

**TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER (TTUHSC)
A3056-01
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals**

I, Douglas M. Stocco, Ph.D., as named Institutional Official for animal care and use at Texas Tech University Health Sciences Center, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. Applicability of Assurance

This Assurance is applicable to all research, research training, experimentation, and biological testing and related activities, hereinafter referred to as activities, involving live vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this Institution.

"Institution" includes the following branches and major components of Texas Tech University Health Sciences Center: All components (Colleges, Schools, Centers, Departments, etc.) that are physically located on the following four (4) TTUHSC campuses: 1) TTUHSC at Lubbock, TX (Main Campus); 2) TTUHSC at Abilene, TX; 3) TTUHSC at Amarillo, TX; and 4) TTUHSC at El Paso, TX. The Abilene, Amarillo, and El Paso campuses are located approximately 165, 120, and 345 miles, respectively, from the Lubbock Campus.

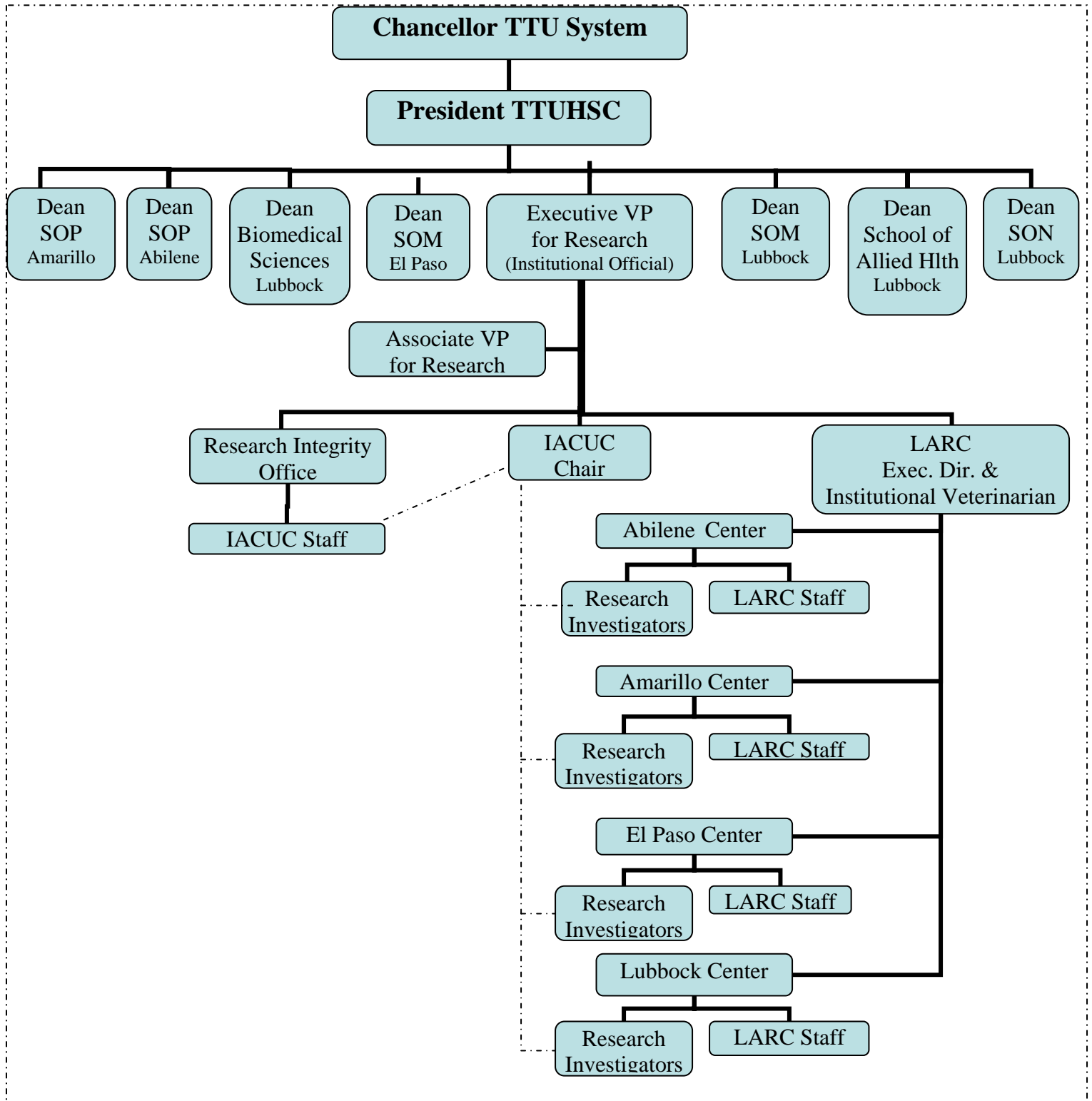
There are no off-campus satellite facilities and/or other covered components.

II Institutional Commitment

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- 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 make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals" ("Guide").

III. Institutional Program for Animal Care and Use

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



SOP = School of Pharmacy; SOM = School of Medicine; SON = School of Nursing

As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.

* The Laboratory Animal Resources Center includes TTUHSC animal facilities located in Abilene, Amarillo, El Paso and Lubbock.

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Lubbock Campus

Name: Gordon Brackee

Qualifications:

- Degrees: B.S., Veterinary Science, 1986, University of MN (UMN); D.V.M., 1988, UMN; M.S. Microbiology, 1992, UMN; Dipomate, ACLAM, 2002
- Training and/or experience in laboratory animal medicine: Fellow in Laboratory Animal Medicine, U of Minnesota Medical School, Minneapolis, MN, 1993-1998; Clinical Laboratory Animal Veterinarian, Wyeth-Ayerst Research, Princeton, NJ; Attending Veterinarian, Princeton University, Princeton, NJ, 2004-2007; Attending Veterinarian, UT Southwestern Medical Center at Dallas, Dallas, TX, 2007; Attending Veterinarian, TTUHSC, Lubbock, TX.

Authority: Dr. Brackee has direct program authority and responsibility for the Institution's animal care and use program including the authority to implement the PHS Policy and the recommendations of the Guide.

Time Contributed to Program: Dr. Brackee is a full time employee of TTUHSC. Approximately one-hundred percent of his time is contributed to the animal care and use program.

❖ The names of the TTUHSC contract veterinarians are available upon request by OLAW.

Name: Contract Veterinarian - Lubbock #1 ❖

Qualifications:

- Degrees: D.V.M., 2000, Texas A & M University; M.S., Animal Science, 1966, Texas Tech University; B.S., Animal Science, 1993, Texas Tech University
- Training and/or experience in laboratory animal medicine Attending Veterinarian, Texas Tech University, 2008-present; TTU IACUC Member, 2007-present

Responsibilities: Serve as primary back-up veterinarian – Lubbock Campus. Also, see detailed list of responsibilities below.

Time Contributed to Program: As needed to provide back-up veterinary care/coverage.

Distance to Campus for Contract Veterinarian: 4 miles

Name: Contract Veterinarian - Lubbock #2 ❖

Qualifications:

- Degrees: D.V.M., 1965, Texas A & M University, 1965; M.S., Parasitic Immunology, 1966, Purdue University; M.S., Animal Nutrition, 1970, Texas Tech University.
- Training and/or experience in laboratory animal medicine: U.S. Army Veterinary Corps, 1966-1968; Private Practice, 1968 to present; TTUHSC IACUC Member 1982-1989.

Responsibilities: Serve as secondary back-up veterinarian – Lubbock Campus. Also, see detailed list of responsibilities below.

Time Contributed to Program: As needed to provide back-up veterinary care/coverage.

Distance to Campus for Contract Veterinarian: 6 miles

Responsibilities of Contract Veterinarians at the Lubbock Campus:

1. Responds promptly to emergency health matters at the request of Institutional Veterinarian, Managing Director, LARC technician(s)/staff, or research staff at the TTUHSC campus in Lubbock.
2. Provides “on-call” animal health support on an ongoing basis including weekends, holidays and after regular business hours for the LARC.
3. Has authority to suspend animal use, and, if necessary, quarantine animals at the LARC, when deemed in the best interest of the animal(s).
4. The Contract Veterinarians are directly responsible to the IVet and act in conjunction with the IVet and the IACUC to maintain the health of animals.
5. In the event of conflict between any action taken by a Contract Veterinarian and the IVet pursuant to carrying out the duties above, the IVet exercises final decision-making authority.

Abilene Campus

Name: Contract Veterinarian – Abilene #1 (Vacant – an active search is underway)❖

Qualifications:

- Degrees:
- Training and/or experience in laboratory animal medicine.

Responsibilities

Conduct weekly visits and be on call if the need arises. Also, see detailed list of responsibilities below.

Time Contributed to Program: Contract Veterinarian – Abilene #1 will be present at the Institution an average of approximately 4 hours per month.

Distance to Campus for Contract Veterinarian: TBD

Provisions for Back-Up Veterinarian Care: On distant campuses Contract Veterinarians provide 24-hour coverage of LARC facilities. In the event of their absence or unavailability, Dr. Brackee provides veterinary coverage. Note: Real-time videoconferencing/telemedicine capability is available.

Amarillo Campus

Name: Contract Veterinarian – Amarillo #1 ❖

Qualifications:

- Degrees: DVM, 1982, Texas A & M University.
- Training and/or experience in laboratory animal medicine: Approximately 26 years in private practice; Attended SCAW Winter Conference, December 8-9, 2008; Attended IACUC 101 Conference, 2/21/07, Stillwater, OK; TTUHSC Rodent Survival Surgery Workshop 10/31/06; TTUHSC Mouse Biotechnology Workshop 9/7/06.

Responsibilities: Conducts weekly visits and is on call if the need arises. Also, see detailed list of responsibilities below.

Time Contributed to Program: Contract Veterinarian – Amarillo #1 is present at the Institution an average of approximately 4 hours per month.

Distance to Campus for Contract Veterinarian: 4 miles

Provisions for Back-Up Veterinarian Care: On distant campuses Contract Veterinarians provide 24-hour coverage of LARC facilities. In the event of their absence or unavailability, Dr. Brackee provides veterinary coverage. Note: Real-time videoconferencing/telemedicine capability is available.

El Paso Campus

Name: Contract Veterinarian – El Paso #1 ❖

Qualifications:

- Degrees: D.V.M., 1992, Texas A & M University

Training and/or experience in laboratory animal medicine: Seventeen years as a private veterinarian practitioner and TTUHSC Contract Veterinarian; TTUHSC BioMethodology Workshop, 2006; IACUC 101, April 2008, Galveston, TX,

Responsibilities: Conducts weekly visits and is on call if the need arises. Also, see detailed list of responsibilities below.

Time Contributed to Program: Contract Veterinarian – El Paso #1 is present at the Institution an average of approximately 4 hours per month.

Distance to Campus for Contract Veterinarian: 18 miles

Provisions for Back-Up Veterinarian Care: On distant campuses Contract Veterinarians provide 24-hour coverage of LARC facilities. In the event of their absence or unavailability, Dr. Brackee provides veterinary coverage. Note: Real-time videoconferencing/telemedicine capability is available.

Responsibilities of Contract Veterinarians at the Abilene, Amarillo, and El Paso Campuses:

1. At least once per week, perform a walk through the applicable TTUHSC animal resource center to observe animals for general health, facility or sanitation issues, and any other issues that should be addressed by the Institutional Veterinarian, and provide any findings of non-compliance in writing to the Institutional Veterinarian or the Managing Director, LARC, within seven (7) business days.
2. Meet with the Institutional Veterinarian or Designee on an as-needed basis to discuss issues related to the applicable TTUHSC animal resource center and for training.
3. Respond promptly to emergency health matters at the request of the Institutional Veterinarian, Managing Director, technician(s) / staff at that TTUHSC campus LARC.
4. Have authority to suspend animal use, and, if necessary, quarantine animals at that TTUHSC campus animal resource center, when deemed in the best interest of the animal(s).
5. Provide veterinary oversight on approved research /training projects as needed at the applicable TTUHSC animal resource center.
6. Provide “on-call” animal health support on an ongoing basis including weekends, holidays and after regular business hours.
7. The Contract Veterinarians are directly responsible to the IVet and act in conjunction with the IVet and the IACUC to maintain the health of animals.
8. In the event of conflict between any action taken by a Contract Veterinarian and the IVet pursuant to carrying out the duties above, the IVet exercises final decision-making authority.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The TTUHSC President and C.E.O. has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at Section IV.A.3.b. Appendix A (attached) includes information about the IACUC Chairperson and each IACUC member, including degrees, position title, and institutional affiliation.

IACUC meetings are primarily conducted by videoconference or alternatively, if the need arises, via telephone conference. All members from a particular location are gathered in a single room and linked to the other locations. The TTUHSC videoconferencing/ teleconferencing capacity allows all applicable TTUHSC campuses to simultaneously be connected. In regard to IACUC functions, all use of telecommunications 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.

D. The IACUC will:

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

The Chair of the Inspection Subcommittee or his or her designee will lead the review of the program during a convened IACUC meeting (normally the April and October meetings to coincide with the semiannual inspections). A revised OLAW sample semiannual program review checklist is provided each member of the IACUC prior to the review meeting. Main topics reviewed are: a) IACUC membership and functions, b) IACUC records and reporting requirements, c) husbandry and veterinary care (all aspects), d) personnel qualifications (experience and training), e) disaster plans, and f) occupational health and safety. Veterinary medical care subtopics include a) preventive medicine, b) animal procurement and transportation, c) surgery, d) pain, distress, analgesia, anesthesia, and euthanasia, and e) drug storage and control. In addition, the evaluation will include a review of the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded from participating in any portion of the reviews.

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

At least once every six months at least two (2) members of the IACUC[≈] will visit all of the Institution's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals is also inspected. The Chair of the Inspection Subcommittee appoints inspection teams (minimum of two individuals per team) for the inspection of the Abilene, Amarillo, El Paso and Lubbock facilities as well as the inspection of investigators' laboratories in which animal research is conducted. The facility inspection teams use the OLAW sample semiannual program review and facility inspection checklist to conduct inspections of the animal holding facilities. Each laboratory inspection team uses the Laboratory Inspection Guideline Checklist created by the IACUC. Each member of the inspection team is encouraged to make written notes about each area as appropriate. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded from participating in any portion of the inspections.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Institutional Official. The IACUC process for developing reports and submitting them to the Institutional Official is as follows:

The Inspection Team Leaders collect individual comments and concerns from their team members and prepare reports which are submitted to the Chair of the Inspection Subcommittee who in-turn forwards the observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, identify specifically any departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such. Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner.

In compliance with PHS Policy IV.B.3., the IACUC files through the Institutional Official, at least annually, a certification to OLAW that the reviews have been conducted and reports any violations of guidelines or assurances which were observed and which have continued after notification of the Institution by the IACUC.

[≈] At distant sites [Abilene, Amarillo, and El Paso] that do not house USDA covered species, the Institutional Animal Care and Use Committee (IACUC) may, at its discretion, determine the best means of conducting an evaluation of the Institution's programs and facilities. The IACUC may invite *ad hoc* consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report. On a rotating basis, should they desire, each member is provided funding to visit distant sites.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows: In accordance with the IACUC standing policy entitled, "Complaints of Mistreatment of Animals and Policy Noncompliance at TTUHSC," any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarian, any member of the IACUC or IACUC staff. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. Any person reporting a concern may choose not to disclose his/her identify. A compliance hotline was established by the Institution to provide an additional option for individuals to report concerns. The Institutional Veterinarian will evaluate complaints and report to the Chair of the IACUC who then calls a meeting of the IACUC Protocol Violations Subcommittee, if considered a significant threat to the animal's wellbeing. If the Institutional Veterinarian is the subject of the complaint, the Institutional Official will appoint an individual to conduct the initial investigation. Persons reporting mistreatment or policy noncompliance are protected from retaliation under state and federal law (TTUHSC OP 10.07). Findings, actions taken and recommendations are provided to the IACUC for approval. That is, all reported concerns will be brought to the attention of the full Committee. If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The Committee will report such actions to the IO and, as warranted, to OLAW.

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 IACUC through its Regulations and Policy Subcommittee will review all guidelines published by PHS as well as other agencies and compare these with practices and policies within the Institution. Policies will be modified to maintain compliance with these guidelines. The IACUC will notify, in writing, the Institutional Official of any areas related to animal usage where improvements or changes should be made to maintain compliance. Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee. The Committee's recommendations are included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter. Such documents are reviewed and approved by the Committee and then submitted to the IO.

6. Review and approve, require modifications in (to secure approval) or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are as follows:

All persons desiring to use animals for either research, testing, or teaching must complete a TTUHSC Protocol form. Protocol forms are submitted to the IACUC office. IACUC Office Staff members input the information into a web-based online system (Integrated Research Information System, iRIS) which assigns an identifying number.

A review team consisting of at a minimum a primary and a secondary reviewer (selected from the scientific members) are appointed by the IACUC Chair in consultation with the IACUC staff. The Institutional Veterinarian is generally the secondary reviewer. Protocols are available to all IACUC members prior to and during convened IACUC meetings.

Pre-review – The review team (identified above) conducts a pre-review of the protocol. Any questions or concerns are relayed in writing to the principal investigator. Once responses are received, the protocol is presented to the full Committee for review.

IACUC Review – Generally, the full committee review (FCR) process is used. Specifically, protocols are distributed to the entire IACUC for review prior to a meeting. As described above, each protocol is assigned one or more reviewers. At a convened meeting with a quorum present, each protocol is presented by the primary reviewer and any outstanding issues are thoroughly discussed. Following the presentation and associated discussion, the IACUC members present vote for either a) approval; b) modifications required to secure approval, or c) withhold approval.

In some circumstances, a designated member review process (DMR) may be used. 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 96 hours and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting. If full-committee review (FCR) is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, is assigned to review those protocols and has the authority to approve, require modifications in (to secure approval), or request full committee review of those protocols. 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. If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

Required modifications. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:

- a. FCR or DMR following the procedures delineated above.
- 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. Provided however, that if any member calls for FCR of the modifications, such modifications can only be reviewed and approved by FCR.
- c. Minor modifications may be confirmed by IACUC administrative/support personnel, if approved by the designated members (if DMR) or unanimously by all members at the meeting in which the protocol was presented (if FCR).

No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC 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.

Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. 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 Instructions don't seem to require this much info. If we put in then we are locked in. Further, the IACUC shall determine that the protocol conforms to the Institution's PHS Assurance and meets the following requirements:

- i. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- ii. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- iii. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- iv. The living conditions of animals will be appropriate for their species and 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.
- v. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- vi. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- vii. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

Members of the IACUC 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. However, under no circumstances may a member who is not physically present at the meeting be counted towards a quorum and/or vote.

7. Review and approve, require modifications in (to secure approval) or withhold approval of changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at

IV.C. The IACUC procedures for reviewing proposed changes in ongoing research projects are as follows: Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph 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 used;
- 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

8. Notify investigators and the Institutional Official 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 as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

Principal Investigators are notified either by e-mail or letter from the IACUC Chairperson and/or via the on-line system, iRIS. The Institutional Official is notified by receiving a copy of the PI's notification letter and/or a copy of the IACUC meeting minutes and/or by the on-line system, iRIS.

