



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

Reference: Assurance Approval for:

D16-00032 (A3056-01)

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
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Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

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February 02, 2018

Quentin Smith, Ph.D. Senior Vice President for Research Texas Tech University Health Sciences Center - Lubbock 3601 4th Street Lubbock, TX 79430-6252

Dear Dr. Smith,

I am pleased to inform you that the Office of Laboratory Animal Welfare (OLAW) reviewed and approved your institution's Animal Welfare Assurance (Assurance) that was submitted in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), revised 2015.

Your Assurance, identification number **D16-00032** (A3056-01), became effective on **February 02, 2018** and will expire on **February 28, 2022**. Please include the Assurance number on all correspondence to OLAW. A copy of the signed Assurance document is enclosed. The signature page provides verification of approval by OLAW and specifies the period during which your institution's Assurance is effective.

The Assurance is a key document in defining the relationship of your Institution with the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that an Annual Report to OLAW is required at least once every 12 months. Annual Reports for the previous calendar year are due by January 31st.

If I may be of any further assistance, please do not hesitate to contact me.

Sincerely,

2/2/2018

X Neera V. Gopee

Signed by: Neera V. Gopee -S

Neera V. Gopee, DVM, PhD, DACLAM, DABT Veterinary Medical Officer Office of Laboratory Animal Welfare, NIH

cc: IACUC Chair

Enclosure: As stated

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER ANIMAL WELFARE ASSURANCE #A3056-01

I, Quentin R. Smith, PhD, as named Institutional Official (IO) for animal care and use at Texas Tech University Health Sciences Center (TTUHSC), provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS and/or NSF. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

TTUHSC at Abilene, TX TTUHSC at Amarillo, TX TTUHSC at Lubbock, TX

- * TTUHSC at El Paso, TX
- * Please note the El Paso campus remains a branch of Lubbock until the process of becoming an independent institution is complete. OLAW will immediately be informed when this occurs.
- B. The following are other institution(s), or branches and components of another institution:

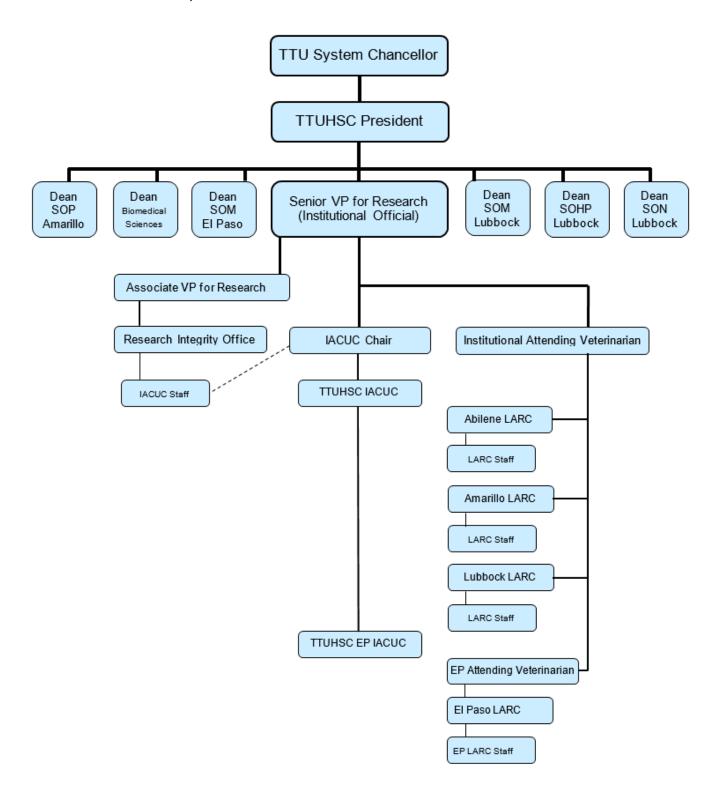
 None.

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the <u>Animal Welfare Act</u> and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "<u>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.</u>"
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use pursuant to <a href="https://doi.org/10.103/j.gov/
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide* for the Care and Use of Laboratory Animals (<u>Guide</u>).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:



- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows.
- † Attending Veterinarian and Contract Veterinarians' names are available to OLAW upon request.
- * Additional Responsibilities and **Authority for Attending/Contract Veterinarians are listed below.
 - Scott Trasti, DVM Institutional Attending Veterinarian (IVET)
 Oualifications
 - Degrees: BS in Veterinary Science from University of MN (UMN) in 1986; DVM from UMN in 1988; MS in Microbiology from UMN in 1992; Diplomate for ACLAM in 2002.
 - Training/Experience: Veterinary Pathology Residency from Cornell University in 1988; PhD from North Carolina State in 2000, Fellowship in Laboratory Animal Pathology at University of North Carolina in Chapel Hill in 2004; Veterinary Pathologist and Clinician at the National University of Singapore; Veterinary Pathologist and Animal Ethics (IACUC) Committee Chair in Perth, Australia; attended the 2016 National AALAS meeting, and attended a swine course in 2016.

Authority: Dr. Trasti has direct program authority and responsibility for the Institution's animal care and use program including access to all animals as stated in TTUHSC OP 73.03. Time contributed to program: Full-time employee, one hundred percent.

2. † Contract Veterinarian – Abilene Qualifications

- Degrees: DVM from Texas A&M University College of Veterinary Medicine in 1992.
- Training/Experience: Local practitioner from 1998-present; regularly attends Laboratory Animal Medicine conferences and seminars for training and continuing education.

Responsibilities: Conduct weekly visits and serve as primary back-up veterinarian for the Abilene campus as needed.

*Additional Responsibilities and **Authority are listed below.

Time contributed to program: Contract Veterinarian is present at the Abilene campus an approximate average of 4 hours per month, and as needed for back-up veterinary care. Distance to Abilene campus: 4 miles.

3. † Contract Veterinarian – Amarillo Qualifications

- Degrees: DVM from Texas A&M College of Veterinary Medicine in 1993.
- Training/Experience: Local practitioner; Consultant Veterinarian to the Amarillo Zoo. Responsibilities: Conduct weekly visits and serve as primary back-up veterinarian for the Amarillo campus.
- *Additional Responsibilities and **Authority are listed below.

Time contributed to program: Contract Veterinarian is present at the Amarillo campus an approximate average of 4 hours per month, and as needed for back-up veterinary care. Distance to Amarillo campus: 2 miles.

4. † Attending Veterinarian – El Paso Oualifications

- Degrees: DVM from Louisiana State University (LSU) in 2007; MS in Laboratory Animal Medicine from Penn State Hershey College in 2009; Diplomate for ACLAM in 2010.
- Training/Experience: DVM from LSU in 2007; Residency in Comparative Medicine at Penn State Hershey College of Medicine in 2009; ACLAM board certification in 2010; Worked at Florida State University, Indiana University School of Medicine, and the University of Florida in the Animal Care Programs in different capacities; Attends National AALAS and ACLAM Forum most years.

Responsibilities: Serve as the attending veterinarian for the El Paso campus.

*Additional Responsibilities and **Authority are listed below.

Time contributed to program: Full-time employee, one hundred percent.

- 5. † Contract Veterinarian El Paso Oualifications
 - Degrees: DVM from Texas A&M University in 1992
 - Training/Experience: Private veterinarian practitioner for 25 years; TTUHSC Contract Veterinarian in El Paso since 2005; Attended the TTUHSC Bio/Methodology Workshop in El Paso in 2006; Attended IACUC 101 in Galveston, Texas in 2008, and attends PRIM&R conferences and AALAS meetings for continuing education and training.

Responsibilities: Conducts weekly visits and serves as primary back-up veterinarian for the El Paso campus.

*Additional Responsibilities and **Authority are listed below.

Time contributed to program: Contract Veterinarian is present at the El Paso campus an average of 4 hours per month.

Distance to El Paso campus: 4 miles.

- * Additional Responsibilities: Respond promptly to emergency health matters at the request of the IVET, Unit Manager, LARC technician(s)/staff, or research staff; Provide on-call or ongoing animal health support during regular LARC business hours, after hours, weekends and holidays when IVET is unavailable; Report directly to the IVET and act in conjunction with the IVET and the IACUC to maintain the health of animals; Communicate with IVET using various media available including real-time videoconferencing/telemedicine; Consent to IVET's final decision-making authority regarding above duties if Attending Veterinarian's or Contract Veterinarian's action differs from IVET's opinion.
- ** Authority: To suspend animal use, and to quarantine animals at the LARC when deemed in the best interest of the animal(s).
- C. The Institutional Animal Care and Use Committees (IACUCs) at this Institution are properly appointed according to PHS Policy IV.A.3.a., and are qualified through the experience and expertise of their members to oversee the Institution's animal care and use program and facilities. TTUHSC currently has two IACUCs, one overseeing research conducted at the Abilene, Amarillo and Lubbock campuses, and the other overseeing research conducted at TTUHSC on the EI Paso campus. The TTUHSC President delegates the authority to appoint the members of the IACUCs to the IO. Each of TTUHSC's two IACUCs consists of at least 5 members, and membership of each IACUC meets the composition requirements of PHS Policy IV.A.3.b. Attached in Part VIII is a list of the chairperson and members of each IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations. To ensure congruency between committees, currently both of the Institution's IACUCs share a single IACUC Chairperson (Chair). Further, the IVET is on both committees. The Chair, IVET and IACUC Administrator attend both meetings. Throughout this document, unless otherwise specified, reference to the IACUC refers to both Committees, as policies and procedures relating to each IACUC's functioning are shared.

D. Each IACUC will:

1. Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. IACUC procedures for conducting semiannual program reviews are as follows:

A committee member will lead the review of the program using the OLAW Semiannual Program Review and Facility Inspection Checklist during a convened meeting. The review includes, but is not limited to, the following Institutional Policies and Responsibilities and Veterinary Care:

- a) Animal care and use program
- b) Disaster planning and emergency preparedness
- c) Member requirements, training, functions and protocol reviews
- d) Records and reporting requirements to regulatory agencies and for investigating animal welfare concerns
- e) Personnel qualifications, training, occupational health and safety and security
- f) Animal care, procurement, transportation, preventive medicine, surgery, pain, distress, anesthesia, analgesia and euthanasia
- g) Drug storage and control

Questions and comments are encouraged during the program review. Program deficiencies noted during the review, if any, are categorized as significant (a threat to the health and safety of the animals or personnel) or minor. A committee vote is taken to acknowledge the program's adherence to topics stated above. The committee members are reminded of the Institution's obligation to ensure compliance with TTUHSC's Animal Welfare PHS Assurance (Assurance) available online, and that a minority report can be filed. No IACUC member is involuntarily excluded from participating in any portion of the program review.

2. Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. IACUC procedures for conducting semiannual facility inspections are as follows:

An inspection team consists of at least two IACUC members. The team uses OLAW's Semiannual Program Review and Facility Inspection Report, and IACUC's Laboratory Inspection Checklist when inspecting the Institution's facilities and laboratories in Abilene, Amarillo, El Paso and Lubbock, where animals are housed or used for more than 12 hours, i.e., animal care, holding and use areas; storage and cagewash areas; and surgery and procedure areas where research is conducted. Animal transporting equipment is also inspected. Members take notes for each area, and deficiencies are categorized as significant or minor. The Committee develops a reasonable and specific plan and schedule for correcting each deficiency. No IACUC member is involuntarily excluded from participating in any portion of the facilities' inspections. Ad hoc consultants may be invited to assist; however, the IACUC maintains responsibility for inspections and reports.

3. Prepare reports of IACUC evaluations according to PHS Policy IV.B.3., and submit the reports to the IO. IACUC procedures for developing reports and submitting them to the IO are as follows:

Each inspection team's leader, or team's designee, collects individual members' comments and concerns. The collection is submitted to the local IACUC Administrator. The Administrator compiles the information and produces a report, formatted using OLAW's Semiannual Program Review and Facility Inspection Report, to the IO identifying which facilities are AAALAC International-accredited. The report is made available to each IACUC to be reviewed, revised as appropriate, and then approved by the Committee. The final report will be signed by a majority of the IACUC members and will include any minority opinions, or so state if there are none. The completed report will be submitted to the IO in a timely manner.

The report contains the Institution's adherence to the *Guide* and the PHS Policy. The report will specifically identify any IACUC-approved departures from the *Guide* and the PHS Policy, and will state if there are no departures. Protocol departures must be approved using the full-committee review (FCR) or designated-member review (DMR) process using a submitted amendment, or other written document. The IACUC considers departures from the *Guide* and PHS Policy, not approved by protocol review or policy, as deficiencies. The program or facility reports will distinguish significant deficiencies from minor deficiencies, and will contain a reasonable and specific plan and schedule for correcting each deficiency, or have the departure properly reviewed and approved. Continuing deficiencies will be tracked by IACUC staff and be discussed as a standing report at monthly IACUC meetings for appropriate action until resolved.

At least annually, each IACUC will file a certification to OLAW, through the IO, that the reviews have been conducted. The IACUCs will report any violations of guidelines or assurances which were observed or continued, after the Institution's annual notification occurs.

4. Review concerns involving the care and use of animals at the Institution. IACUC procedures for reviewing concerns are as follows:

Whistleblower notices are located in the animal facilities with instructions to individuals on how to report animal welfare concerns. Any individual, who in good faith, reports an animal welfare concern, will be protected against reprisals pursuant to state-law, TTUHSC OP 52.04 and TTUHSCEP OP 52.04. Concerns may be reported to the IO, the IVET, the Attending Veterinarian at TTUHSC in El Paso, an IACUC member, to IACUC staff, or anonymously using Ethicspoint, the Institution's compliance hotline accessible in TTUHSCEP OP 52.03 and TTUHSCEP OP 52.03. If the IVET is the subject of the complaint, the IO will appoint an individual to conduct the initial investigation.

Reported concerns may be brought to the attention of the Chair, the IVET and the Attending Veterinarian at TTUHSC in El Paso as necessary, the Protocol Violations Subcommittee, and/or the full Committee as warranted, and considering the level of threat to an animal's wellbeing. Initial reports to both the IO and OLAW may be made verbally. The Chair will convene a meeting to discuss, investigate, and address the reported concern. The findings and recommendations will be communicated to the IO, the Committee, OLAW (for PHSfunded projects) verbally and/or in writing. Committee actions taken, and committee recommendations made are recorded in the IACUC meeting minutes.

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

The IO and the Committee have online access to the Institution's Integrated Research Information System (IRIS) here for the El Paso campus. The system retains the IACUC meeting agendas, meeting minutes, and proposed policy changes and reports. Documentation related to the animal program and facilities, and personnel training issues discussed by the Committee, with recommendations for improvements, are available at any time. Recommendations to the IO may also be made verbally and/or by separate letter. Guidelines published by PHS and other regulatory agencies are reviewed by the IACUC and/or the IACUC Regulations and Policy Subcommittee, and compared with Institutional policies and practices. Proposed changes and recommendations of the latter to maintain compliance are also available in iRIS for IO and Committee review.

6. Review and approve, require modifications (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

The Principle Investigator (PI) or PI's designated personnel submits an initial proposal via iRIS, whereupon an identifying number is automatically assigned. IACUC staff performs an administrative pre-review screening, informing the PI of minor clerical or incompletion errors needing PI's correction. Screened initial submissions are assigned to an IACUC review team, appointed by the Chair in consultation with IACUC staff. The team, consisting of at least a primary reviewer (scientist) and a secondary reviewer (the IVET/Attending Veterinarian), receives an iRIS reviewer assignment notice. The review team conducts a review of the protocol. Any questions or concerns are relayed in writing to the PI. After the PI's responses are received, the protocol is presented for FCR.

If a DMR is requested, the IACUC staff may contact the potential designated reviewer to ensure the review can be completed in a timely fashion. Protocols are available to all IACUC members prior to, and during, convened IACUC meetings. No member may participate in IACUC review or approval of a protocol in which the member has a conflict of interest (COI), except to provide information requested by the IACUC. A member with a COI cannot contribute to the constitution of a quorum.

The IACUCs may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC. Use of telecommunications to conduct IACUC functions will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

Reviews due for protocols and amendments are assigned by the IACUC staff in consultation with the Chair. IACUC staff attempt to balance the committee's review workload; however, protocols may be given to a specific reviewer based upon knowledge or expertise which would ensure a thorough review. When possible, amendments to a protocol are assigned to the same reviewer to ensure continuity of reviews.

The IACUCs use only FCR or DMR to review protocols, as stated in IACUC Policy #7.

Full-Committee Review

The FCR process is generally used, and described in IACUC Policy #13. Protocols are available to the entire Committee for review prior to a meeting, and assigned to one or more reviewers as described above. IACUC members are expected to regularly attend meetings. Members who cannot attend a meeting are encouraged to submit written comments and/or questions for consideration by the members present. An absent member will not be counted towards a quorum, and will not have a vote.

IACUC meetings are primarily conducted by videoconference, or alternatively, via telephone conference if needed. Members from each campus are gathered in a single room on their campus, and connected simultaneously to the other locations using TTUHSC's <u>TechLink</u> and/or TTUHSCEP's <u>TechLink</u> capabilities, and using laptops provided by TTUHSC's <u>IT</u> department or TTUHSCEP's <u>IT</u> department, to access iRIS for protocol review.

Each protocol is presented by the Primary Reviewer (PR) during the convened meeting with quorum, and any outstanding issues are thoroughly discussed. Then, the IACUC reviewer or designated presenter recommends a protocol outcome to the committee for a vote to a) approve, b) require modifications [to secure approval], or c) withhold approval.

Review of Required modifications Subsequent to FCR -

When the IACUC requires modifications [to secure approval] of a protocol, such modifications are reviewed as follows:

- a) FCR or DMR following all applicable procedures as delineated in the PHS Policy and in Part III.D.6 of this Assurance; or,
- b) DMR subsequent to FCR, if approved unanimously by all members at the meeting at which the required modifications are delineated, AND if the entire current Committee has previously approved and documented a policy of DMR for required modifications. However, if any member calls for FCR of the modifications, such modifications can only be reviewed and approved by FCR.

If the IACUC uses DMR, the approval date is the date that the designated member(s) approve the study. Minor modifications may be confirmed by IACUC administrative staff, if approved by the designated members (if DMR) or unanimously by all members at the meeting in which the protocol was presented (if FCR).

Designated-Member Review

A DMR process may be used in some circumstances. In such instances the protocol is distributed to all IACUC members to allow all members the opportunity to call for FCR. Records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after three full business days and approval of protocols via DMR are maintained and recorded in the next convened IACUC meeting minutes.

If FCR is requested, protocol approval may be granted only after review at a convened meeting with quorum, and with the majority vote to approve. If FCR is not requested, at

least one member of the IACUC, designated by the Chair and qualified to conduct the DMR, is assigned to review the protocol, and has the authority to a) approve, b) require modifications [to secure approval], or c) request a FCR of the protocol.

Other IACUC members may provide the designated reviewer(s) with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the DMR method may not be conditioned. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol is referred for FCR. When a designated review team is assigned a DMR, each team member will be notified via iRIS. Each documentation revision is available, with an appropriate time for review and comment to the PR, prior to approval of the protocol. Any member of the DMR team may request the protocol be referred for FCR. The possible outcomes of DMR are a) approval, b) require modifications [to secure approval], and c) request a FCR of the protocol. "Withhold approval" is not a possible outcome of DMR.

The IACUC will conduct a FCR or DMR of components related to the care and use of animals to determine if components in the proposed protocols or in approved, ongoing protocols with significant changes, are in accordance with PHS Policy, before approving. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the *Guide* unless acceptable justification for a departure is presented.

The IACUC shall determine that the protocol conforms to the Institution's Assurance and meets the following requirements:

- a) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- b) Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- c) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, and methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals unless a deviation is justified for scientific reasons in writing by the PI.
- d) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
- e) The animals' living conditions will be appropriate for their species and will contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
- f) Medical care for animals will be available and provided by a qualified veterinarian.
- 7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Review and approval of significant changes are handled in the same manner as new protocols in Part III.D.6 above. Examples of changes considered to be significant include, but are not limited to, changes:

- a) in the objectives of a study;
- b) from non survival to survival surgery;
- c) resulting in greater discomfort or in a greater degree of invasiveness;
- d) in the species or in approximate number of animals used1
- e) in Principal Investigator;
- f) in anesthetic agent(s) or the use or withholding of analgesics;
- g) in the method of euthanasia; and
- h) in the duration, frequency, or number of procedures performed on an animal

¹Changes of less than 10% in the approximate number of animals used of mice of the genus Mus and rats of the genus Rattus that are bred for use in research may, at the IACUC's discretion, be considered minor (not significant).

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The IACUC notifies PIs via e-mail or iRIS correspondence. Stipulations, stating issues which may include suggested action for corrections, are sent to PIs via iRIS. PIs are expected to address and highlight changes for each stipulation in the revised protocol, and add commentary in the stipulation responses if needed. PIs are notified via iRIS if approval is withheld, with the reason for the Committee's decision. Then, the PI is provided with an opportunity to respond in person or in writing. Notifications of decisions made and/or actions taken regarding protocols are maintained and available in iRIS, with access for viewing at any time by the IO and the PI's Department Chair.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

IACUC and LARC staff conduct Post-Approval Monitoring activities. Designated staff have access to approved protocols to compare with actual animal health and ongoing activities after protocols are approved. Personnel may perform random audits to initiate discussion with PIs, recommend actions for improvements, and ensure compliance. Non-compliance found during audits will be communicated with the IVET/Attending Veterinarian, LARC and/or IACUC staff, the Chair and/or PI as needed for follow-up and resolution according to Part III.D.4 of this Assurance. Scheduled and non-scheduled reviews to determine data, methods, and value of various metrics (i.e., harm/benefit analysis, animal use, timeliness of processes) continue to be developed.

Protocols for USDA Regulated Species and Non-USDA Regulated Species are reviewed at least annually. Annual reviews are assigned to a designated member per IACUC Policy #7 and Policy #13 before the 12-month anniversary date of the initial approval. Annual Status Reports submitted by PIs include a progress report of the previous year and goals for the upcoming year. Annual reviews are placed on the iRIS Agenda, and are recorded in the IACUC meeting minutes. The protocol is approved on or before the 12-month anniversary date of the initial approval. All IACUC members have access to review and comment on annual reviews. The IACUC meeting minutes are reviewed and approved by the Committee.

Protocols are approved for a maximum of 36 months, and expire no later than the three-year anniversary of the initial IACUC review. If activities will continue beyond the expiration date, a Renewal protocol must be submitted, reviewed, and approved [prior to expiration of the original or preceding protocol] as described in Part III.D.6 of this Assurance. De novo reviews of continuing activities include submission of a new protocol form defined as 'Renewal'. The Renewal must be complete as it supplants all previous protocol documents including all amendments made to the original protocol during the previous three years. The Renewal includes PI's detailed summary of work performed during the past 12-month period.

10. Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting with quorum and a majority vote.

Suspensions, whether temporary or permanent, will be reported to OLAW in accordance with NIH Notice of February 24, 2005, NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the Institution's Assurance, the IO in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report the suspension with a full explanation in writing to OLAW. Preliminary reports may be made verbally.

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

1. Administration/management

The Institution's President appointed a Managing Director for the Office of Institutional Health, who reports to the Executive/Senior Vice-President of Academic Affairs and Institutional Health Committee at TTUHSC El Paso to implement the Health Surveillance Program in TTUHSC OP 75.11/TTUHSCEP OP 75.11. Each Institution has established this program to meet both its responsibilities toward employees, students and its obligation under federal and state regulations. The principal objective is to provide this program for all employees at risk with a plan to meet specific risks and requirements according to appropriate benefit/cost considerations for each employee. This program applies to all campuses of TTUHSC, and delineates processes by population, including but not limited to animal handlers who work in the LARC on any campus who have contact with laboratory animals or animal living quarters on a regular basis.

Health surveillance guidelines are designed to protect both people and the laboratory animals, and are based on the *Guide*; Biosafety in Microbiological and Biomedical Laboratories, 5th Edition (2008), and other relevant published information. The Institutional Health Managing Director works with the Dean or Dean's designee of each School (School of Pharmacy, School of Biomedical Sciences, School of Medicine, School of Health Professions, and School of Nursing) to provide and administer each school's Designated Health Surveillance Unit. This Unit will be responsible for maintaining records, providing immunizations and testing, providing training, and serving as the initial point of contact for all probable exposures and operating as the cost center for the program.

The Institution's Infection Prevention and Control Committee meets to review infection control and OHSP matters. The Committee notifies the IVET and requests attendance at a meeting if any concerns arise. The Institution's nurses reviews the Risk Assessment for Animal Care Health Questionnaire for personnel who will have animal access in the vivarium.

2. Scope

All animal care and use personnel are enrolled in the Occupational Health and Safety Program (OSHP). Use of hazardous biologic, chemical or physical agents is also considered. Enrollment takes into account occupational duties: animal care personnel (direct exposure), PI's staff (direct and indirect exposure), those with bystander exposure (indirect), and visitors (indirect). Personnel's Risk Assessment for Animal Care Health Questionnaire is used to determine the direct exposure level:

- a) Level one access includes researchers and animal care staff with direct animal contact and must fulfill the highest level of care and training. Research personnel with direct animal contact are identified on the animal protocol form. Level 1 personnel are identified upon hire (i.e., LARC staff) and when added as personnel to an IACUC protocol.
- b) Level two access includes personnel from the Physical Plant and Security personnel, who are required to train using video presentation, and to sign-in/out of the facility. Physical plant personnel who have exposure to vivarium ductwork and/or maintenance of HVAC filters are required to wear eye and respiratory protection and have additional training. Level 2 personnel are enrolled by their supervisor (i.e., physical plant and security personnel) upon hiring or assignment of a task that is at risk for animal exposure.

c) Level three access includes visitors (non-personnel) that are authorized by the LARC to access the vivarium support areas. Those with casual level 3 exposure are provided an informational OHSP brochure during mandatory sign-in/out procedures.

3. Health Evaluations

A Risk Assessment for Animal Contact Health Questionnaire is distributed to all non-enrolled animal users identified from the IACUC protocol form (i.e., new or renewal protocol and/or amendments) by the IACUC Staff. The animal user completes and sends the completed Questionnaire to the Institution's nurse for evaluation and recommendations regarding immunizations. The signed Questionnaire is retained by the nurse in a HIPAA compliant manner. Individuals on active animal protocols have the option to update their Questionnaire if their health status has changed, and submit it to the nurse for additional evaluation/recommendations.

4. Hazard Identification and Risk Assessment

It is the IACUC's position that the PI is most capable of assessing the risk to themselves and their workers in their unique laboratory situation. Therefore, the IACUC recommends that the PI work in concert with the Infection Control Nurse and appropriate members of the LARC staff to provide necessary training to laboratory personnel. The IACUC relies on the various safety committees within the TTUHSC to assess the dangers of procedures that use hazardous biologic, chemical or physical agents, including ionizing and non-ionizing radiation.

Prior to the approval on any animal use protocol in which hazardous agents, i.e., radioactive materials, infectious agents, carcinogens, toxins, noxious agents, malignant cells, recombinant DNA, etc., are used, confirmation of the appropriate safety committee's approval (i.e., Radiation Safety Committee, <u>Institutional Biosafety and/or Recombinant DNA Committee</u>, <u>Embryonic Stem Cell Oversight Committee</u>, etc.) must be provided by the PI using those agents to the IACUC before the protocol will be approved.

5. Procedures in Place to Alleviate Hazards and Minimize Risks

The LARC provides, replaces and launders scrub suits at all LARC sites. Work shoes/boots, disposable gloves, masks, head covers, lab coats, eye protection and hearing protection for use by the LARC staff is also provided by the LARC. The Lubbock, Amarillo and El Paso campuses have in-house facilities to launder work clothing. The Abilene campus uses a commercial service to launder work clothing for the Abilene LARC personnel.

Employees are instructed to wash hands after handling animals or wearing gloves. All personnel are required to maintain a high standard of personal cleanliness. Employees are instructed to dispose of designated gowns, gloves, shoe covers, etc. in designated receptacles prior to leaving the animal facility. In addition, protective clothing is not to be taken off any of the TTUHSC campuses and/or worn outside the animal facility, unless the employee is performing work related duties such as transporting animals or procuring supplies for the animal facility.

Lockers for Personnel are available in the Lubbock, Amarillo, El Paso, and Abilene sites. Each locker room has shower facilities. Various types of protective clothing are available and worn depending upon the assigned duties. Gloves (latex and nitrile) are available for use in animal rooms and support areas. Rubber gauntlet gloves are available in the cage wash areas and other areas when needed for protection against chemicals or hot equipment being taken directly out of cage wash machines. Hot mill gloves are used for handling hot autoclaved equipment.

Safety glasses, goggles and face shields are available for use with chemicals in cage wash and when working with hazards. Earmuffs and/or ear plugs are available and required for use in high noise areas such as cage wash and dog rooms. Filter masks and respirators are available for use in animal rooms and support areas. OSHA-approved cartridge respirators or N95 disposable respirators are used by workers when dumping cages, and for working with animals with study related or species specific hazards. Safety Services performs fit tests after the employee receives medical clearance from the Institution's nurse.

Aprons are available for use in cage wash and other areas where protection from chemicals, and other agents are is required. Caps, gowns and shoe covers are kept in all biohazard areas, and their use is required. Protective footwear including steel-toed shoes or boots, or other protective footwear is available for all LARC staff.

Policies regarding eating, drinking, and smoking in animal facilities are as follows. Eating and drinking are not allowed in any animal rooms, hallways, or support rooms of the vivaria. Break areas where employees may eat are located adjacent to the vivaria at each site. TTUHSC has a no-smoking policy; therefore, smoking is not permitted anywhere inside any building or campus. Cosmetics may not be applied in animal rooms. Health programs for personnel potentially exposed to specific hazardous agents are as follows:

