



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

August 29, 2022

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

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 August 26, 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 30 post-operative mice did not have their post-operative monitoring cards filled out because staff had not been trained on this topic and the protocol did not specify the monitoring requirements. The mice had been monitored and recovered as expected, although the documentation was not present.

The corrective actions consisted of amending the protocol to describe the post-operative monitoring and retraining the staff in pain recognition, pain scoring, and removal of wound clips. The Institutional Animal Care and Use Committee (IACUC) chair counseled the Principal Investigator and staff, the staff undertook retraining, and the laboratory was placed on enhanced post-approval monitoring.

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 Contact



A3823-10E

OFFICE OF RESEARCH

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CONFIDENTIAL

August 26, 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 research after an assessment of the following protocol:

Protocol: AN-8678: Mapping Epigenomic Changes in Models of Obesity and Cancer

Species: Mice

Funding Sources: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) K01-DK125602 and
-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:

7/2/2022 - Post-Operative Documentation^{ii, iii} & Required Training^{iv}

During routine animal care and husbandry rounds, 30 mice were observed with recent tumor implants without surgery monitoring cage cards. It was discovered that the surgery was performed by another investigator, as part of a core service

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

ⁱⁱ The GUIDE, 8th Ed. p115: "Researchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced – that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns."

ⁱⁱⁱ The GUIDE, 8th Ed. p115: "Successful surgical outcomes require appropriate attention to presurgical planning, personnel training, anesthesia, aseptic and surgical technique, assessment of animal well-being, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and postoperative care."

^{iv} PHS Policy IV.C.1.f: "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures"

^v PHS Policy IV.B.7: "As an agent of the institution, the IACUC shall with respect to the PHS-conducted or supported activities review and approve, require modifications in (to secure approval), or withdrawal approval of proposed significant changes regarding the use of animals in ongoing activities"

under an IACUC approved protocol. All mice received appropriate analgesics and anesthetics and were transferred on the second day, when they still required post-operative monitoring. The post-operative monitoring cards completed for the surgery were placed behind the regular cage cards and new surgery cage cards were attached by mistake. The research staff performed post-operative monitoring, but they did not know how to correctly fill out the post-operative monitoring cards, which were left blank. Since receiving mice that still required post-operative monitoring was not described on this protocol, appropriate training on post-operative monitoring had not been completed.

All 30 mice recovered without incident and were maintained in the study as planned.

7/2/2022 - Unapproved Procedure^v

The approved protocol did not describe receiving mice requiring post-operative monitoring. An amendment to add the receipt of tumor-bearing mice from the core was subsequently submitted and approved by the IACUC.

8/9/2022 – 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. All laboratory staff members must be appropriately trained in wound evaluation, recognition of pain, rodent pain condition scores and removal of wound clips before performing post-operative monitoring of post-surgical mice during the acute post-operative period.
2. The IACUC Chair will conduct a mandatory meeting with the Principal Investigator and laboratory personnel to discuss this determination letter, required corrective actions, and plans for ensuring compliance.
3. Two comprehensive Post-Approval Monitoring (PAM) reviews focused on surgery, will be conducted within the next six months.
4. All research personnel are required to complete the interactive “Top 10 Pitfalls in Animal Research and how to Avoid Them” training.

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 Institute of Diabetes and Digestive and Kidney Diseases 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: (b) (6)
Sent: Friday, August 26, 2022 4:47 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: [EXTERNAL] OLAW Reports- Assurance D16-00475
Attachments: OLAW Notification D16-00475 AN-6102 signedMD.pdf; OLAW Notification D16-00475 CCM signedMD.pdf; OLAW Notification D16-00475 AN-8015 signedMD.pdf; OLAW Notification D16-00475 AN-5896 signedMD.pdf; OLAW Notification D16-00475 AN-8678 signedMD.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

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)

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