



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

March 29, 2019

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

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 March 6, 2019 letter regarding noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals which was preceded by a preliminary report submitted by phone on January 31, 2019. According to the information supplied, OLAW understands that on January 18, 2019, protocol deviations consisting of exceeding the IACUC-approved duration of a 60-minute event by 15 minutes in one sheep and exceeding the volume for blood withdrawn and exceeding the duration of the 60-minute event by 5 minutes in another sheep. It was reported that the involved animal activity was subcontracted to the University of Texas Medical Branch, Galveston for grant 1R44GM122095.

Corrective actions included submission of an amendment of the protocol and revision of a checklist used by the laboratory to include procedure-specific criteria to prevent exceeding duration or volume. Additionally, the investigator reminded staff to verify parameters with the IACUC protocol and perform procedures in accordance with the approved protocol.

OLAW concurs that the incident warranted reporting. As the subcontracted entity, please inform the direct awardee that they are required to contact the NIH awarding unit to report this noncompliance as required by terms and conditions of their grant. OLAW is satisfied that appropriate actions have been taken to investigate this incident and the additional actions taken to prevent recurrence are appropriate. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jane Na, DVM
Veterinary Medical Officer, OLAW
National Institutes of Health

cc: IACUC Chair

Dr. Robert M. Gibbens, Director Western Region, USDA, APHIS, AC

March 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 # 1v.

Dear Dr. Morse,

As a follow up to a telephone conversation held on January 31, 2019, we wish to provide the following information.

On January 18, 2019, two (2) sheep were used on an IACUC approved hemorrhagic shock study. The goals of the study include achieving a blood volume loss that corresponds to a predetermined mean arterial blood pressure (MAP) for a specified duration of time. Regarding the first of the two animals, post-hemorrhagic maintenance time was 75 minutes exceeding the IACUC protocol approved duration by 15 minutes. In the second animal, the amount of withdrawn blood to achieve target MAP was exceeded by 24.4 mL/kg and the post-hemorrhagic maintenance time was exceeded by five minutes over the approved IACUC protocol. The protocol deviation was recognized 01/18/19 by research staff and reported to ARC Veterinarians same day. Following business day (01/22/19) the adverse event was reported to ARC Attending Veterinarian and IACUC Chair.

The IACUC discussed the event during its meeting on January 24, 2019 at which time it asked the investigator to provide further details as the original electronic report forwarded was scarce in detail. The investigator forwarded a much more comprehensive report on January 25, 2019. The IACUC further discussed the non-compliance during its meetings on February 7, 2019 and February 21. The revised report alluded to the use of a "Timeout" checklist. The committee suggested changes to the laboratories "timeout" checklist to include procedure specific criteria that would try to alleviate the same occurrence. Further refinements to include humane endpoint being listed on the form for quick reference were also requested. The Investigator made the changes to the satisfaction of the committee.

The investigator has submitted a protocol amendment broadening the physiologic ranges determined in this early portion of the study to better correlate blood volume to the target mean arterial blood pressure. The PI will ensure that all animal manipulations are conducted in accordance with the approved IACUC protocol. The PI staff reminded the research team to verify study parameters in the IACUC protocol located in the main lab and to reinforce protocol compliance by performing detailed pre-procedural checklists to ensure the procedures performed at TICU are in protocol compliance and notify the PI if there are any issues or concerns.



Health

Research Services
Institutional 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/iauc>

This protocol is funded by an NIH grant NIGM 1R44GM122095 "Effect of R-1703 Administration on Hemorrhagic Shock in Female Merino Sheep" awarded to the Salzman Group (formerly Radical Therapeutics) who has subcontracted the animal work to UTMB.

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

Sincerely,
(b) (6)

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, March 7, 2019 2:10 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UTMB, Galveston D16-00202 (A3314-01) case report 1V

Thanks for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Thursday, March 7, 2019 11:46 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Brining, Douglas L. <dbrinin@UTMB.EDU>; (b) (6)
(b) (6) Niesel, David W. <dniesel@UTMB.EDU>; (b) (6)
(b) (6)
Subject: UTMB, Galveston D16-00202 (A3314-01) case report 1V

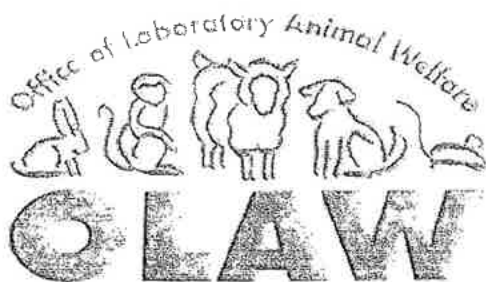
Please see final report from incident relayed via telephone on January 31, 2019.

Sincerely,

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

(b) (6)





Initial Report of Noncompliance

By: [Signature]Date: 1/31/19Time: 12:00Name of Person reporting: (b) (6)Telephone #: (b) (6)Fax #: (b) (6)Email: (b) (6)Doug BuningName of Institution: U. Texas - Med. Branch
Assurance number: _____Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? PI exceeded blood volume + duration on one protocol + duration on a second protocol. "Acute Blood Loss in Sheep"Species involved: Ovis ariesPersonnel involved: PI

Dates and times: _____

Animal deaths: No

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

Projected submission to OLAW of final report from Institutional Official:

260d.

OFFICE USE ONLY

Case # _____