



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

June 24, 2021

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

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 June 15, 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 June 2, 2021. According to the information provided, OLAW understands that on May 25, 2021, the incision sites on two rats that had undergone an approved procedure were sutured by an individual who was not approved on the protocol as a surgeon. The incision sites were not adequately apposed. The individual responsible for this incident is an approved surgeon on other collaborating Principal Investigator's protocols. The individual was only approved as a manipulator on the protocol for which this incident occurred. The animals involved in this incident were supported by NIH funding.

Corrective and preventive measures included a protocol amendment to update the role of the individual responsible for the deviation to surgeon. It was recommended the individual retake the Aseptic Surgical Techniques-Rodents course as this will allow the individual to receive more recent training on suturing techniques. Following training, the individual will be certified as an independent surgeon by a member of the veterinary staff. 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: 2021.06.24 09:53:41 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact

June 15, 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) to you on June 2, 2021.

On May 25, 2021, the AWC received a report of conduct of animal-related activities without appropriate AWC review and approval. The incision site of two rats having undergone a spinal contusion injury (SCI) was sutured by an individual who is approved on the protocol as a manipulator but not a surgeon. The SCI surgical procedures were performed by an approved surgeon on May 25, 2021, and observed by the individual responsible for this incident in order to begin learning the SCI model. Although the individual responsible for this incident is an approved surgeon on other collaborating Principal Investigator's protocols containing the approved SCI, the individual was only approved as manipulator on the protocol for which this incident occurred.

Both the individual and the approved surgeon were counseled on the importance of confirming proper personnel roles as described on the protocols. A protocol amendment to update the individual's role to surgeon was approved on June 7, 2021. Because the individual completed Aseptic Surgical Techniques-Rodents course on June 10, 2016, and is now undergoing training on the SCI model, it was recommended the individual retake the aseptic course as refresher retraining. The refresher training will allow the individual to receive more recent training on suturing techniques as the incision sites were not adequately apposed. Prior to the individual performing the SCI procedure independently, following training, the individual will be certified as an independent surgeon by a member of the veterinary staff.

The animals involved in this incident were supported by NIH funding (1R01NS110707-03). No significant costs associated with this event were identified. Funds will be returned if associated costs are identified.

Brent Morse, D.V.M., DACLAM
Re: Assurance A3413-01
June 15, 2021
Page 2 of 2.

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. Christophe Ribelayga, IACUC Chair

(b) (6)
AWC Office

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 21, 2021 6:52 AM
To: [REDACTED] (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Final Reports - Assurance A3413-01

Thank you for these reports. We will send responses soon.

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

From: [REDACTED] (b) (6)
Sent: Wednesday, June 16, 2021 10:50 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>; [REDACTED] (b) (6) Animal Welfare Committee, GM <awc@uth.tmc.edu>
Subject: OLAW Final Reports - 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 two PDFs concerning the above-referenced.
Please advise if you have any issues with receiving the attachments.

Thanks and regards,

[REDACTED] (b) (6)



Initial Report of Noncompliance

By: BCM

Date: 6/2/2021

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):

Lab staff member being trained as surgeon on one protocol, but sutured an animal on an NIH funded protocol on which she was not approved.

Species involved: mouse
 Personnel involved: researcher
 Dates and times: ?
 Animal deaths: yes

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

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY
 Case #