Decisions made and/or actions taken regarding protocols are maintained and available within the online system, iRIS.

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 in accordance with the PHS Policy at IV.C. 1-4. at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

All ongoing activities are monitored continuously by the animal care and use staff and the associated protocols along with annual status reports, that include a progress report of the previous year and goals for the upcoming year, are reviewed by a member or members of the IACUC at least annually. Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.

Protocols are approved for a maximum of 36 months. That is, all protocols 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 Paragraph III.D.6. above. These *de novo* reviews of continuing activities includes submission of a new protocol form defined as 'Renewal'. The renewal must be complete as it supplants all previous documents in the file including all amendments made to the original protocol during the previous three years. A detailed summary of work performed on the protocol during the past twelve-month period is required.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedure 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 of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. 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 Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

E. The Occupational Health and Safety Program (hereafter referred to as Employee Health Program) for personnel who work in laboratory animal facilities or have contact with animals is as follows:

1. Program Policy: The Institution has established an Employee Health Program for employees of TTUHSC who work with animals. The purpose of this program is to provide employees with education about protection from and treatment of occupationally-related health problems. The Institution has established this program to meet both its responsibilities toward employees and its obligation under federal and state regulations. Toxoplasma is an infectious agent found primarily in cat feces. It can infect unborn babies in women exposed during pregnancy who do not have immunity to the agent. Asymptomatic (i.e. without clinical signs) Toxoplasma infection is common before child-bearing years, and many women have elevated antibody levels indicative of immunity. To help assess the level of immunity against this agent, serum samples can be tested. Cat feces should be avoided, and gloves should be worn when working in areas potentially contaminated with cat feces. Thorough hand washing after handling any potential source of infection is also necessary. Working with hazardous agents, x-rays, radioactive materials and toxic chemicals is discouraged during pregnancy. Anesthetic gases pose a particular risk to pregnant women and their babies and it is therefore discouraged on pregnant women. Situations that may cause immunosuppression include splenectomy, corticosteroid use (such as for asthma), certain immunosuppressive diseases and chemotherapy among others. Immunosuppressed individuals are encouraged to notify the employee health physician if any of these situations apply **before** starting work with animals. Vaccination against tetanus is offered as part of the basis participation in the program. 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 working in concert with the Infectious Control Nurse and appropriate members of the LARC staff provide necessary training to laboratory personnel.

Personnel are advised during training that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that 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.

2. Standard Operating Procedures:

- a. Objective: 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.
- b. All animal users are enrolled in the employee health and safety program. Use of hazardous biologic, chemical or physical agents is just one of the criteria considered when determining the level of the employee health and safety program the person is assigned.
- c. Medical Evaluation and Preventive Medicine for Personnel: The employee health and safety program for research animal users involves all personnel who come in direct contact, and indirect (bystander) contact, with research animals depending on a risk assessment evaluation. We have documented three levels of animal contact with recommendations for each level. Briefly, level one access includes researchers and animal care staff with direct animal contact and must fulfill the highest level of care and training including Medical History Questionnaire. Research personnel with direct animal contact are identified on the animal protocol form. Level two access includes personnel from the Physical Plant and Security personnel who are required to train using video presentation and 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 three access includes visitors (non-personnel) that are authorized by the LARC Director to access the vivarium support areas. They are also required to sign-in/out of the facility and receive our Occupation Health and Safety brochure with instruction about common hazards.

Administrative oversight and responsibility for the program resides within the Personnel Health/Medical Surveillance Oversight Committee which is a standing committee appointed by the President of TTUHSC and includes representation from the Office of the Executive Vice President for Academic Affairs, the Office of General Counsel, the Infection Control Committee, the Associate Dean for Research, the Director of Safety Services and the Director of the LARC. The Dean/Regional Dean at each Center will designate a central unit on their respective campus responsible for the Occupational Health and Safety Program. The program structure must be consistent with the TTUHSC OP 75.11 and must be approved by the Personnel Health/Medical Surveillance Oversight Committee. The designated unit will be responsible for maintaining records, providing immunizations and testing, providing training, serving as the initial point of contact for all probable exposures and operating as the cost center for the program.

