



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

December 3, 2021

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

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 November 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 October 29, 2021. According to the information provided, OLAW understands that on July 1 and August 26, 2021, five and four cages of mice, respectively, underwent surgical procedures. Although the individual who performed the surgical procedures had completed all the required training courses and had been certified as a rodent surgeon, the individual was approved as a manipulator only on the protocols for which the surgeries occurred. Furthermore, the injection procedure is approved on the protocol for which the surgeries occurred on August 26 and not the protocol for which the surgeries occurred on July 1. Also, six of the nine post-operative cage cards showed two days of post-operative monitoring instead of the three days as approved on the protocol. No apparent adverse clinical consequences resulted from this incident as all mice were bright, alert, and active with normal food and water intake. This activity is PHS-supported.

Corrective and preventive actions included the submission of a protocol amendment to update the role of the individual from manipulator to surgeon; the implementation of a protocol reference chart summarizing personnel roles and the specific procedures approved on each of the PI's protocols; the PI will combine multiple rodent protocols into two rodent protocols; individual responsible for this incident were counseled to review and discuss post-operative care and monitoring. 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: 2021.12.03 10:49:04 -05'00'

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

cc: IACUC contact

November 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 animal procedures not approved on the AWC protocol and participation in animal-related activities by trained personnel without appropriate AWC 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 October 29, 2021.

On September 28, 2021, the AWC received a report of conduct of animal procedures not approved on the AWC protocol and participation in animal-related activities by trained personnel without appropriate AWC approval. More specifically, on July 1 and August 26, 2021, five and four cages of mice, respectively, underwent surgical procedures for the intracerebral injection of amyloid-beta fibrils. Although the individual who performed the surgical procedures had completed all the Center for Laboratory Animal Medicine and Care (CLAMC) training courses to include Aseptic Surgical Techniques-Rodents and had been certified as a rodent surgeon, the individual was approved as a manipulator only on the protocols for which the surgeries occurred. Furthermore, the injection of the amyloid-beta fibrils is approved on the protocol for which the surgeries occurred on August 26 and not the protocol for which the surgeries occurred on July 1. Six of the nine post-operative cage cards showed two days of post-operative monitoring instead of the three days as approved on the protocol. However, no clinical consequences resulted from this incident as all mice were bright, alert, and active with normal food and water intake.

A protocol amendment to update the role of the individual from manipulator to surgeon was approved on October 5, 2021, for the protocol for which the injection of the amyloid-beta fibrils is approved. The amendment to update the role of the individual from manipulator to surgeon for the second protocol was approved on November 17, 2021.

Brent Morse, D.V.M., DACLAM
Re: Assurance A3413-01
November 19, 2021
Page 2 of 2.

On October 12, 2021, CLAMC veterinary and AWC office staff met with the Principal Investigator (PI) and all approved laboratory personnel to recommend the implementation of a protocol reference chart summarizing personnel roles and the specific procedures approved on each of the PI's protocols. The reference chart is to be placed in the housing, procedure, and surgery rooms the PI utilizes to provide a quick reference for personnel to review the procedures approved on each protocol. Furthermore, the PI will combine his multiple rodent protocols into two rodent protocols to assist the PI better manage his protocols. Trained approved personnel will update their roles from manipulators to surgeons to prevent incidents like this from reoccurring. On October 26, 2021, CLAMC veterinary and AWC office staff met with the individual responsible for this incident to review and discuss post-operative care and monitoring.

The animals involved in this incident were supported by NIH funding (3R01AI132695-05S1 and 1RF1AG059321-01A1). 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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 1, 2021 10:42 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Response to Final Report - Case 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: Wednesday, December 1, 2021 10:12 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>; 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, UTHHealth—***

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: 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):

Surgery performed on mice on July 1, 2021 (5 cages) and August 26 (4 cages) by person who was approved a "manipulator" but not as surgeon. Also, mice only monitored 2 days post-op instead of 3 as required. No negative outcomes for animal welfare.

Species involved: Mus musculus

Personnel involved: Researcher

Dates and times: see above

Animal deaths: no

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

Protocol amendment approved to add surgeon. Ten protocols to be combined into two. Flow charts will be posted for research staff.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY

Case #