



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

October 15, 2018

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

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 September 28, 2018 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at the University of North Texas Health Science Center. According to the information supplied, OLAW understands that on July 31, 2018, a post approval monitoring visit to an investigator's laboratory for rat survival surgeries identified a repeat occurrence of personnel conducting surgery without appropriate aseptic technique. The involved animal activity was reported to be PHS supported.

The IACUC notified the principal investigator (PI) of the suspension of all animal activities under the PI's protocols. The planned corrective actions include extensive retraining on aseptic technique and probation with a minimum of one year during which all survival surgeries must be performed within the animal facility. Once privileges to perform survival surgeries in the PI's laboratory are reinstituted, the laboratory will be subject to unannounced audits by the IACUC. Additionally, the IACUC will review its training program oversight and make recommendations on the prevention of this type of noncompliance.

OLAW believes that the described corrective actions are appropriate to reduce the likelihood of recurrence of this noncompliance. Note that suspensions of animal activities on PHS-supported studies must be reported to the funding component. Refer to <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html> for further information. We appreciate being informed of these matters and find no cause for further action by this Office at this time.

Sincerely,

(b) (6)

Jane Na, DVM  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare

cc: IACUC Contact

September 28, 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 improper aseptic technique on protocols approved for survival surgery performed on rats. The research is supported by PHS funding. This incident was first reported to OLAW on September 11, 2018 via a telephone conversation between Venita Thornton, DVM, Director, Division of Compliance Oversight, OLAW and Egeene Daniels, DVM, Attending Veterinarian and Director, Department of Laboratory Animal Medicine.

**Description of Reportable Incident:**

On July 31, 2018, a post approval monitoring of the surgery was conducted by the IACUC Administrator and an IACUC Member on behalf of the UNTHSC Institutional Animal Care and Use Committee (IACUC).

During this visit, it was discovered that procedural asepsis was not being performed during major survival surgical procedures on rats in the investigator's laboratory. This is a repeated incident of non-compliance. In order to conform to Guide recommendations, survival surgery on rodents does not require a special facility but should be performed using appropriate surgical attire, sterile instruments, surgical gloves, and aseptic procedures that minimize the introduction of microorganisms and prevent infections. Post-operative infections can and do occur in rodents. Such infections may not be apparent and cause undue distress to animals and confound research results. All surgical practices must conform to the Guide.

Instruments for survival surgery on rodents were disinfected by spraying with ethanol. Disinfectants, such as alcohol, are not effective sterilants for preparation of instruments for survival surgical procedures. Appropriate sterilization procedures should be used to prepare surgical instruments for aseptic surgical procedures.

On August 28, 2018, the IACUC discussed the incident and agreed to the corrective actions:

1. The IACUC chair sent a written notification to the PI on August 28, 2018 informing the PI of the suspension of all animal activities under all of the PI's protocol effective immediately.
2. A letter was sent to the PI from the IACUC indicating the importance of maintaining compliance, and a plan to move forward.
3. The PI will be provided with extensive re-training on aseptic techniques.
4. The PI will be placed on probation for no less than a year during which his survival surgeries will only be allowed in the animal facility where the PI and his staff can be monitored by DLAM personnel and IACUC members.
5. The PI will be subject to unannounced audits performed by the IACUC once the PI regains access to the laboratory for survival surgeries.
6. The IACUC will review its oversight of the training program and make recommendations to prevent this type of non-compliance.

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, Ph.D.  
Vice President, Research & Innovation  
Professor, Dept. of Microbiology, Immunology & Genetics

Cc Michael Forster, PhD, IACUC Chairman  
Egeene Daniels, DVM, Director, Department of Laboratory Animal Medicine

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Brian Gladue, Ph.D., Director, Office of Research Compliance

## **Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, October 01, 2018 10:03 AM  
**To:** Ghorpade, Anuja; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Letter - Reporting Noncompliance

Thank you for providing this final report. 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) On Behalf Of Ghorpade, Anuja  
**Sent:** Friday, September 28, 2018 3:54 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.

Thank you.

Best regards,

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