



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 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



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)

On November 15, 2019, the Animal Welfare Committee (AWC) received a report involving a departure from approved surgical procedures. The approved protocol involved the placement of a titanium fixation bone plate along the inferior border of the mandible after the creation of a mandibular defect but prior to closure of the incision site as a prophylactic measure. Three rabbits that were subjected to a mandibular defect surgery on November 12, 2018, did not receive the fixation bone plate. All three rabbits recovered from anesthesia without any complications, were monitored for appetite and activity, and the incision site was carefully monitored. The rabbits did not experience any adverse clinical consequences.

The Principal Investigator (PI) was under the impression the approved surgical procedure did not include the placement of the bone plate. Following this incident a protocol amendment was submitted to remove the placement of the bone plate from the surgical procedure. Under another approved animal use umbrella protocol, the PI was approved for a similar mandibular defect surgery without the inclusion of the fixation bone plate in rabbits. Prior to this incident, the PI had successfully completed the defect surgery on 20 rabbits without the inclusion of the bone plate. Similar to the three rabbits in this incident, the previous 20 rabbits did not show any clinical consequences. The protocol amendment to remove the fixation bone plate was approved on November 26, 2018.

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

Brent Morse, D.V.M., DACLAM
Re: Assurance A3413-01; RCR-18-020
May 24, 2019
Page 2 of 2.

The animals involved in the deviation were supported by NIH funding (R01 DE 024747). 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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

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)
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)



Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, May 15, 2019 7:37 AM
To: (b) (6)
Subject: RE: Open OLAW cases

Thank you (b) (6) Yes, that will be fine. We appreciate the effort this takes for you and your institution.

Sincerely, Brent Morse

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

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From: (b) (6)
Sent: Tuesday, May 14, 2019 4:28 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: RE: Open OLAW cases

Hello Dr. Morse,

All three cases have been resolved. However, I have not submitted a final report for each case. I will begin drafting the final reports tomorrow and once complete obtain Dr. Blackburn's signature so that I can email them to you. I anticipate having these final reports for you by the end of the week. Is this acceptable? Thank you.

Best Regards,

(b) (6)

(b) (6)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, May 14, 2019 2:51 PM
To: (b) (6)
Subject: Open OLAW cases
Importance: High

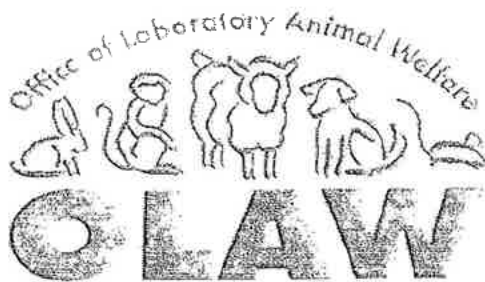
Hello (b) (6)

Your institution currently has three open compliance cases with OLAW including one you called-in around April 25th concerning frogs and another around February 26th concerning Watanabe rabbits not being fed for a day at a new satellite location. The third case was called-in around November 16, 2018 regarding mandibular bone plates not being applied in rabbits. Has this case been resolved? Is there a final report available? Please let me know and thank you for your attention to this.

Best regards, Brent Morse

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

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Initial Report of Noncompliance

By: [Signature]

Date: 11/16/18

Time: Voicemail

Name of Person reporting: (b) (6)
Telephone #:
Fax #:
Email:

Name of Institution: UTexas - HSC - Houston
Assurance number: A3413

Did incident involve PHS funded activity? Yes
Funding component: _____
Was funding component contacted (if necessary): _____

What happened? No mandibular bone plate applied as protocol - required in 3 rabbits on 11/12/18. Rabbits recovering O.K.
Species involved: Rabbit
Personnel involved: Surgeon
Dates and times: 11/12/18
Animal deaths: No
(20 rabbits on separate protocol at another institution did fine w/o bone plate)

Projected plan and schedule for correction/prevention (if known):
Modify protocol to remove requirement for plate.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # _____