

### 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 <u>Telephone</u>: (301) 496-7163 <u>Eacsimile</u>: (301) 402-7065

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

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 May 20, 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 May 20. According to the information provided it is understood that 30 mice were inoculated with a substance that was not described or approved for the project to which the animals were assigned. Once identified, the animals were transferred to the correct protocol where the procedure was described and approved. This oversight did not result in additional pain or discomfort for these animals. This was a repeat noncompliance. 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 implementing a mouse order tracking form which will require identifying the intended protocol before an animal order is placed.

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,

(b) (6)

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



nstitutional Animal Care & Use Committee

301 University Blvd., Route 0156 Galveston, TX 77555-0156 Office: (409) 266-9427 Fax: (409) 266-9470 Website: http://research.utmb.edu/iacuc

May 20, 2019

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 1W.

Dear Dr. Morse:

As a follow up to a telephone conversation on May 20, 2019, we wish to provide the following information.

Thirty (30) mice assigned to a project were inoculated with a substance that was not described or approved for the project to which the animals were associated. Once identified, the animals were transferred to the correct protocol were the procedure was described and approved by the IACUC. The animals did not go through any additional pain or discomfort from this action. This is a repeat incident of that also occurred with this project in January 2017.

The IACUC quorum met on May 9, 2017, to discuss the self-reported event. The researcher attended the meeting. The Committee's findings were as follows:

**Non-compliance:** The animals were inoculated with an agent that was not described nor approved on the protocol to which the animals were assigned. The non- compliance was corrected shortly after being recognized by transferring the animals to the correct protocol. Animal health and welfare was not compromised by this action.

**Corrective Action:** The laboratory did not follow the implemented procedures developed from the last incident. The Principal investigator of the project spoke to the committee. The lab has implemented a mouse order tracking form. Lab members will have to complete parts of this form, which includes indicating the intended protocol of use, prior to the animal order being placed.

The Committee accepted the plan of action as proposed by the researcher.

This protocol is funded through the National Institute of Allergy and Infectious Diseases award entitled "Advancement of Treatments for Ebola and Marburg Virus Infections, #1U19Al109711-0I",

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.



301 University Blvd., Route 0156 Galveston, TX 77555-0156 Office: (409) 266-9427 Fax: (409) 266-9470 Website: http://research.utmb.edu/lacu;

Sincerelv. (b) (6)

Dr. David W. Niesel, PhD Institutional Official Associate Chief Research Officer Senior Vice President and Dean Graduate School of Biomedical Sciences

Linioaded to

# Morse, Brent (NIH/OD) [E]

From: Sent: To: Cc: Subject: Morse, Brent (NIH/OD) [E] Friday, May 24, 2019 11:12 AM (b) (6) Niesel, David W.; <sup>(b) (6)</sup> RE: OLAW Case 1W

Brining, Douglas L.; (b) (6)

Thank you for this report (b) (6) We will send an official response soon. Have a great weekend.

Sincerely, 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.

1

From: (b) (6)

Sent: Friday, May 24, 2019 10:32 AM To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov> Cc: Niesel, David W. <dniesel@UTMB.EDU>; <sup>(b) (6)</sup> (b) (6) Brining, Douglas L. <dlbrinin@UTMB.EDU>; <sup>(b) (6)</sup> Subject: OLAW Case 1W

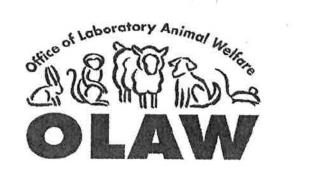
Dr. Morse

Please find final report concerning case 1W attached.

## 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: Bym

Date:

Time: 10:00

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

Name of Institution: Assurance number:

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

What happened? Lane Species involved: Personnel involved: Resear Dates and times: Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #