



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 10I]

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 problems occurred with wound closures in mice following tumor resection surgery. Specifically, wounds could not be properly closed due to inadequate fur removal and due to the nature of the invasive tumor. Also, inadequate training and experience of the surgeon were contributory factors.

The corrective actions consisted of the veterinarian evaluating the mice, euthanizing four mice, repairing the closure site in eleven mice which subsequently recovered, and directing that additional surgeries be stopped. The surgeon, who was also the Training Ambassador (TA), was retrained and reassessed in the conduct of these surgeries. The laboratory staff was counseled and retrained, the protocol was amended to clarify the resection procedure, following retraining the TA will be responsible for training other staff, the next surgery will be monitored by a veterinarian, the laboratory was placed under enhanced post-approval monitoring and must also provide ongoing updates to the Institutional Animal Care and Use Committee (IACUC), and the IACUC chair will counsel the Principal Investigator and laboratory staff. At the programmatic level, meetings will be held between veterinary and research staff to discuss compliance and an additional online rodent surgery training module was developed.

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

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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-6102: In Vivo Analysis of Tumor Initiation Potential and Metastasis

Species: Mice

Funding Sources: National Institutes of Health (NIH) R01-CA234479 and non-PHS Funding Source

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

7/6/2022 – Procedure Performed as Describedⁱⁱ and Appropriate Trainingⁱⁱⁱ

During routine clinical veterinarian evaluations, 15 mice were found with recent tumor resection surgery that needed attention for wound closures resulting from the surgical technique used. Tumor resection is mentioned, but the closure technique is not fully described. The wound closure issues resulted from inadequate removal of fur and difficulty repairing and closing the layers appropriately in the setting of invasive tumor, a complicated closure situation. All mice were evaluated by the Clinical Veterinarian. Four mice were euthanized during the evaluation and eleven mice had the wounds repaired appropriately and recovered without incident.

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 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"

ⁱⁱⁱ 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"

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. The Attending Veterinarian halted all surgeries until the IACUC reviewed the finding, and the Training Ambassador (TA) who performed the surgical procedures has been retrained and reassessed in the conduct of surgery of all potential procedures described.
2. The Principal Investigator (PI) discussed the poor surgical outcomes with all the laboratory members.
3. The PI submitted an amendment to fully describe the tumor resection procedure.
4. The TA must be retrained through the TA program and become proficient in tumor resection. Once retrained as indicated, the TA will be responsible for retraining all the research staff listed in section R of the protocol in tumor resection and the orthotopic implantation of cancer cells in the pancreas survival surgical procedures.
5. The next scheduled tumor resection surgery must be completed with observation by a Clinical Veterinarian.
6. Two comprehensive post approval monitoring (PAM) reviews focused on surgery, will be conducted within the next six months.
7. The IACUC Chair will conduct a mandatory meeting with the PI and all laboratory personnel to discuss the determination letter, required corrective actions, and plans for ensuring compliance.
8. All research personnel have completed the interactive training session "Top 10 Pitfalls and How to Avoid Them."
9. The PI will confirm in writing, monthly review of records and procedures to ensure compliance for the next six months.

In addition to the protocol specific corrective actions above, central animal facility leadership will host college-wide, veterinary-led animal researcher meetings where compliance and surgical concerns will be discussed. In addition to these meetings, the IACUC in collaboration with CCM, will create an additional online rodent surgery refresher training module to provide continuing education and training for all rodent surgeons.

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: (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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