



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

May 28, 2019

Re: Animal Welfare Assurance  
#A3711-01 (OLAW Case S)

Dr. Brian Gladue  
Acting Vice President for Research  
University of North Texas  
Health Science Center  
3500 Camp Bowie Blvd., EAD 858  
Fort Worth, Texas 76107

Dear Dr. Gladue,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 10, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of North Texas Health Science Center, following up on an initial telephone report on March 14, 2019. According to the information provided, OLAW understands that more mice were used on a protocol than approved, the mice were not euthanized at the established endpoint, and an unapproved substance was given.

The corrective actions consisted of counseling the Principal Investigator (PI), having the PI submit a new protocol request, and having the PI and staff undertake retraining.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Please send all future, signed copies of noncompliance reports electronically to [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov).

Sincerely,

(b) (6)

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

cc: IACUC Chair

April 10, 2019

Axel Wolff, MS, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Dear Dr. Wolff,

The University of North Texas Health Science Center, in accordance with Assurance D16-00417 (A3711-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident of protocol deviation. This incident was first reported to OLAW on March 14<sup>th</sup>, 2019 via a telephone conversation between Brent Morse, DVM, Director, Division of Compliance Oversight, OLAW and Egeenee Daniels, DVM, Attending Veterinarian and Director, Department of Laboratory Animal Medicine.

**Description of Reportable Incident:**

On March 5, 2019, a subcommittee of the IACUC met with a Principal Investigator and confirmed a suspicion that a procedure was performed on animals that was not approved in an animal care and use protocol. This was considered a protocol deviation which the IACUC discussed on March 26, 2019 and agreed to the following corrective actions:

1. A letter detailing the incident, acknowledging the intent to submit a new protocol to cover this study, and a corrective action plan within the PI's laboratory to ensure that such an oversight does not occur in the future.
2. A new protocol must be submitted to the IACUC for review and approval prior to the continuation of the studies.
3. Refresher CITI training for PI and all lab personnel.

The University of North Texas Health Science Center is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Nathalie Sumien, Ph.D., IACUC Chair at (b) (6)

Thank you for your consideration of this matter.

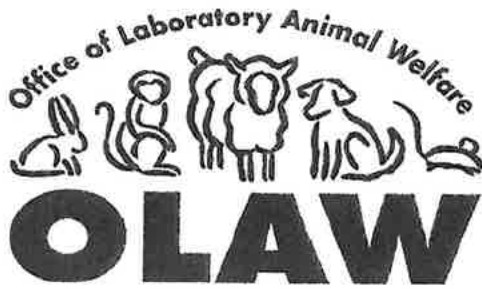
Sincerely,

(b) (6)

Brian Gladue, PhD  
Acting Vice President for Research  
Institutional Official  
University of North Texas Health Science Center

CC: Nathalie Sumien, PhD, IACUC Chairman  
Egeenee Daniels, DVM, Director, Department of Laboratory Animal Medicine  
(b) (6)

A3711.5



## Initial Report of Noncompliance

By: awl

Date: 3/14/19

Time: 1:45

Name of Person reporting: Egencia Daniels

Telephone #: (b)(6)

Fax #:

Email:

Name of Institution: U of North Texas HSC Ft. Worth

Assurance number: A3711

Did incident involve PHS funded activity? No

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

More mice used than on protocol, mice kept on longer than approved  
added peptide not on protocol

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Counsel PI, retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_