



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 10L]

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 skin clips applied to 15 mice following surgery had not been properly attached. This type of clip was different from that used previously and required a different method of application.

The corrective actions consisted of having a veterinarian evaluate the mice, euthanizing two of them, replacing the clips on the remainder, and providing supportive care which led to a successful recovery. The Principal Investigator (PI) and staff were counseled by the Institutional Animal Care and Use Committee (IACUC) chair and veterinarian, and the PI agreed to ensure appropriate oversight of the surgeries. The PI will ensure that surgeries are conducted as approved, document the procedures, and share with the IACUC. The laboratory will be subjected to enhanced post-approval monitoring, the laboratory staff was retrained, and any future noncompliance will result in escalating sanctions. At the institutional level, veterinary staff will meet with investigators to discuss surgical issues and compliance, and an additional online rodent surgery refresher course has been implemented.

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



One Baylor Plaza, BCM310
Houston, Texas 77030-3411

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mdickins@bcm.edu

OFFICE OF RESEARCH

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-6191: Preclinical Testing of Target Directed Therapies for Liver Cancer using a Mouse Xenograft

Species: Mice

Funding Source: Non-PHS Funding

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

8/3/2022 – Closure after procedureⁱⁱ

During an animal health inspection by a veterinary technician, 15 mice were found with skin clips not properly applied following a liver xenograft surgery. The skin clips used were different than the type used previously, which required a different amount of tension to seat properly. All mice had the muscle layer sutured and closed appropriately and received appropriate analgesics. Upon evaluation by a clinical veterinarian, two mice were euthanized and the remaining 13 had the wound clips replaced, received supportive care and recovered without incident.

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

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

1. The IACUC Chair will conduct a mandatory meeting with the Principal Investigator (PI) and laboratory personnel to discuss the finding, required corrective actions, and plans for ensuring compliance.
2. The PI must have a consultation with a clinical veterinarian regarding these surgeries.
3. The PI has provided a robust and comprehensive plan ensuring compliance and appropriate oversight for surgical processes:

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."

- This surgical oversight plan includes a description of the process of oversight of surgeries, description of monitoring of substances including analgesia that will be provided at each surgery and a verification process that such activities were performed by the surgeon, e.g. review and sign-off by the PI, lab manager, or another trained lab surgeon (i.e. "buddy system")
 - The PI is responsible for working with the personnel performing surgery to ensure the quality of all surgical procedures in the laboratory and to ensure that all the surgeries are performed appropriately. The PI must provide in writing, for the next six months and for all surgical procedures performed during that time by the laboratory, a plan for monitoring and oversight of the surgeries.
4. Two comprehensive Post-Approval Monitoring (PAM) reviews focused on surgery, will be conducted within the next six months, where one of which will be conducted with a clinical veterinarian present.
 5. All research personnel are required to complete the interactive "Top 10 Pitfalls in Animal Research and how to Avoid Them" training.
 6. Escalating required corrective actions including, but not limited to suspension of animal research privileges will occur if they are compliant with the compliance oversight plan or compliance is not achieved moving forward.

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 the 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 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

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)