



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

November 16, 2022

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

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 November 4, 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 twelve mice were rehoused together after initially being separated for fighting and that the cage markers were moved to other cages, which complicated animal tracking and monitoring. Three mice were to be euthanized in accordance with a veterinary order, but this was not heeded by the laboratory staff.

The corrective actions consisted of locating all of the moved mice and treating them. The mice slated for euthanasia were appropriately euthanized. The Institutional Animal Care and Use Committee (IACUC) chair will counsel the Principal Investigator and Section Chief on the noncompliance and will also have the laboratory staff, animal care, and veterinary staff develop a monitoring plan for the mice. The laboratory was directed to not rehouse mice separated for fighting, to not remove cage notifications, to not move mice identified with problems to other cages, to not relocate marked cages on the rack, and to always follow veterinary orders.

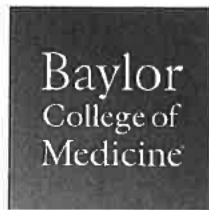
Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

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

November 4, 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-4309: The Role of the Mammalian Circadian Clock in Tumor Suppression

Species: Mice

Funding Source: National Institutes of Health (NIH) R01-CA238988, National Cancer Institutes (NCI) R01-CA230848 and 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:

Re-housing separated Miceⁱⁱ, Facility cage markers removed from cagesⁱⁱⁱ and Clinical Veterinary recommendations not followed^{iv, v}

8/1/2022 – On several occasions mice were found rehoused together after being separated by central animal facility personnel for fighting. Approximately 12 mice were involved. During this same time, the facility cage markers were removed from cages and relocated to other cages, complicating tracking and monitoring the care of animals identified for additional observation and treatment. All mice were located and treated appropriately.

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.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., p112, "All animals should be observed for signs of illness, injury or abnormal behavior by a person trained to recognize such signs."

^{iv} PHS Policy IV.C.1.c: "Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure, or if appropriate, during the procedure."

^v The Guide, p.123: "Euthanasia may be planned and necessary at the end of a protocol or as a means to relieve pain or distress that cannot be alleviated by analgesics, sedatives, or other treatments. Criteria for euthanasia include protocol-specific endpoints (such as degree of physical or behavioral deficit or tumor size) that will enable a prompt decision by the veterinarian and the investigator to ensure that the endpoint is humane and, whenever possible, the scientific objective of the protocol is achieved."

In addition, clinical veterinary recommendations for euthanasia of three mice were not followed by the laboratory. After clinical veterinary followup, these mice were euthanized appropriately.

10/11/2022 – Determination at a fully convened IACUC meeting

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

1. The IACUC Chair will conduct a meeting with the Principal Investigator (PI) and the Section Chief to discuss the findings, non-compliance and the determination made by the IACUC.
2. The IACUC Chair will conduct a meeting with the PI and laboratory personnel, central animal facility care staff and CCM staff, and the facility Clinical Veterinarian to develop a mutually agreeable plan to monitor the circadian mutant mice to prevent issues like this from happening again.
3. The PI and all laboratory research personnel must adhere to the following:
 - Mice that have been separated for fighting cannot be re-housed by the PI or laboratory personnel
 - Active cage markers and notifications can only be removed by central animal facility staff
 - Animals identified with any issues cannot be moved to other cages
 - Cages with markers cannot be relocated from their original position on the housing rack
 - Clinical veterinary recommendations for treatment and required euthanasia must be followed, as prescribed.

This finding of non-compliance does not appear to pose any potential or actual effect on costs related to this PHS-supported research.

This notification will also be sent to AAALAC International, the National Institutes of Health 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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 7, 2022 7:06 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Reports- Assurance D16-00475

Good morning (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: Friday, November 4, 2022 2:24 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)