



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

October 16, 2019

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

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 October 2, 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 10 mice were subjected to a parabiosis separation surgery that was not described in the protocol. The animals had been given appropriate analgesia and exhibited no adverse effects as a result of the unapproved surgery.

The corrective actions consisted of stopping further surgeries, amending the protocol, and requiring the Principal Investigator (PI) to submit an oversight plan to the Institutional Animal Care and Use Committee (IACUC). The plan is to include all surgeries, all substances given to animals, and all anesthetics/analgesics and confirmation that they were given. Once the plan is approved by the IACUC, the chair will counsel the PI and staff. The PI is to review records, procedures, and compliance with staff and is to verify review of surgical records and to report any deviations to the IACUC. The laboratory was placed under enhanced post-approval monitoring.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. Your prompt and thorough resolution of this matter is commendable and consisted with the PHS Policy philosophy of monitored self-regulation.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



A3823-8D

**OFFICE OF RESEARCH**

One Baylor Plaza, BCM310  
Houston, Texas 77030-3411

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mdlckins@bcm.edu

**CONFIDENTIAL**

October 2, 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-6216 Tumor-Induced Systemic Effects of the Immune System

**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*<sup>I</sup> with the federal regulations:

**Unapproved Surgical Procedure<sup>II, III</sup>**

During a routine health check, ten mice were found to have undergone a parabiosis separation surgery that was not described in the IACUC approved protocol. The mice received appropriate analgesia and postoperative care and there were no health concerns after evaluation by a clinical veterinarian.

**Corrective Actions:**

1. The unapproved surgical procedure was immediately halted by the PI.
2. The PI submitted an amendment to include the additional surgery and it was approved by the IACUC.
3. 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").
  - o 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.

<sup>I</sup> 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"

<sup>II</sup> PHS Policy IV.B.7. "As an agent of the Institution, the IACUC shall with respect to PHS-conducted or supported activities review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities"

- 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.
4. 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.
5. 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 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

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, October 4, 2019 6:35 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Report- Assurance D16-00475

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

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**From:** (b) (6)  
**Sent:** Thursday, October 3, 2019 2:50 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,

(b) (6)

(b) (6)