The Employee Health and Infection Control Office, the Research Integrity Office and the IACUC monitor the overall program. Enrollment records are maintained within the LARC office and necessary inoculations and health records are maintained by the Infectious Control Nurse. Generally, the IACUC Staff provide the LARC office information regarding animal users identified from the protocol form (i.e., new or renewal protocol and/or amendments). A member of the LARC staff then sends a Medical History Questionnaire and Employee Health for Animal Users booklet to all non-enrolled animal users. The employee sends completed (or declined) Medical History Questionnaire to the Employee Health and Infection Control Office for evaluation by a Registered Nurse who recommends and/or requires follow-up care. The employee then completes the required actions or signs

declination statement (i.e. declining immunizations, etc). The signed memorandum is retained with Employee Health and Infection Control. On the anniversary of their enrollment, individuals still active in the Program are advised to complete an updated Medical History Questionnaire if their health status has changed and submit it to the Employee Health nurse for additional evaluation/recommendations.

- d. Personal Hygiene and Protection: At all LARC sites, scrub suits are provided, laundered and replaced by LARC as needed. Also provided are work shoes/boots, disposable gloves, masks, head covers, lab coats, eye protection and hearing protection for use by the LARC staff. There are in-house facilities to launder work clothing at the Lubbock, Amarillo and El Paso Centers. A Commercial Service launders work clothing for the Abilene Center.

Employees are instructed to wash hands after handling animals or wearing gloves. 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. Suites in the ABSL3 biohazard area (El Paso) are equipped with wall mounted hand wash sanitizers.

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. EH&S performs fit tests after the employee receives medical clearance from the occupational health nurse.

Aprons are available for use in cage wash and other areas where protection from chemicals, etc, 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.

- e. 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.

- f. Hazard Identification and Risk Assessment: 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. All biohazard protocols are reviewed by the Biosafety and Biohazard Committees. Any recommendations are given full consideration and compliance. 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; a copy of the appropriate safety committee's approval and recommendations/requirements must be attached to the protocol form. The Institutional Veterinarian is a member of the Infectious Control Committee.
- g. Procedures Involving Hazards: The use of hazardous biological, chemical or physical agents must be approved by the appropriate safety committee (Radiation Safety Committee, Biohazards Committee, Recombinant DNA Committee), as appropriate prior to approval by the IACUC.

Health programs for personnel potentially exposed to specific hazardous agents are as follows:

ABSL3 Laboratory (El Paso): All workers in the ABSL-3 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 and had five two-hour practical training sessions, on health related and regulatory issues.

Control of Rabies: Dogs are vaccinated prior to arrival with killed Rabies vaccine. In addition, we offer vaccination to all individuals with exposure to dogs or other species that can carry rabies.

Control of Hepatitis and other blood-borne agents: Individuals working with human blood and tissues are provided additional training by EH&S. Animal care staff is included with additional training provided by the LARC Director or Supervisor. All human tissue work is performed in a biosafety cabinet. PPE requirements include lab coats, gloves, masks, eye protection, and sleeve covers. Individuals with potential for exposure are also offered vaccination, as necessary.

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. The RN, Emergency Room, or private physician, as appropriate, treats wounds of higher severity. The LARC Veterinarians are notified to evaluate an aggressive animal and the cage or cage-card is identified for personnel to have caution when handling this animal.

