



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

July 26, 2021

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

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 July 20, 2021 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 a mouse was subjected to retro-orbital blood collection and eye enucleation without anesthesia although these activities had not been approved in the protocol. The mouse died after the procedure and prior to the planned euthanasia.

The corrective actions consisted of revoking the animal use privileges for the investigator responsible, requiring the other animal users on the protocol to undertake hands-on retraining for all protocol procedures, and placing the laboratory 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. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair



A3823-9T

OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

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CONFIDENTIAL

July 20, 2021

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-7001: Novel Pancreatic Cancer Therapies in Preclinical Mouse PDX Models

Species: Mice

Funding Source: National Cancer Institute (NCI): U54-CA224076, R01-CA183984, Non-PHS Funding

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

Anesthesia Use and Unapproved Procedureⁱⁱ

5/14/2021 – Unapproved Procedure Performed

The IACUC received a self-report from the Principal Investigator on June 9, 2021, describing an incident involving a researcher who performed retro-orbital blood collection without anesthesia and eye enucleation prior to planned euthanasia in one mouse. The use of anesthesia for blood collection is required as described in the IACUC approved protocol, and enucleation is not described or approved. The mouse died shortly after the procedure prior to planned euthanasia.

7/13/2021 – Determination at a fully convened IACUC meeting

To protect the welfare of animals and prevent future recurrence, the IACUC required following corrective actions:

1. The researcher responsible is no longer approved to participate in animal research at Baylor College of Medicine.
2. All animal users on this protocol must complete hands-on training with central animal facility training personnel, for all procedures described in 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.B.7: "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"

3. Two Post-Approval Monitoring (PAM) sessions will be conducted within the next six months.

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

This notification will also be sent to AAALAC International, the National Cancer Institute, 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
Sr. 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: Friday, July 23, 2021 7:39 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: Thursday, July 22, 2021 5:00 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)