



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

January 14, 2022

Re: Animal Welfare Assurance
A3823-01 [OLAW Case 9W]

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 January 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 ten mice received intraocular injections but failed to receive the preoperative systemic analgesia specified in the approved protocol. The mice did receive a local anesthetic, were monitored, and all but one were found to be in good condition by a veterinarian. The one hunched mouse was successfully treated and recovered.

The corrective actions consisted of the Principal Investigator (PI) counseling the laboratory staff and reviewing the content of the protocol. The laboratory staff undertook retraining, the laboratory was placed under enhanced post-approval monitoring, and the PI will maintain monthly compliance records which will be reviewed by the Institutional Animal Care and Use Committee (IACUC).

According to the information provided, 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 Contact



A3023-9W

OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

(713) 798 – 2104
(713) 798 – 2721 FAX
mdickins@bcm.edu

CONFIDENTIAL

January 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 finding in animal research after an assessment of the following protocol:

Protocol: AN-6542: Gene Therapy for Ocular Diseases

Species: Mice

Funding Sources: 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:

Preoperative Analgesicⁱⁱ

10/18/2021 – Pre-operative analgesic

A total of 10 mice underwent intraocular injections without the preoperative systemic analgesia described in the IACUC-approved protocol. All mice received a local anesthetic as described in the protocol and were monitored daily for 3 consecutive days following the intraocular injections. A Clinical Veterinarian evaluated the mice and all were in good condition, except for one mouse that was moving slowly with hunched posture. This mouse was given fluid, nutrients and heat, and recovered without incident.

12/14/2021 – Determination, review and approval of the surgical oversight plan 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 PI held a laboratory meeting with the research staff, reviewed and discussed the approved protocol procedures and reminded everyone about their responsibility to know what procedures, anesthetics and analgesics are approved on the protocol.

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."

2. All research personnel are required to complete the interactive "Top 10 Pitfalls in Animal Research and how to Avoid Them" training.
3. Two comprehensive Post-Approval Monitoring (PAM) reviews, will be conducted within the next six months.
4. The Principal Investigator will confirm in writing monthly compliance (checklist, lab meeting summary, or description of material reviewed) through oversight and review of records for procedures for the next six months, and that documentation will be reviewed when the records are reviewed.

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

cc: Principal Investigator
Research Compliance Services files

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 5, 2022 7:36 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

From: (b) (6)
Sent: Monday, January 3, 2022 4:50 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] OLAW Report- Assurance D16-00475

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

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)