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) 402-7065

August 29, 2019

Re: Animal Welfare Assurance
A3413-01 [OLAW Case 2I]

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 August 20, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals 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 July 12, 2019. According to the information provided, OLAW understands that on April 24, 2019 an anesthetized mouse was found unattended in the CLAMC vivarium surgical suite. The mouse was undergoing a craniotomy surgical procedure and required additional anesthesia which was delivered once the surgeon returned approximately six minutes later. It was also determined that although the mouse appeared to have been properly prepped for surgery, there were issues with aseptic technique and sterile preparation of instruments. The surgeon then chemically disinfected the instruments, the incision was closed, and the mouse recovered. The mouse, and four other mice that had undergone the procedure, recovered without incident and were provided protocol approved post-operative analgesics. The involved animal activity was funded by the PHS.

Corrective and preventive actions included informing the surgeon and the PI that no further scheduled surgeries should be performed until re-training and re-certification had occurred. Subsequently, all required re-training and re-certification has taken place including all surgeons and the PI. No significant costs related to this incident were 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 subsequent to the incident. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact

UTHealth
The University of Texas
Health Science Center at Houston

Office of the Executive Vice President and Chief Academic Officer

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

August 20, 2019

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 Institutional Animal Care and Use Committee at the University of Texas Health Science Center at Houston (UTHealth) provides this report of non-compliance involving failure to incorporate sterile and aseptic surgical techniques and inadequate intraoperative monitoring of an anesthetized animal. 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 July 12, 2019.

On April 24, 2019, (b) (6) entered a Center for Laboratory Animal Medicine and Care (CLAMC) vivarium surgical suite and noted an anesthetized mouse undergoing a craniotomy surgical procedure. Although the craniotomy procedure is an approved procedure, it was noted that the surgeon was not present and there was evidence of aseptic and sterile techniques not being employed resulting in a departure from the approved protocol and the institutional policy on rodent survival surgery. The approximate time from entry into the surgical suite, and the return of the surgeon was six minutes. During this six-minute time frame, (b) (6) performed a toe pinch reflex and noted a slight reflex requiring the re-administration of the ketamine/xylazine anesthetic cocktail. In addition, it was noted that the surgical instruments were laying in a brown paper towel instead of a sterile field. Although the surgical site was aseptically prepared, there was no evidence of sterile drapes being utilized and no evidence of the surgical instruments being subjected to initial steam autoclave as approved on the protocol. It was observed that the hot-bead sterilizer was in the off position. (b) (6) also observed a cage of four mice being provided heat support that were recovering from anesthesia. These four mice presumably underwent surgical procedures under non-sterile conditions. Immediately following the return of the surgeon the mouse was given a second injection of ketamine and xylazine. The surgical tools were chemically disinfected, and the surgeon re-dawned sterile surgical gloves and was allowed to close the surgical site and recover the mouse. The mouse was provided the post-operative analgesic as approved on the protocol, and the mouse recovered from anesthesia without any complications. Similarly, the other four mice recovered from anesthesia without any complications and were provided post-operative analgesics as approved on the protocol.

(b) (6) contacted the CLAMC clinical veterinarian to inform him of the incident, and the veterinarian immediately met with (b) (6) and the surgeon to discuss the incident and to monitor the recovery of all the mice. The surgeon was instructed not to perform any additional surgeries until the surgeon was certified to perform surgeries independently following retraining. On the afternoon of April 24, (b) (6) emailed the Principal Investigator (PI) informing him of the incident and recommended that all surgeons

713.500.3544 phone 713.500.3059 fax
7000 Fannin St., UCT-1732
Houston, TX 77030

withhold from performing any scheduled surgical procedures until (b) (6) and the veterinarian met in person with the PI to discuss the incident in further detail. The meeting occurred the following day on April 25, and an initial corrective action plan was discussed that involved certification of the surgeon responsible for the non-compliance. Because a CLAMC Aseptic Surgical Techniques-Rodent course was scheduled for the following afternoon on April 26 it was recommended all approved surgeons attend this course to receive re-training on aseptic and sterile techniques. All mice were evaluated by (b) (6) on April 25 and April 26. All the mice were observed to be bright, alert, and active with no clinical consequences and were being monitored by laboratory personnel as approved on the protocol.

At the scheduled fully convened meeting of the Animal Welfare Committee (ACW) on April 26 the non-compliance was discussed with the committee. Members were informed that the approved surgeons, including the surgeon responsible for the non-compliance, were taking the scheduled April 26 Aseptic Surgical Techniques-Rodent course. The committee recommended that the PI retake the aseptic techniques course as well. The PI completed the June 14 Aseptic Surgical Techniques-Rodent course.

On April 30, two surgical procedures were supervised by (b) (6) and the CLAMC veterinarian. All the approved surgeons, including the PI, were in attendance. The first surgical procedure served to certify the surgeon responsible for the non-compliance as an independent surgeon following successful completion of the craniotomy procedure utilizing aseptic and sterile techniques, per the institutional policy on rodent survival surgery and following methodology described in the approved protocol. The surgeon successfully completed the procedure and was granted the ability to continue performing surgical procedures unsupervised. The second surgical procedure was performed by a newly approved surgeon who was seeking certification as an independent surgeon. The newly approved surgeon successfully completed the craniotomy procedure and was certified as an independent surgeon. Therefore, all approved surgeons and the PI observed two surgical procedures and allowed (b) (6) and the clinical veterinarian to provide additional retraining.

The animals involved in the deviation were supported by NIH funding (5 RO1 DK092605-04). 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. Christophe Ribelayga, IACUC Chair
(b) (6)
AWC Office

Na, Jane (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 23, 2019 4:14 PM
To: (b) (6)
Cc: Blackburn, Michael R; Ribelayga, Christophe P; (b) (6) Animal Welfare Committee, GM; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Assurance A3413-01

Dear (b) (6)

Thank you for providing these four final reports. All four attachments were received. We will send official responses soon.

Jane

Jane Na, DVM, CPIA
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
Phone (301) 402-1922
E-fax (301) 451-5609

From: (b) (6)
Sent: Friday, August 23, 2019 2:49 PM
To: 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: Assurance A3413-01
Importance: High

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

Dear Dr. Morse,

Please find attached four (4) PDFs concerning the above referenced.

Please advise if you have any issues with receiving the attachments.

Thanks and regards,
(b) (6)

(b) (6)

A3413-21

Office of Laboratory Animal Welfare

OLAW

Initial Report of Noncompliance

By:

Date: 7/19/19

Time: Voicemail from 7/12/19 @ 7:30pm

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): _____

What happened? 5 mice. Protocol deviation. Not using aseptic technique. No clinical consequences

Species involved: Mice

Personnel involved: Researchers

Dates and times:

Animal deaths: No

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

Retraining for all surgeons in lab + PI has been completed.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #_____