



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) 402-7065

November 6, 2019

Re: Animal Welfare Assurance
A3823-01 [OLAW Case 8I]

Dr. Mary Dickinson
Vice President and Dean of Research
Baylor College of Medicine
One Baylor Plaza, BCM335
Houston, TX 77030

Dear Dr. Dickinson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 5, 2019 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 an investigator was conducting surgery in mice without having completed the final proficiency assessment of the institutional training.

The corrective actions consisted of having the investigator complete the proficiency assessment which satisfied all requirements of the institutional surgical training. The surgical procedures were stopped and the Institutional Animal Care and Use Committee (IACUC) required the Principal Investigator (PI) to submit a surgical oversight plan to include the following:

- Accounting for all surgeries, substances given to animals, anesthetics/analgesics, and certifying that all procedures were performed as described in the protocol
- The plan must be approved by the IACUC or surgeries will be suspended
- Once the plan is approved, the IACUC chair will counsel the PI and staff
- The PI will be responsible for reviewing records, procedures, and compliance
- The PI will document review of surgical records and will notify the IACUC of any deviations

In addition, the laboratory was placed under enhanced post-approval monitoring; records of surgery, anesthesia/analgesia, and adherence to the plan will be reviewed monthly; and continuing noncompliance will result in escalating sanctions.

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



A3823-8I
no open case
OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

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mdickins@bcm.edu

CONFIDENTIAL

November 5, 2019

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-3949: T Cell Therapy for Brain Tumors

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*¹ with the federal regulations:

Required Training²

During a review of required surgical training records it was discovered that the researcher responsible did not complete the final proficiency assessment of the institutional training prior to conducting surgical procedures. The researcher successfully completed all other required modules, including the on-line portion, the pre-operative laboratory and intra-post-operative laboratory modules. As of this letter, the researcher has successfully completed the proficiency assessment, meeting all requirements of the required institutional surgical training.

Corrective Actions:

1. Surgical procedures were halted by the PI.
2. The IACUC requires a comprehensive plan from the PI to ensure appropriate oversight of compliance by all personnel involved in surgery.
 - o The oversight plan must include a process of accounting of all surgeries conducted, substances delivered to an animal during the perioperative periods, including anesthetic and analgesic drugs (pre- & post-surgery), and a verification process that such activities were performed by the surgeon, e.g. review and sign-off by a lab manager or another lab surgeon (i.e. a "buddy system").

¹ 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"

² *The Guide for the Care and Use of Laboratory Animals*. 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."

- The plan will be reviewed at the next convened IACUC meeting for approval. If the plan is not approved, all surgeries will be suspended until a satisfactory plan is approved by the IACUC.
 - Once the plan is approved, the IACUC Chair will convene a mandatory meeting with the PI and laboratory personnel to review and discuss the determination, the required corrective actions, and the plans for ensuring compliance.
 - The Principal Investigator (PI) will review records, procedures, and compliance (e.g. any checklists, discussion at lab meetings, and description of material reviewed).
 - The PI will document in writing their review of the surgical records and notify the IACUC of any deviations from approved procedures.
3. There will be increased oversight of the surgeries performed under supervision of the PI by the IACUC for six months after approval of the plan.
- There will be two Post-Approval Monitoring (PAM) reviews focused on surgery within 6 months of the IACUC determination.
 - A monthly review of all surgery, anesthesia, and analgesia records and adherence to the plan will be conducted.
4. If compliance with the IACUC approved plan or the increased oversight is not maintained, there will be escalating punitive corrective actions including, but not limited to suspension of all surgical privileges.

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 Dickinson, PhD
Vice President and Dean of Research
Institutional Official
Baylor College of Medicine

cc: Principal Investigator
Department Chair
Research Compliance Services files

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 05, 2019 3:43 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: OLAW Report- Assurance D16-00475

Thank you for providing this report (b) (6) We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)
Sent: Tuesday, November 05, 2019 12:01 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: OLAW Report- Assurance D16-00475

Dear Dr. Morse,

Please find the attached notification 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,

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(b) (6)



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