



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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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

August 13, 2019

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

Dr. David Niesel
Associate Chief Research Officer
Senior VP & Dean, Graduate School
of Biomedical Sciences
University of Texas Medical Branch
301 University Boulevard
Galveston, TX 77555-0156

Dear Dr. Niesel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 6, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas Medical Branch. According to the information provided, OLAW understands that ten nonhuman primates on a study were not observed twice daily as described in the approved protocol on one occasion. Although the technician performed only a single observation, there were no problems with the animals or study activities due to this action.

The corrective action consisted of applying human resources administrative measures with the technician.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



Health

Research Services
Institutional Animal Care & Use Committee

301 University Blvd., Route 0156
Galveston, TX 77555-0156

Office: (409) 266-9427

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Website: <http://research.utmb.edu/iacuc>

August 6, 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 1X.

Dear Dr. Morse:

On June 18, 2019, 10 Non-Human primates were challenged with a biological agent. The protocol includes at a minimum, twice (2) times a day observations following post inoculation. The researcher had contracted with the Animal Resources Center (ARC) for their personnel to perform the observations and associated endpoint scoring. On July 8, 2019, the ARC technician failed to perform the second observation as detailed in the IACUC protocol. There were no animal welfare or scientific issues that resulted from the missed observation and the animals were not showing any clinical signs of disease during the morning observation and humane scoring. The Animal Resource Center, Executive Director took appropriate administrative actions. The AV notified the IACUC committee of the incident during the meeting held on July 25, 2019. The committee agreed that the incident would be forwarded to OLAW and that the administrative action taken was sufficient.

Non-compliance: Observations of animals did not occur in accordance with the written protocol.

Corrective Action: Human Resources administrative action was taken.

This protocol is funded through the National Institute of Allergy and Infectious Diseases award entitled "Pre-Clinical Models of Infectious Diseases - Part B: Non-Human Primate (NHP) Models of Infectious Diseases" associated with Contract No. HHSN272201700040I and NIH Task order HHSN27200009.

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)

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

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, August 12, 2019 2:11 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Niesel, David W.; (b) (6)
Subject: RE: Report 1X

Thank you for providing this report (b) (6). 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

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From: (b) (6)
Sent: Monday, August 12, 2019 2:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Niesel, David W. <dniesel@UTMB.EDU>; (b) (6)
(b) (6)
Subject: Report 1X

Dr. Morse

Please see the above report. Let me know if you have any questions or concerns.

Thank you

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(b) (6)