



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

October 12, 2022

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

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 October 3, 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 19 mice were subjected to a stereotactic intracranial injection and either a castration or ovariectomy although these activities were not described in the approved protocol, and two of the mice had protruding skin sutures. Also, the incision closure for the intracranial injection was not described in the protocol. Three mice were euthanized and the remainder recovered uneventfully.

The immediate action taken consisted of the Attending Veterinarian stopping the conduct of additional surgeries until the Institutional Animal Care and Use Committee (IACUC) investigated the matter and until all laboratory staff conducting surgery were retrained. Corrective actions consisted of amending the protocol to cover all procedures, retraining all staff performing surgery, having a veterinarian oversee the next surgery, having the Principal Investigator (PI) develop a surgical oversight plan and submit ongoing updates and surgical logs to the IACUC, placing the laboratory under enhanced post-approval monitoring, and having the IACUC chair counsel the PI and staff.

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

October 3, 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-6098: Central Homeostatic Mechanisms Controlling Energy Balance, Glycemic Control and Blood Pressure Regulation

Species: Mice

Funding Source: Non-PHS Funding Source

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

8/4/2022 – Procedures Not Performed as Described^{i,ii,iii,iv} & Unapproved Method Performed^v

During a routine health check by central animal facility personnel on July 31, 2022, two mice that underwent an ovariectomy were observed to have protruding skin sutures, possibly related to improper wound closure technique. Upon further assessment, it was determined that 19 mice had undergone both a stereotactic intracranial injection and castration or ovariectomy during the same anesthesia session, which is not described in the approved protocol. Also, the method used for wound closure for the intracranial injection procedure was not included in the approved protocol. Three mice were euthanized at the time of the routine health check and the remaining 16 mice 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 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} 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."

^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"

A protocol amendment was submitted to describe performing both intracranial injection and castration/ovariectomy in the same session and to include the alternative wound closure method for the intracranial injection, which was subsequently approved.

9/13/2022 – 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 findings, and all laboratory members performing surgery have undergone retraining.
2. All laboratory staff members performing surgery must be retrained through the institutional surgery training program.
3. The next scheduled surgery must be observed with a Clinical Veterinarian present.
4. The PI has provided a robust and comprehensive plan to ensure compliance and appropriate oversight for surgical processes:
 - 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 TA 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 (ex: create and keep a daily log of all the surgeries performed and provide description of the oversight/animal monitoring).
5. Two comprehensive post approval monitoring (PAM) reviews focused on surgery, will be conducted within the next six months.
6. The IACUC Chair will conduct a meeting with the PI and all laboratory personnel to discuss the determination letter, required corrective actions, and plans for ensuring compliance.
7. All research personnel have completed the interactive training session "Top 10 Pitfalls and How to Avoid Them."

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

Ward, Joan (NIH/OD) [E]

From: (b) (6)
Sent: Monday, October 3, 2022 1:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: [EXTERNAL] OLAW Reports- Assurance D16-00475
Attachments: OLAW Notification D16-00475 AN-6098 10.03.22 signedMD.pdf; OLAW Notification D16-00475 AN-4101 10.03.22 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)