- a) ABSL3 Laboratory (El Paso). All workers in the ABSL3 facility undergo extensive training. Procedures and PPE requirements are exhaustively covered in a biosafety manual produced for this facility and available upon request for review. Personnel are required to sign a consent form to work in this facility. Animals are exposed and housed in biocontainment facilities, individual animal holding rooms, or in mixed areas using individually ventilated microisolator caging.
- b) Control of Hepatitis and other blood-borne agents. Safety Services provides training for individuals working with human blood and tissues. Animal care staff is included with additional training provided by the LARC Veterinarian. All human tissue work is performed in a biosafety cabinet. Personal protective equipment requirements include lab coats, gloves, masks, eye protection, and sleeve covers. Individuals with potential for exposure are also offered vaccinations, as necessary.
- c) Control of animal bites. TTUHSC personnel who handle animals are instructed to avoid animal bites during the animal handling portion of their training. Minor wounds are treated by administering local first aid. Wounds of higher severity can be treated by a nurse, the emergency room, or a private physician as appropriate. The LARC Veterinarians are notified to evaluate an aggressive animal, and the cage or cage-card is identified so personnel is cautioned when handling this animal.
- d) Control of allergies to animals. TTUHSC provides services regarding research animal related allergies. Personnel are instructed to report asthma/allergy symptoms to the nurse on the Questionnaire, so participants can be offered further evaluation that may include both skin and serological testing for allergies, pulmonary function testing, and referral to a Pulmonologist, as appropriate. Participants with documented animal allergy and eye, skin, or nose/sinus symptoms can be provided with additional education regarding exposure reduction and the PPE needed. Participants with occupational asthma may be restricted from further exposure to the animal species to which they're sensitized. To reduce exposure to animal allergens, the conventional rodent areas in Lubbock were converted to ventilated microisolator caging with HEPA filtered exhaust which result in fewer open-topped, and filter-topped rodent cages. The other sites (Abilene, Amarillo and El Paso) already had 100% ventilated microisolator caging systems in use. The animal care staff and researchers who utilize the BioBubble Clean room in Lubbock with the 'Stay Clean' Changing Station (laminar-flow, HEPA-filtered) are required to wear N95 respirators that have been fit-tested by Safety Services. Likewise, cagewash personnel are required to perform cage dumping activities in front of HEPA-filtered dust collection devices (BioBubble Bedding Disposal Unit). Open-topped rodent rooms and/or filter-topped static microisolator caging have utilized Safety Services' airborne particle counter to demonstrate very low levels of suspended allergen particles (less than 5
- e) Control of radiation exposure. Some protocols are developed for high risk isotope use in animals. Individuals with radiation exposure are required to take radiation-safety training classes. Personnel taking radiographs or caring for animals exposed to radioactive matter are provided with radiation detection badges.
- f) Control of biological agents. Personnel caring for animals exposed to biological agents are provided masks, gowns, gloves, full face shields and/or disposable full body jumpsuits, when necessary. All personnel assigned to studies using biological agents receive specialized training. Biosafety cabinets and/or dump stations are also used.

g) Control of chemical exposure. Personnel caring for animals exposed to hazardous chemicals are provided masks, gowns, gloves, full face shields and/or disposable full body jumpsuits, when necessary. Biosafety cabinets, chemical fume hoods, and/or dump stations are also used.

A representative from Safety Services is appointed to each IACUC, so the LARC can be aware of specific proposals that include hazardous agents. The LARC contact PIs when ordered animals arrive, to assure that all OPs for the care of the exposed animals, waste disposal, etc., are complete, and that the animals are delivered to the appropriate facilities.

Cages and cage racks are sprayed with appropriate disinfectant, airflow is controlled, bedding is autoclaved, etc., when appropriate. Hazardous agents are contained within the study environment and in the animal housing areas. Biohazardous wastes are rendered safe by autoclaving or incineration. Animal wastes and animal carcasses are disposed of according to established protocols. Autoclaves used to decontaminate hazardous agents are checked daily by use of temperature sensitive tapes/strips and bimonthly by use of biological indicators for steam sterilization.

Animals treated with hazardous chemicals, biological or radioactive materials are disposed of according to federal and state guidelines. Rooms or areas containing exposed animals are identified and posted. Safety procedures for using volatile anesthetics and how anesthetic gases are scavenged. Anesthetic machines and 'double' nose cones are exhausted through a tube which is directed into an activated charcoal canister (regularly monitored via weight acquisition) or a room exhaust system. Open drop jars and nose cones on rodents are used under a fume hood or Class II, Type B2 hood.

Specific hazardous agents, wastes, caging, and supplies are autoclaved or chemically treated when removed from the room. Specific protocols and hazard door signs for each study are developed in conjunction with Safety Services for the agents used and are posted on the animal room door. These protocols contain information relative to animal care, waste disposal, protective clothing required, emergency notification, disposition of animal carcasses, etc.

Animal technicians are notified by their supervisor of any hazardous agents being used prior to the initiation of any study and informed of any necessary precautions that must be taken. Protective clothing must be worn at all times by personnel in the animal room. Animals exposed to biohazard agents remain in these areas until study termination. Animals are housed within conventional areas either in dedicated rooms and/or within HEPA-filtered, ventilated microisolator caging (negative) with the airflow pattern for animal housing rooms from the hallway into the room, and room air being exhausted directly to the outside, except for the dedicated ABSL3 facility within the El Paso vivarium.

The ABSL3 facility in El Paso contains two rooms for animal housing with the Techniplast Isocage (negative pressure) and change hoods (Class II, Type B2) for mice exposed to infectious agents. The facility contains all necessary support equipment and spaces required for ABSL3 registration with USDA APHIS VS due to the nature of the agents used within the facility. Likewise, the floors are broadcast epoxy and all floor drains are sealed. Air is HEPA-filtered in and out of the rooms. Air pressure in rooms is negative relative to adjacent halls, and halls within the ABSL3 facility is negative relative to the remainder of the animal facility. A pass-through autoclave is present in the facility dedicated to autoclaving biohazardous waste. A personnel locker room and shower are located at the entrance/exit of the ABSL3 facility. Access to the facility is granted by the IVET, EP Attending Veterinarian, Laboratory Manager, Biosafety Officer, and VP for Research.

6. Immunizations

Immunizations at TTUHSC are suggested, but not required. However, un-vaccinated personnel may be excluded from participation in studies with known vaccine antidote if vaccine is refused. The decision for exclusion is risk-based and upon recommendation by the

OSHP and Safety Services personnel to the PI. All needed vaccines are available to personnel, specifically tetanus, rabies, flu, etc.

7. <u>Pregnancy</u>, <u>Illness or Decreased Immunocompetence Precautions</u>

During the health history evaluation, certified medical personnel may identify those who are pregnant, or have illness/decrease immunocompetence. The nurse will provide information and training pertinent to their individual situation. Personnel may be advised that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence, they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals.

If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/or health care professional, human resources, etc. Likewise, all personnel are advised to contact the Institutional nurse should they experience any change in health status and require additional information.

8. Access for Non-Animal Users

Provisions for persons not involved in animal care and/or use, but need to enter the areas, are identified by the access levels in Part III.E.2.a-c of this Assurance.

9. Treatment of bites, scratches, illness or injury

Injury or exposure events are reported to the Supervisor and/or Manager. First aid treatment is administered at the patient location, if necessary, and immediate medical treatment sought for serious injuries. The patient may then receive secondary treatment in the nurse's office and/or an emergency room. Emergency help is available from the University Police.

10. Procedures/program for reporting and tracking injuries and illnesses

Injuries are promptly reported to Human Resources and a "Workers Compensation First Report of Injury" form filed. Personnel are instructed to report animal related injuries to the OHSP Nurse. When seeking medical attention for an illness or injury, a complete description of exposure to animals as described in the health history provided to medical personnel. Any spills or potential hazards are reported to the Office of Safety Services.

11. Other OHSP Information

Nonhuman primates are not currently being used.

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Part X. Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Training and instruction in animal care and use are mandatory at the Institution for all individuals whose work brings them into contact with live laboratory animals. The training program addresses four major constituencies. The first is the professional laboratory animal care staff members who are employed to provide care for research animals in the LARC. The second constituency is personnel actually using animals in experimentation and is comprised of faculty, postdoctoral and other professional research associates, graduate students, laboratory technicians, medical students, undergraduate students and other students working on a temporary or part-time basis. The major constituency consists of those persons who are observing or participating in supervised educational experiences involving live laboratory animals. The fourth constituency is the IACUC members.

1. LARC Staff

- a) Is primarily the responsibility of the IVET/Attending Veterinarian
- b) Programs employed are made available to laboratory animal care technicians by the American Association for Laboratory Animal Science
- c) AAALAS technician certification program is administered by the IVET

d) Animal caretaker classes, "hands on" and "on-the-job" sessions are regularly held. Additional training is available on the TTUHSC <u>IACUC website</u>, and provided as new operating procedures and forms are developed

2. Laboratory Animal Investigators

- a) The TTUHSC PHS Assurance and policies governing live animal use are posted on the TTUHSC IACUC website. Animal experimenters are referred to these resources prior to their initial approval for animal work, and reminded by inspection committees during semi-annual inspections.
- b) The training process for PIs and their personnel working with animals is initiated by the submission of a new protocol application/renewal (which must list all personnel to be involved with the animal work) or an amendment (adding personnel or adding a species to an existing approved protocol).
- c) The day-to-day operation and record keeping necessitated by the training requirement is administered by the LARC or IACUC staff.
- d) Personnel's completed training is confirmed in iRIS and CITI by IACUC and/or LARC staff.
- e) Personnel with incomplete training are notified that the training requirements must be met before the item (application/renewal/amendment) can be approved. After the protocol form is approved, PIs are notified that personnel are authorized to use the animals and gain admission to the LARC facility.
- f) The training program has the following elements:
 - A series of online modules which specifically address the training topic requirements listed in 9 CFR, Part 2, Subpart C, Section 2.32(c).
 - Collaborative Institutional Training Initiative (<u>CITI</u>) is TTUHSC's online vendor offering individuals working with animals in laboratories a complete series of modules relating to proposed use of animals.
 - Personnel complete CITI's courses which outline the current laws and regulations, the
 ethics of animal experimentation, the responsibility of each person to ensure that
 animals receive humane treatment, the responsibilities and function of the IACUC and
 the 3 Rs of animal research.
 - CITI course "Investigators, Staff and Students" covers the 3Rs in Module #1812
 (Alternatives) and Module #1813 (Avoiding Unnecessary Duplication). Completion of
 CITI course "Reducing Pain and Distress in Laboratory Mice and Rats" is required for
 personnel working with rodents. PIs are required to provide justification for animal
 numbers to obtain valid results as explained in same CITI Course, Module #1811.
 Practice of this training is confirmed in the "Animal Species and Numbers" section,
 and in the "Literature Search" section of the IACUC protocol form during review. The
 IACUC protocol form refers PIs to databases to assist during searches to minimize the
 number of animals required to obtain valid results. IACUC reviewers issue stipulations
 and provide recommendations to PIs with additional guidance as needed.
 - Personnel complete modules relevant to the species which they are using which outlines the principles of husbandry and demonstrating basic experimental procedures. Training records are maintained with CITI and in iRIS.
 - Personnel using exotic species or employing new techniques are offered one-on-one instruction and assistance from the LARC professional staff, generally provided in the form of workshops (anesthesia, euthanasia and survival surgery workshops).
 - Records of participation in LARC-initiated training exercises are kept by the LARC.

3. Individuals Observing or Participating in Supervised Educational Experiences

- a) Animal use in the educational mission of the Institution is subject to IACUC oversight.
- b) A protocol form must be submitted and approved before animals may be used. The purpose, value and availability of alternatives, and the competence of the instructor are considered during the review.
- Individuals receiving the educational experience are informed prior to the use of the animals that the use of the animals has been approved by the IACUC;
- d) they have a responsibility to contribute to the humane and purposeful use of animals in the educational experience; and,
- e) they are to promptly address any concerns of animal use to the supervising instructor and, if warranted, the IACUC.

4. Training of IACUC Members

- a) Each IACUC member is provided with an electronic copy (hard copies provided if requested by the member) or a weblink to access the following:
 - PHS Policy for the Humane Care and Use of Laboratory Animals;
 - National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
 - ARENA/OLAW IACUC Guidebook;
 - AVMA Guidelines on Euthanasia; and,
 - this Assurance.
- b) Orientation of new members is provided by one or a combination of the IACUC Chair, the IVET/Attending Veterinarian, the Training/Information Subcommittee Chair and/or IACUC Staff. A PowerPoint presentation is available, and weblinks to OLAW FAQ's, the USDA, the Guide, and other resources are provided.
- c) Completion of CITI's module Essentials for IACUC is required.
- d) Completion of OLAW's Tutorial: PHS Policy on Humane Care and Use of Laboratory Animals Tutorial located here is encouraged, as well as annual review of OLAW's website and familiarization with other pertinent modules and information available online.
- e) Regular members of the IACUC are encouraged to attend conferences (e.g., IACUC 101, IACUC 201, IACUC Advanced, PRIM&R, SCAW) which focus on the care and use of animals and issues of regulation and compliance. Training conducted during convened meetings include reports by members that attended such meetings. Separate training sessions can be provided upon request.
- f) Opportunities and materials (i.e., webinars, newsletters, Lab Animal articles, HSUS Pain and Distress Reports, AWIC Bulletins) are provided by the IACUC staff, and participation or review is confirmed.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

(1) This Institution is Category 1 — accredited by the <u>Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)</u>. As noted above, the reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
 - 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 - 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
 - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Quentin Smith, PhD
 - 5. Records of accrediting body determinations

- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
 - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 - 3. Any change in the IACUC membership
 - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Quentin Smith, PhD
 - 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - 1. Any serious or continuing noncompliance with the PHS Policy
 - 2. Any serious deviations from the provisions of the *Guide*
 - 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Quentin R. Smith, PhD

Title: Senior Vice President for Research

Name of Institution: Texas Tech University Health Sciences Center

Address: 3601 4th Street, Lubbock TX 79430-6252

Fax:

E-mail: quentin.smith@ttuhsc.edu

806-743-3600

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of

animals as specified above.

