



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) 480-3387

September 3, 2021

Re: Animal Welfare Assurance  
A3314-01 [OLAW Case 2B]

Ms. Sharon Comvalius-Goddard  
Associate Vice President  
Research Regulations and Compliance  
University of Texas Medical Branch  
301 University Boulevard, Route 0156  
Galveston, TX 77555-0156

Dear Ms. Comvalius-Goddard,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 1, 2021 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 August 31, 2021. According to the information provided it is understood that on 17 August 2021, during a post approval monitoring (PAM) visit, a PI was observed performing an oral gavage procedure to inoculate mice. It was subsequently determined that four (4) animals had been previously inoculated four weeks earlier. The approved protocol detailed only a single inoculation procedure. The PI immediately discontinued the reinoculation procedure. There were no detrimental impacts to the health and welfare of the animals resulting from the second inoculation. This project is funded through and NIH grant.

Corrective and preventive actions included the researcher discontinuing further inoculations and submit an amendment to the protocol. Furthermore, the researcher will ensure all laboratory personnel have a current copy of the protocol and are trained on the procedures as described within. Staff are to review the protocol prior to the performance of all procedures to ensure the procedure is outlined and approved. If not, an amendment will be submitted to the committee for review and approval prior to implementation of a new procedure. The committee accepted the researcher's initial actions and plans to alleviate the same mistake in the future.

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

Sincerely,

**Brent C. Morse -S** Digitally signed by Brent C. Morse -S  
Date: 2021.09.03 11:33:55 -04'00'

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

cc: IACUC contact



**Health**

Institutional Animal Care & Use Committee  
Research Regulations and Compliance

301 University Blvd., Route 0158  
Galveston, TX 77555-0158  
(409) 266-9427  
Email: [IACUC.oup@UTMB.EDU](mailto:IACUC.oup@UTMB.EDU)

September 1, 2021

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) case (A3314-2B).

Dear Dr. Morse:

As a follow up to our telephone report provided on August 31, 2021, a description of the incident and follow up action by the IACUC are presented.

On 17 August 2021, during a post approval monitoring (PAM) visit, a PI was observed performing an oral gavage procedure to inoculate mice. The procedure was performed in accordance with the approved IACUC protocol. During discussions that occurred during the visit, it became clear that four (4) animals had been previously inoculated four weeks earlier. The researcher had tested the animals via PCR post inoculation and found that they had not developed an appropriate parasite burden. The approved protocol detailed only a single inoculation procedure. The PI immediately discontinued the reinoculation procedure. There were no detrimental impacts to the health and welfare of the animals resulting from the second inoculation.

The researcher self-reported the incident to the IACUC. The committee reviewed and discussed the report at a quorum meeting held on August 26, 2021. The researcher's immediate actions were to cease further inoculations and submit an amendment to the protocol. Furthermore, the researcher will ensure all laboratory personnel have a current copy of the protocol and are trained on the procedures as described within. Staff are to review the protocol prior to the performance of all procedures to ensure the procedure is outlined and approved. If not, an amendment will be submitted to the committee for review and approval prior to implementation of a new procedure. The committee accepted the researcher's initial actions and plans to alleviate the same mistake in the future.

This project is funded through and NIH grant. 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,

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Sharon Comvalius-Goddard, Ed.D., MPH  
Institutional Official  
Associate Vice President, Research Regulations & Compliance



## Initial Report of Noncompliance

By: BCM

Date: 8/31/2021

Time: 2:00

Name of Person reporting: Doug Brining, AV; Allan Silva

Telephone #:

Fax #:

Email:

Name of Institution: UTMB

Assurance number: A3314

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary): No

What happened?

During a PAM session it was determined that 4 mice had received a second oral gavage inoculation. Protocol only approved for one. No health or welfare issues.

Species involved: mice

Personnel involved: research personnel

Dates and times: 8/17/2021

Animal deaths: no

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

PI counseled. Amendment submitted to allow for 2<sup>nd</sup> innoc.

Projected submission to OLAW of final report from Institutional Official:

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Case #