



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

April 28, 2021

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

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 April 19, 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 March 30, 2021. According to the information provided, OLAW understands that on March 19, 2021, your institution received a report that two cages of mice underwent a stereotaxic injection surgical procedure, one cage on February 24 and the second cage on March 2, 2021. The stereotaxic injection surgical procedure is described and approved on the collaborating Principal Investigator's (PI's) protocol but not the protocol for which the deviation occurred. Similarly, the individual responsible for the deviation is an approved surgeon for performing the stereotaxic injection procedure on the collaborating PI's protocol and is qualified and trained to perform the procedure. No clinical consequences resulted from this incident. All mice were adequately monitored post-operatively and were provided the appropriate analgesia, as described on the collaborating PI's protocol. The animals involved in this incident were supported by NIH funding.

Corrective and preventive measures included a protocol amendment to add the stereotaxic injection surgical procedure and to update the role of the individual responsible for the deviation. 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, as far as described. We assume that the personnel involved were counseled on the importance of confirming both proper procedures and proper personnel are described on the appropriate approved protocol before commencing work with animals. 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: 2021.04.29 09:13:53 -04'00'

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

cc: IACUC contact



**Office of the Executive Vice President
and Chief Academic Officer**

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

A3413-3A

April 19, 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 surgical procedures not approved on the AWC protocol. In accordance with Assurance A3413-01 and PHS Policy IV.F.3.a, a preliminary report was made by the (b) (6) to you on March 30, 2021.

On March 19, 2021, the AWC received a report of surgical procedures not approved on the AWC protocol. Two cages of mice underwent a stereotaxic injection surgical procedure, one cage on February 24 and the second cage on March 2, 2021. The stereotaxic injection surgical procedure is described and approved on the collaborating Principal Investigator's (PI's) protocol and not the protocol for which the deviation occurred. Similarly, the individual responsible for the deviation is an approved surgeon for performing the stereotaxic injection procedure on the collaborating PI's protocol and is qualified and trained to perform the procedure. No clinical consequences resulted from this incident. All mice were adequately monitored post-operatively and were provided the appropriate analgesia, as described on the collaborating PI's protocol, and properly documented on the post-operative cage cards. The protocol amendment to add the stereotaxic injection surgical procedure and to update the role of the individual responsible for the deviation from manipulator to surgeon was approved on April 6, 2021.

The animals involved in this incident were supported by NIH funding (5R01DK114037-03). No significant costs associated with this event were identified. Funds will be returned if associated costs are identified.

The AWC Protocol Deviation Subcommittee 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. Christophe Ribelayga, IACUC Chair

(b) (6)

AWC Office

(b) (6) phone

(b) (6) fax

7000 Fannin St., UCT-1732, Houston, TX 77030

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 28, 2021 7:39 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Final Report - Assurance A3413-01

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

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

From: (b) (6)
Sent: Tuesday, April 27, 2021 11:56 AM
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>; Ribelayga, Christophe P <Christophe.P.Ribelayga@uth.tmc.edu>; (b) (6) Animal Welfare Committee, GM <awc@uth.tmc.edu>
Subject: OLAW Final Report - Assurance 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 attachment.

Thanks and regards,

(b) (6)



Initial Report of Noncompliance

By: BCM

Date: 3/30/2021

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? ?
 Funding component:
 Was funding component contacted (if necessary):

Two cages of mice underwent unapproved stereotaxic surgery. Surgery was performed by trained surgeon on collaborating PI's protocol. Post-SX the mice were transferred to the proper protocol. No animal welfare concerns. Proper post-op care, monitoring and analgesia.

Species involved: Mus musculus
 Personnel involved: Researcher
 Dates and times: 2/4/21 and 3/2/21
 Animal deaths: no

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

Projected submission to OLAW of final report from Institutional Official:

< 60 days

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 Case #