Phone:

Signature:

Date: December 11, 2017

806-743-3615

B. PHS Approving Official

Neera Gopee, D.V.M., Ph.D., DACLAM, DABT Veterinary Medical Officer Office of Laboratory Animal Welfare (OLAW) 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 gopeenv@od.nih.gov

Signature: Means 1) Ox les

Date: 02-02-2018

Assurance Number: 016-00032 (A3056-01)

Effective Date: 02-02 - 2018

Expiration Date: 02-28-2022

VIII. Membership of the IACUC

Date: December 11, 2017

Name of Institution: Texas Tech University Health Sciences Center

Assurance Number: A3056-01

IACUC Chairperson

Name*: Samuel Prien

Title*: Professor, Dept of Ob/Gyn, Lubbock Degree/Credentials*: PhD, HCLD

Address*: 3601 4th Street, Lubbock TX 79430

E-mail*: samuel.prien@ttuhsc.edu

Phone*: 806-743-2027		Fax*: 806-743-4746					
IACUC Roster (Abilene, Amarillo, Lubbock)							
Member Name/Code**	Degree/ Credentials	Position Title***		PHS Policy Membership Requirements****			
1	DVM, MS	Institutional Veterinarian / Associate Professor		V	Lubbock		
2	MD	Professor		S	Amarillo		
3	PhD	Professor		S	Lubbock		
4	PhD	Professor		S	Lubbock		
5	PhD	Assistant Professor		S	Abilene		
6	PhD	Professor		S	Lubbock		
7	MD, PhD	Associate Professor		S	Lubbock		
8	PhD	Assistant Professor		S	Amarillo		
9	PhD	Associate Pr	rofessor	S	Lubbock		
10	PhD	Associate Pr	rofessor	S	Lubbock		
11	PhD	Associate Pr	rofessor	S	Lubbock		
12	MSEd, MALS, AHIP	Librarian		NS	Lubbock		
13	BA, MTh	Pastor, Cou	nselor	NS, NA	Lubbock		
14	AAS	Analyst		NS	Lubbock		
15	AS	Unit Coordir	nator	NS	Amarillo		
16	BS, RLAT	Animal Facil	lity Manager	Non-Voting Ex-Officio	Amarillo		
17	JD	Legal Couns	sel	Non-Voting	Lubbock		
18	MS, RLAT	Animal Facil	lity Manager	Non-Voting Ex-Officio	Lubbock		
19	MPA	Safety Serv	ices Senior Officer	Non-Voting	Abilene		
20	MS	Safety Serv	ices Section Mgr	Non-Voting	Lubbock		
21	BS	Safety Serv	ices Manager	Non-Voting	Amarillo		
22	MS	IACUC Adm	inistrator	Non-Voting	Lubbock		
23	BS	IACUC Coor	dinator	Non-Voting	Lubbock		

IACUC Roster (El Paso)						
Member Name/Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****			
24	DVM, MS, DACLAM	Attending Veterinarian	V	El Paso		
25	PhD	Assistant Professor	S	El Paso		
26	PhD	Associate Professor	S	El Paso		
27	PhD	Professor	S	El Paso		
28	PhD	Professor	S	El Paso		
29	PhD	Associate Professor	S	El Paso		
30	PhD	Assistant Professor	S	El Paso		
31	PhD	Librarian	NS	El Paso		
32	BS	Safety Services Manager	Non-Voting	El Paso		
33	BS	College Student	NS, NA	El Paso		
34	DVM	Contract Veterinarian	Non-Voting	El Paso		
35	AAS	Animal Health Technician	Non-Voting Ex-Officio	El Paso		
36	BS	Safety Services Asst Director	Non-Voting	El Paso		
37	JD	Legal Counsel	Non-Voting	El Paso		
38	MS	Safety Services Sr Director	Non-Voting	El Paso		
39	BS	IACUC Coordinator	Non-Voting	El Paso		

^{*} Mandatory information for IACUC Chairperson is included.

V = Veterinarian S = Scientist NS = Non Scientist NA = Nonaffiliated

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact				
Name:	Sara Grano			
Title:	IACUC Administrator / Lubbock-Abilene-Amarillo IACUC Coordinator			
Phone:	806-743-2027	E-mail: sara.grano@ttuhsc.edu		

^{**} Member names are represented by a number in this submission to OLAW. Qualifications are provided. The identity of each member is readily ascertainable by TTUHSC, and available to authorized OLAW or other PHS representative upon request.

^{***} Specific position titles for all members are listed. All members are appointed by the CEO (or an individual with specific written delegation to appoint members) and are voting members. Non-voting members are identified.

^{****} PHS Policy Membership Requirements are abbreviated as follows:

X. Facility and Species Inventory

Date: December 11, 2017						
Name of Institution: Texas Tech University Health Sciences Center						
Assurance Number: A3056-01						
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory			
TTUHSC Abilene	3,093	Mice Rats	718 0			
TTUHSC Amarillo	7,000	Mice Rats	921 56			
TTUHSC El Paso	14,352	Mice Rats	700 100			
TTUHSC Lubbock	**33,040 319	Mice** Rats** Hamsters** Pigs	6,420 126 15/year 12/year			
	187 434	Frogs Dogs	30 * 0			

Unless otherwise indicated, mice and rats means mice of the genus mus and rats of the genus rattus that are purposely bred for research.

^{*} No dogs have been housed in over 8 years.

^{**} Mouse rooms are capable of housing any small species. This figure includes all service areas.