



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

January 9, 2020

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

Michael R. Blackburn, Ph.D.
Executive Vice President and
Chief Academic Officer
University of Texas Health Science Center-Houston
7000 Fannin St., (b) (4)
Houston, TX 77030

Dear Dr. Blackburn,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 20, 2019 letter providing additional information, requested in our August 29, 2019 letter to you regarding an incident within the animal care and use program at the University of Texas Health Science Center at Houston. According to the additional information provided, OLAW understands that the non-UTHealth imaging facility referenced in your original report is an institution that has an OLAW Assurance and that all direct costs associated with the shipping and any subsequent unapproved manipulation of the animals at the imaging facility were paid from a nonfederal source and not the NINDS grant (NS-096186).

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 of the additional information provided 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
Tijuanna DeCoster, Chief Grants Management Officer, NINDS



**Office of the Executive Vice President
and Chief Academic Officer**

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

December 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: OLAW Case A3413-2H

Dear Dr. Morse,

The Institutional Animal Care and Use Committee at the University of Texas Health Science Center at Houston (UTHealth) acknowledges receipt of your August 29, 2019 letter requesting further information associated with OLAW Case A3413-2H. It was confirmed that the non-UTHealth imaging facility does have an OLAW Assurance (A4739-01). A review of the billing records showed that all direct costs associated with the shipping and any subsequent unapproved manipulation of the animals at the imaging facility were paid from a nonfederal source and not the NINDS grant.

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

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 08, 2020 1:37 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Blackburn, Michael R; Ribelayga, Christophe P; (b) (6) Animal Welfare Committee, GM
Subject: RE: OLAW Case A3413-2H

Thank you for providing this additional requested information. We will send an official response 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: Wednesday, January 08, 2020 11:41 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>; Ribelayga, Christophe P <Christophe.P.Ribelayga@uth.tmc.edu>; (b) (6) Animal Welfare Committee, GM <awc@uth.tmc.edu>
Subject: OLAW Case A3413-2H
Importance: High

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

Dear Dr. Morse,

Please find attached one (1) PDF concerning the above-referenced.
Please advise if you have any issues with receiving the attachment.

Thanks and regards,
(b) (6)

(b) (6)

(b) (6)

From: (b) (6)
Sent: Monday, December 23, 2019 9:22 AM
To: Blackburn, Michael R <Michael.R.Blackburn@uth.tmc.edu>
Subject: OLAW Letter Approval Needed
Importance: High

Good Morning –

(b) (6) is requesting your review and approval of the attached. Once I receive your approval, I will forward it as he has directed.

NOTES regarding the timing of this letter:

The OLAW letter dated August 29, 2019, is attached as a reference. The AWC office never received this letter. Dr. Brent Morse is now aware and was advised that a response will be submitted soon. Please have Dr. Blackburn review and sign and then convert to PDF. Once signed, please email it to Dr. Brent Morse. Please reference **OLAW CASE A3413-2H** in the correspondence. Please CC Dr. Christophe Ribelayga, myself, and the AWC office.

Thanks!

(b) (6)

(b) (6)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, December 10, 2019 3:27 PM
To: (b) (6)
Subject: OLAW letter
Attachments: 2129_001.pdf

Importance: High

Hello (b) (6)

As discussed, please see the attached letter requesting further information regarding OLAW case A3413-2H. Sorry you didn't receive this earlier but I'm sure we can clarify this issue now. Thank you for your help.

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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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 2H]

Michael R. Blackburn, Ph.D.
Executive Vice President and
Chief Academic Officer
University of Texas Health Science Center-Houston
7000 Fannin St., (b) (4)
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 30, 2019 a PI self-reported that between April 3 and April 17, 2019 an unapproved suture material was used to close the surgical incision site on three mice. There were no resultant clinical consequences. In addition, during the same period, seven mice that had undergone surgical procedures were shipped to a facility outside of UTHealth for imaging. The shipping and subsequent manipulation outside of UTHealth were not approved on the protocol. There were no clinical consequences noted. The involved animal activity was funded by the PHS (NS-096186).

Corrective and preventive actions included the PI stopping any further shipping of animals unless an approved protocol amendment is obtained. All personnel performing surgery were re-educated regarding proper suture types and closing patterns. Also, the CLAMC business office will verify that a protocol has been approved for shipment when receiving an export request for mice with special conditions such as mice having undergone previous manipulation.

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. Although you have determined that "No significant costs related to this incident were identified" **OLAW requests further information.** Please confirm whether or not the non-UTHealth imaging facility is an institution that has an OLAW Assurance. If not, please report this to OLAW as a noncompliance along with corrective and preventive measures since all performance sites where animals are used on a PHS-funded activity must be covered by an OLAW Assurance. Whether assured or not, the costs associated with the shipping and any subsequent unapproved manipulation of the animals at the imaging facility must not be charged to the NINDS grant. We appreciate being informed of this matter and request that you provide the information **by September 30, 2019.** Please reference **OLAW Case A3413-2H** in your correspondence. Thank you.

Sincerely,

(b) (6)

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

cc: IACUC Contact
Tijuanna DeCoster, Chief Grants Management Officer, NINDS



**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 departures from the approved protocol. In accordance with Assurance A3413-01 and PHS Policy IV.F.3.a., a preliminary report was made by the [REDACTED] (b) (6) to you on July 12, 2019.

On April 30, 2019, a Principal Investigator (PI) self-reported to the Animal Welfare Committee (AWC) departures from the approved protocol. Specifically, the surgical incision site of three mice was closed with silk suture. The approved protocol indicates that the surgical site will be closed with monofilament suture. The surgical procedures were conducted between April 3 and April 17, 2019. No clinical consequences resulted from the use of the unapproved suture. The PI also reported the shipment of seven mice having undergone surgical procedures between April 3 and April 17, 2019 to a facility outside of UTHealth for imaging. The shipping and subsequent manipulation outside of UTHealth are not approved on the protocol. At the time of the non-compliance all mice were healthy, and no clinical consequences were noted.

All personnel performing surgery were re-educated regarding the proper suture type for closing specific surgical sites. Additionally, personnel were re-educated on the differing suture types and usage and closing patterns. The PI no longer plans to ship animals. However, if any future shipments are planned, the protocol will be amended accordingly. Additionally, the Center for Laboratory Animal Medicine and Care business office will review the protocol or verify with the AWC office or export veterinarian to confirm that the protocol has been approved for shipment when receiving an export form for mice with special conditions such as mice having undergone a previous manipulation.

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
August 20, 2019
Page 2 of 2.

The animals involved in the deviation were supported by NIH funding (NS-096186). 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

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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)



Initial Report of Noncompliance

By: (b) (6)

Date: 7/19/19

Time: Voicemail from 7/12/19

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution:

Assurance number:

Univ of Texas Health - Houston
A3413

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary):

What happened? Silk suture used to close skin in stroke surgery. Mice were then shipped although that was not in protocol

Species involved: Mice

Personnel involved: Researchers

Dates and times: 4/3 + 4/17/19

Animal deaths:

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

Will not use silk. Will not ship animals

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #