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

June 6, 2019

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

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 May 24, 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 report to this office on April 2, 2019 and a follow-up report on April 24th. According to the information provided, OLAW understands that on March 26, 2019 it was determined that a pregnant ewe, which had been anesthetized for experimental surgery, was carrying fetuses that were too old on which to perform the surgery to create a spina bifida defect followed by a repair surgery two weeks later as approved in the protocol. It was decided, after discussion between the laboratory personnel and a veterinarian, to perform both the defect creation and the repair procedure at that time as a possible refinement. The ewe recovered from the surgery without complications and both fetuses were alive and viable one week later and the ewe was doing well. The involved animal activity was funded by the PHS.

OLAW understands that the protocol could be amended in the future to include the concurrent creation and repair surgeries and that your institution relies on the animal vendor's information guidance with respect to ewe breeding dates.

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 action was taken at the time of the incident and to investigate the issue. OLAW does advise, however, that the issue may have been avoided if the IACUC had taken advantage of the use of Veterinary Verification and Consultation (VVC) as described in Notice NOT-OD-14-126 available at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html. Our office is available to discuss how this can be applied at your institution and may have been utilized in this specific example. 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
Robert Gibbens, D.V.M., USDA-APHIS-AC

A3413-2E

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

May 24, 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 a departure from approved surgical procedures. 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 April 2, 2019. A follow-up report was made by the (b) (6) to you on April 24, 2019.

On March 26, 2019, the Animal Welfare Committee (AWC) received a report involving a departure from approved surgical procedures. The approved protocol involves the creation of a spina bifida defect creation surgery followed by a repair surgery approximately two weeks later in a sheep model. Pregnant ewes are anesthetized and the fetuses undergo the defect creation procedure at 76 to 79 days of gestation. During a surgical procedure to create the defect surgery on March 26, 2019, it was discovered that the fetuses were larger than expected, reflective of a ewe more likely at 87 to 90 days of gestation. Unfortunately, at this gestational age it is too late to perform the creation surgery followed by a repair surgery two weeks later. Following discussion between the Center for Laboratory Animal Medicine and Care (CLAMC) veterinarian and laboratory personnel a decision was made to perform both the defect creation and repair procedure as a possible refinement and if successful could be of scientific value to the research group. The ewe recovered from the extended anesthesia period without any complications and received post-operative care as approved on the protocol. Ultrasonography one week following the surgery revealed both fetuses were alive and viable and at the time the ewe was doing well.

Based on the results obtained the protocol could potentially be amended in the future to include a concurrent creation and repair surgery in cases where the pregnant ewe is greater than 79 days in gestation at the time of the spinal defect creation surgery. However, personnel will be diligent when ewes are received whose breeding date is questionable in the future as laboratory and

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

CLAMC personnel rely on the animal vendor's information guidance with respect to ewe breeding dates.

The animals involved in the deviation were supported by NIH funding (5 R21HD092754-02). 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. Diane Bick, IACUC Chair
(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 03, 2019 12:29 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD); Blackburn, Michael R; Bick, Diane L; (b) (6)
Subject: RE: Assurance A3413-01

Thank you for sending these final reports. We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: (b) (6)
Sent: Monday, June 03, 2019 12:16 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Blackburn, Michael R <Michael.R.Blackburn@uth.tmc.edu>; Bick, Diane L <Diane.L.Bick@uth.tmc.edu>; (b) (6)
(b) (6)
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 the attached four (4) PDFs with regard to the above-referenced.

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

Thanks and regards,
(b) (6)

(b) (6)

(b) (6)

[redacted]