From:	<u>Gibbens, Robert - APHIS</u>
To:	Cody M - APHIS Yager (cody.m.yager@usda.gov)
Subject:	FW: OLAW Cases A3413-2B, 2C & 2E
Date:	Thursday, June 6, 2019 2:15:00 PM
Attachments:	<u>2780 001.pdf</u>
	<u>2781 001.pdf</u>
	2782 001 ndf

fyi

From: Ward, Joan (NIH/OD) [E] [mailto:wardjoa@od.nih.gov]
Sent: Thursday, June 6, 2019 12:10 PM
To: michael.r.blackburn@uth.tmc.edu
Cc: (b) (6)
Gibbens, Robert - APHIS
<robert.m.gibbens@usda.gov>

Subject: OLAW Cases A3413-2B, 2C & 2E

Dear Dr. Blackburn,

Attached please find Dr. Brent Morse's final responses to OLAW Cases A3413-2B, 2C & 2E.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards, Joan

Joan Ward Program Specialist Office of Laboratory Animal Welfare National Institutes of Health 6700B Rockledge Dr., Suite 2500 Bethesda, MD 20892 301-496-7163 wardjoa@od.nih.gov

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

June 6, 2019

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 402-7065

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

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 telephone report to this office on November 16, 2018. According to the information provided, OLAW understands that on November 12, 2018 three rabbits underwent surgery to successfully create a bone defect in the mandible, but a protocol-described fixation with a titanium bone plate was not included in the surgeries. The three rabbits recovered from the anesthesia, were monitored, and did not experience any adverse clinical consequences. It is noted that the PI had performed a similar surgery on 20 rabbits on a separate protocol that did not require the bone plate and those rabbits also did not show any clinical consequences. The involved animal activity was funded by the PHS.

The corrective action was to remove the requirement for the bone plate from the protocol. No significant costs associated with this event 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 is satisfied that appropriate actions have been taken to investigate and correct the issue. 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

DEPARTMENT OF HEALTH & HUMAN SERVICES



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

June 6, 2019

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Fassimile: (301) 402-7065

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

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 telephone report to this office on February 21, 2019. According to the information provided, OLAW understands that on February 16, 2019 fifteen Watanabe rabbits were not provided their daily amount of rabbit chow. This oversight was discovered on February 17th and the rabbits were given their daily amount of rabbit chow and the rabbits did not show any adverse clinical consequences. The involved animal activity was not funded by the PHS.

The corrective actions were to update the room signage and to provide the weekend husbandry technicians access to the computer shared dive listing the room order for the weekend. The weekend supervisors now verify that rabbits have been fed their daily feed ration.

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 is satisfied that appropriate actions have been taken to investigate and correct the issue. 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

DEPARTMENT OF HEALTH & HUMAN SERVICES



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

June 6, 2019

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 402-7065 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 20-02690_000019