



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

September 30, 2021

Re: Animal Welfare Assurance
A3413-01 [OLAW Case 3D]

Michael R. Blackburn, Ph.D.
Executive Vice President and
Chief Academic Officer
University of Texas Health Science Center-Houston
7000 Fannin St., UCT-1732
Houston, TX 77030

Dear Dr. Blackburn,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 17, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Texas Health Science Center at Houston. Your letter supplemented the information contained in an initial telephone report to this office on September 1, 2021. According to the information provided, OLAW understands that on August 26, 2021, a report was received by your institution that four cages of mice ($n = 13$) were tail clipped for genotyping. Although the protocol is approved for tail clipping, the mice are to be tail clipped between 21 and 28 days of age. Mice from these four cages were older than 28 days of age at the time of clipping. The tail clipping was performed under isoflurane anesthesia. However, lab personnel did not ensure adequate hemostasis before the mice were returned to their respective cages. The animals involved in this incident were supported by NIH funding.

Corrective and preventive measures: on August 26, 2021, the Principal Investigator (PI) met with all laboratory personnel and instructed personnel to no longer tail clip mice older than 28 days of age. Additionally, the PI reminded personnel to ensure adequate hemostasis of tail clipped mice and to monitor the mice for fifteen minutes after returning the mice to the cages. Personnel responsible for this incident will be retrained and retake the Center for Laboratory Animal Medicine and Care Practical Research Methodology-Rodents course. Although a majority of the mice will be genotyped between 21 and 28 days of age, a protocol amendment was approved on September 15, 2021, for approval of tail clipping after 28 days of age, if necessary, to determine the genotype of the older mice.

It is understood that no significant costs associated with this event were identified but that funds will be returned if associated costs are identified.

OLAW appreciates the consideration of this matter by the University of Texas Health Science Center at Houston, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW agrees that appropriate corrective and preventive actions were taken. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2021.10.01 08:32:01 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

September 17, 2021

Brent Morse, D.V.M., DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Assurance A3413-01

Dear Dr. Morse,

The Animal Welfare Committee (AWC), the Institutional Animal Care and Use Committee for the University of Texas Health Science Center at Houston (UTHealth) provides this report of conduct of animal-related activities without appropriate AWC review and approval. In accordance with Assurance A3413-01 and PHS Policy IV.F.3.a., a preliminary report was made by the (b) (6) (b) (6) to you on September 1, 2021.

On August 26, 2021, the AWC received a report of conduct of animal-related activities without appropriate AWC review and approval. Four cages of mice (n = 13) were tail clipped for genotyping. Although the protocol is approved for tail clipping, the mice are to be tail clipped between 21 and 28 days of age. Mice from these four cages were older than 28 days of age at the time of clipping. The tail clipping was performed under isoflurane anesthesia. However, lab personnel did not ensure adequate hemostasis before the mice were returned to their respective cages. Per the institutional policy, all mice must be monitored for fifteen minutes after returning the mice to the cages to ensure adequate hemostasis and to observe for potential complications. No other complications or clinical consequences were noted.

On August 26, 2021, the Principal Investigator (PI) met with all laboratory personnel and instructed personnel to no longer tail clip mice older than 28 days of age. Additionally, the PI reminded personnel to ensure adequate hemostasis of tail clipped mice and to monitor the mice for fifteen minutes after returning the mice to the cages to observe for potential complications. Personnel responsible for this incident will be retrained and retake the Center for Laboratory Animal Medicine and Care Practical Research Methodology-Rodents course. Although a majority of the mice will be genotyped between 21 and 28 days of age, a protocol amendment was approved on September 15, 2021, for approval of tail clipping after 28 days of age, if necessary, to determine the genotype of the older mice.

Brent Morse, D.V.M., DACLAM
Re: Assurance 3413-01
September 17, 2021
Page 2 of 2.

The animals involved in this incident were supported by NIH funding (5R01CA215186-04). No significant costs associated with this event were identified. Funds will be returned if associated costs are identified.

The AWC Protocol Deviation Subcommittee has investigated the incident, evaluated the corrective action plan, and feels that the incident has been successfully resolved.

Please do not hesitate to contact me if you have any questions or comments.

Sincerely,

(b) (6)

Michael R. Blackburn, Ph.D.
Executive Vice President and Chief Academic Officer

MRB/tsl

cc: Dr. Juan Herrera, IACUC Chair

(b) (6)

AWC Office

Walker, Keri (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 24, 2021 9:40 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD); OLAW Division of Compliance Oversight (NIH/OD)
Cc: Blackburn, Michael R; Herrera, Juan; (b) (6) Animal Welfare Committee, GM
Subject: RE: OLAW Response to Final Report - Case A3413-01

Thank you for this report. We will send a response soon.

Keri

*Keri Walker
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-435-2390
keri.walker@nih.gov*

From: (b) (6)
Sent: Thursday, September 23, 2021 12:20 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Blackburn, Michael R <Michael.R.Blackburn@uth.tmc.edu>; Herrera, Juan <Juan.Herrera@uth.tmc.edu>; (b) (6) (b) (6) Animal Welfare Committee, GM <awc@uth.tmc.edu>
Subject: OLAW Response to Final Report - Case A3413-01
Importance: High

***Sent on behalf of Michael R. Blackburn, Ph.D.,
EVP & Chief Academic Officer / Institutional Official, UTHealth—***

Good Morning, Dr. Morse,

I have attached one PDF concerning the above-referenced.
Please advise if you have any issues with receiving the attachments.

Thanks and regards,

(b) (6)



Initial Report of Noncompliance

By: BCM

Date: 9/1/2021

Time: Voicemail

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Univ. of Texas Health (Houston)

Assurance number: A3413

Did incident involve PHS funded activity? yes

Funding component: ?

Was funding component contacted (if necessary):

13 mice underwent tail clipping >28 d/o. Anesthetized but not properly monitored and inadequate hemostasis.

Species involved: Mus musculus

Personnel involved: Researcher

Dates and times: 8/26/21

Animal deaths: no

Projected plan and schedule for correction/prevention (if known):

PI counseled lab staff. Staff will be retrained. Protocol amendment submitted for >28 d/o if necessary.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY

Case #