



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 8G]

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 4, 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 provision of post-operative analgesia was delayed for five mice. Specifically, the administration of the analgesic was delayed on the third day following surgery and the animals were not monitored on that day. The mice were evaluated by a veterinarian and found to be in good condition.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) requiring the Principal Investigator to submit a surgical oversight plan requiring 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 Principal Investigator (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, continuing noncompliance will result in escalating sanctions, and the protocol will be amended if a sustained release analgesic is to be used.

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



43823-86
OFFICE OF RESEARCH

One Baylor Plaza, BCM310
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CONFIDENTIAL

October 4, 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-544: Reproductive Hormones: Biological and Molecular Actions

Species: Mice

Funding Sources: National Institutes of Health (NIH) R01-HD007857, P01-DK113954; National Institute of Child Health and Human Development (NICHD) R01-HD082786, R01-HD008188 and 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:

Post-operative Analgesia and Post-operative Monitoring^{ii,iii}

Five mice that underwent abdominal surgery according to the IACUC approved protocol, however, they received a delayed dose of post-operative analgesia for the third day, which is a different schedule than described in the protocol. In addition, post-operative monitoring by the research associate did not occur on that day. All five mice were evaluated by a clinical veterinarian and recovered from surgery 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 taken with respect to: a. any serious or continuing noncompliance with this Policy;"

ⁱⁱ PHS Policy IV.C.1.b: "Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator."

ⁱⁱⁱ The *Guide for the Care and Use of Laboratory Animals* p.119, "An important component of postsurgical care is observation of the animal and intervention as necessary during recovery from anesthesia and surgery (Haskin and Eisele 1997). The intensity of monitoring will vary with the species and the procedure and may be greater during the intermediate anesthetic recovery period...Particular attention should be given to the thermoregulation, cardiovascular and respiratory function, electrolyte and fluid balance, and management of postoperative pain or discomfort...Appropriate medical records should also be maintained..."

Corrective Actions:

1. 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.
 - o 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.
 - o The Principal Investigator (PI) will review records, procedures, and compliance (e.g. any checklists, discussion at lab meetings, and description of material reviewed).
 - o The PI will document in writing their review of the surgical records and notify the IACUC of any deviations from approved procedures.
2. 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.
 - o There will be two Post-Approval Monitoring (PAM) reviews focused on surgery within 6 months of the IACUC determination.
 - o A monthly review of all surgery, anesthesia, and analgesia records and adherence to the plan will be conducted.
3. 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.
4. If buprenorphine sustained release will be used, an amendment to the protocol must be reviewed and approved by the IACUC.

This finding of non-compliance does not appear to pose any potential or actual effect on cost related to this PHS supported research.

This notification will also be sent to AAALAC International, the National Institutes of Health, the National Institutes of Child Health and Human Development and the non-PHS funding sources 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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 7, 2019 6:53 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Report - Assurance D16-0475

Thanks for these reports, (b) (6) We will send responses soon.

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

From: (b) (6)
Sent: Friday, October 4, 2019 2:34 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: OLAW Report - Assurance D16-0475

Dear Dr. Morse,
Please find attached notification of an adverse event 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)

