



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
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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) 480-3387

July 24, 2020

Re: Animal Welfare Assurance  
A3314-01 [OLAW Case 1Y]

Dr. David W. Niesel  
Associate Chief Research Officer  
Senior Vice President and Dean of  
Graduate School of Biomedical Sciences  
University of Texas Medical Branch  
301 University Boulevard, Route 0156  
Galveston, TX 77555-0156

Dear Dr. Niesel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 2, 2019 letter reporting a non-compliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Texas Medical Branch - Galveston. Your letter supplements the information provided in the initial telephone report to our office on June 17, 2020. According to the information provided it is understood that six rats underwent a minor surgical procedure on June 9<sup>th</sup>. The next day it was determined that the dosing interval of analgesic for the rats exceeded that which was described in the protocol. The animals were then administered the analgesic as per the protocol and evaluated by a veterinarian. There were no indications of pain or discomfort. It is understood that this animal activity was supported by funding from the PHS.

Corrective and preventative actions, in addition to that described above, included the laboratory personnel being required to complete training in pain management, post-procedural care and minimizing pain and distress.

The prompt consideration of this matter by the University of Texas Medical Branch - Galveston was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate and should help to prevent future incidents. We appreciate you reporting this matter and find no cause for further action by this office.

Sincerely,

**Brent C. Morse -S**

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

Digitally signed by Brent C.  
Morse -S  
Date: 2020.07.24 09:02:30 -04'00'

cc: IACUC Contact

July 2, 2020

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

**Re:** University of Texas Medical Branch, Galveston: Animal Welfare Assurance D16-00202 (A3314-01)  
case 1Y

Dear Dr. Morse:

As a follow up to our telephone report provided on June 17, 2020, a description of the incident with the IAUCUC actions are presented.

Six (6) rats underwent a minor surgical procedure on June 9, 2020. The procedure was overseen by the Post Approval Monitors as well as the Attending Veterinarian. A follow up observation of the animals the next morning by the Post Approval Monitor noted that the administration of analgesics exceeded the dosing interval outlined in the animal care and use protocol. When the lab was notified, all animals were dosed according to the protocol. An ARC veterinarian was contacted and evaluated the animals. The animals were found to be in good condition with no evidence of pain or discomfort.

The Laboratory personnel will be required to take a number of AALAS learning library classes on pain management, post-procedure care, and minimizing pain and distress. The laboratory will also be observed more frequently by the ARC Veterinary Team and Post Approval Monitors to ensure ongoing protocol compliance.

The protocol is funded by the National Institute of Diabetes and Digestive and Kidney Diseases grant #5R01DK11181902 entitled, "**A Preclinical Model of Peripubertal and Adult Visceral Hypersensitivity.**"

We believe we have taken appropriate and sufficient action in the incidents above. If you have any questions, please do not hesitate to contact me.

Sincerely,

(b) (6)

**David W. Niesel, Ph.D.**  
**Institutional Official**  
Senior Vice President and Dean,  
Graduate School of Biomedical Sciences  
Associate Chief Research Officer  
Lawrence E. Ethridge, Jr. Professor  
Professor, Microbiology and Immunology University of Texas Medical Branch

**Walker, Keri (NIH/OD) [C]**

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**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Sunday, July 5, 2020 4:24 PM  
**To:** Walker, Keri (NIH/OD) [C]  
**Subject:** FW: OLAW Case 1Y  
**Attachments:** OLAW Letter case 1Y.pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hello Keri. Please use the attached and this email to start a new case. You can put it in my mailbox when it is ready.

Thanks Brent

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

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**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Sunday, July 05, 2020 4:22 PM  
**To:** (b) (6)  
**Cc:** (b) (6) Niesel, David W.  
<dniesel@UTMB.EDU>  
**Subject:** RE: OLAW Case 1Y

Thank you Allan. I'll 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

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**From:** (b) (6)  
**Sent:** Thursday, July 02, 2020 10:34 AM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Cc:** (b) (6) Niesel, David W.

<dniesel@UTMB.EDU>

**Subject:** OLAW Case 1Y

Dr. Morse

Please see our report as a follow up to our conversation on 6/17/2020.

Thank you

Confidential IACUC Communication  
Texas Health & Safety Code § 161.031 et seq.  
Do Not Distribute Without Authorization

(b) (6)





## Initial Report of Noncompliance

By: (b) (6)

Date: 6/17/20

Time: 9:30

Name of Person reporting:

Telephone #:

Fax #:

Email:

Name of Institution:

Assurance number:

U. Texas Med. Branch - Galveston  
A3314

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary):

What happened? Post-operative Buprenorphine dose missed after in-utero stress model surgery.

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

Rat  
Researcher

6/10/20

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

IACUC "meets" 6/19/20

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #