2022, the wire bar lids and cage tops in the immunocompetent animal rooms of the Transgenic Mouse Facility were not changed at the interval described in the established standard operating procedures. The wire bar lids and cage tops were changed at the prescribed intervals in the immunodeficient animal and quarantine areas of this facility. After a thorough review, no animal welfare concerns or incidents related to this deviation were identified.

3/08/2022 – *Determination, review and approval of the central animal facility implemented corrective actions at a fully convened IACUC meeting*

ⁱ The Guide for the Care and Use of Laboratory Animals 8th ed. p. 70: "In general, enclosures and accessories, such as tops should be sanitized at least once every two weeks.

ⁱⁱ PHS Policy IV.C.1.a: "Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design"

ⁱⁱⁱ The Guide for the Care and Use of Laboratory Animals 8th ed. p. 15: "All personnel involved with the care and use of animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to ensure high-quality science and animal well-being."

To protect the welfare of animals and prevent future recurrence, the IACUC and central animal facility implemented the following corrective actions:

- The central facility Director of Operations met with the facility manager and all animal care personnel on January 18, 2022, to review the standard interval for cage change procedures.
- The facility Clinical Veterinarians have created a training presentation for the facility supervisors and managers with a focus on understanding the expectations from the 8th edition of The Guide, central animal care procedures and correct husbandry practices. The training has been completed on February 16, 2022.
- Additional animal care staff members were moved from other areas to provide short-term assistance to change all cages in the facility. As of February 4, 2022, all wire bars were changed out and as of March 1, 2022, all cage tops were changed out. All cage changes have resumed at the prescribed cage change intervals.
- The Clinical Veterinarians are monitoring the cages and change logs as they perform facility walk throughs.
- Additional staff will be hired to facilitate compliance with the prescribed cage change intervals.

This notification will also be sent to AAALAC International.

Please do not hesitate to contact me if you have any questions.

Sincerely,

(b) (6)

Mary E. Dickinson, PhD
Sr. Vice President and Dean of Research
Institutional Official
Baylor College of Medicine

cc: Research Compliance Services files

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, March 23, 2022 7:33 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: Tuesday, March 22, 2022 2:42 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] OLAW Report- Assurance D16-00475

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

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)