



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

November 19, 2018

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

Dr. Anuja Ghorpade.
Vice President for Research and Innovation
University of North Texas
Health Science Center
3500 Camp Bowie Blvd. – EAD 858
Fort Worth, Texas 76107

Dear Dr. Ghorpade,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 8, 2018 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of North Texas Health Science Center. Your letter supplemented the information in a preliminary telephone report on October 29, 2018. From the information provide, it is understood that on September 28th it was discovered that a procedure was performed on mice that was not approved in an animal care and use protocol. This deviation was also associated with safety concerns for university personnel. It is understood that the animals were not on a project funded by the PHS or NSF.

Corrective and preventive actions included a letter detailing the incident and a corrective action plan within the PI's laboratory to ensure that such an oversight does not occur in the future. An amendment must also be submitted to the IACUC for review and approval prior to the continuation of such a procedure.

OLAW believes that the corrective measures by the University of North Texas Health Science Center are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring, self-correction, and self-reporting. We appreciate being informed of 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

cc: IACUC contact

November 8, 2018

Brent Morse, 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. Morse,

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 October 29, 2018 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 September 28, 2018, it was discovered that a procedure was performed on animals that was not approved in an animal care and use protocol. This was considered a protocol deviation, associated with safety concerns for university personnel.

On October 23, 2018, the IACUC discussed the incident and agreed to the corrective actions:

1. A letter detailing the incident, acknowledging the intent to submit an amendment to cover this procedure, and a corrective action plan within the PI's laboratory to ensure that such an oversight does not occur in the future.
2. An amendment must be submitted to the IACUC for review and approval prior to the continuation of such procedure.

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)

Anuja Ghorpade, PhD
Vice President, Research & Innovation
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)
Brian Gladue, Ph.D., Director, Office of Research Compliance

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 09, 2018 7:06 AM
To: Ghorpade, Anuja
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW letter-Reporting Noncompliance

Thank you for this report. We will send a response soon.

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

From: (b) (6) **On Behalf Of** Ghorpade, Anuja
Sent: Thursday, November 08, 2018 6:13 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: OLAW letter-Reporting Noncompliance

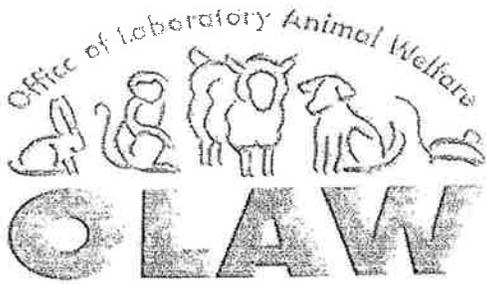
Greetings Dr. Morse,

Please find the OLAW Letter – Reporting Noncompliance attached on behalf of Dr. Anuja Ghorpade, Vice President for Research at the University of North Texas Health Science Center.

Best regards,

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: *[Signature]*

Date: *10/29/18*

Time: *3:00*

Name of Person reporting: *Egeence Daniels, A/V*

Telephone #: *[Redacted]*

(b) (6)

Fax #:

Email:

Name of Institution: *Univ. of N. Texas - HSC*

Assurance number: *A3711*

Did incident involve PHS funded activity? *No*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Radioisotope injected into 2 mouse mice. Not on protocol.

Species involved: *Mouse*

Personnel involved: *PI*

Dates and times: *3 weeks ago*

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 # _____