Control of allergies to animals: TTUHSC provides extensive services regarding research animal related allergies. Personnel training provide information regarding the symptoms and significance of animal related allergies. All personnel are also instructed to report any allergy symptoms to the Registered Nurse. The health history questionnaire is also our screening instrument for the development of work-related symptoms of asthma/allergy. When participants report potential allergy symptoms they are 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 are given medical treatment, increased PPE, and education regarding exposure reduction. Participants with occupational asthma

may be restricted from further exposure to the animal species to which they're sensitized. We continue to reduce exposure to animal allergens. For example, conventional rodent areas in Lubbock are being converted to ventilated microisolator caging with HEPA filtered exhaust (i.e. this results in fewer open-topped, and filter-topped rodent cages), while all other sites (Amarillo, El Paso, and Abilene) have 100% ventilated microisolator caging systems in current use. The animal care staff and researchers who utilize the BioBubble Clean room in Lubbock with the BioBubble 'Stay Clean' Changing Station (laminar-flow, HEPA-filtered) are required to wear N95 respirators that have been fit-tested by our EH&S. Likewise, cagewash personnel are required to perform cage dumping activities in front of HEPA-filtered dust collection devices (BioBubble Bedding Disposal Unit). Finally, for those rodent rooms with open-topped, and/or filter-topped static microisolator caging we have utilized the EH&S airborne particle counter to demonstrate very low levels of suspended allergen particles (less than 5 micron).

Control of radiation exposure: Personnel taking radiographs or caring for animals exposed to radioactive substances are provided radiation detection badges, which are monitored monthly. Specific protocols are developed for high risk isotope use in animals. Individuals with radiation exposure are required to take the radiation safety training classes.

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.

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.

Procedures to report exposure and potential hazards is as follows: In the event of injury or exposure, incidents are reported to the Supervisor and/or Manager. First aid is administered if necessary and immediate medical treatment sought for serious injuries if applicable. Emergency help is available by calling the University Police. 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 Registered 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 EH&S.

The oversight process and husbandry practices in place to ensure personnel safety, including any personal protective equipment provided when work assignment involves hazardous agents is as follows: A representative of EH&S is appointed to the IACUC. This representative and the LARC are aware of specific proposals that include hazardous agents. When investigators use protocol numbers to order animals, they are contacted by the LARC to assure that all SOPs for the care of the exposed animals, waste disposal, etc., are complete and that the animals are delivered to the appropriate facilities. Personnel caring for animals exposed to hazardous agents are provided as appropriate: masks, respirators, gowns, gloves, full face shields, disposable full body jumpsuits, and radiation detection badges when necessary. All personnel assigned to studies using hazardous agents receive specialized training. Cages 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 area as follows: Depending upon the agent or circumstances, animals are exposed and housed in biocontainment facilities (ABSL3 El Paso), individual animal holding rooms, or in mixed areas using individually ventilated microisolator caging. Animal care personnel are instructed about precautions necessary for personal safety and about special animal care and waste disposal procedures that are necessary. Animal wastes and animal carcasses are disposed of according to established protocols (i.e. autoclave sterilization, double red-bag, etc). Biohazardous wastes are rendered safe by autoclaving, decontamination or incineration. 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 is as follows: 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.

As required by the specific hazardous agent, wastes, caging, and supplies are autoclaved or chemically treated when removed from the room. Cage racks are chemically disinfected prior to removal. Specific protocols and hazard door signs for each study are developed in conjunction with EH&S for the agent being 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.

TTUHSC has one special facility for mice exposed to infectious agents at the dedicated, ABSL3 facility within the El Paso vivarium. Otherwise, animals are housed within conventional areas either in dedicated rooms and/or within HEPA-filtered, ventilated microisolator caging (negative). In the conventional areas, the airflow pattern for animal housing rooms is from the hallway into the room and room air is exhausted directly to the outside. 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). 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. The facility is accessible via governmental clearance, or escorted visitors may enter by permission from the Laboratory Director.

Currently, there are no studies involving the use of nonhuman primates.
Provision of additional training - Not Applicable
Provision of bite/wound kits and follow-up care - Not Applicable
Provision of additional protective clothing - Not Applicable

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory (by species) of animals in each facility is provided in the attached table entitled 'Facility and Species Inventory' (**Attachment B**).
- 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 five 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 third major constituency consists of those persons who are observing or participating in supervised educational experiences involving live laboratory animals. The fourth major constituency is the IACUC members.

1. Training of LARC staff:

The training of the LARC staff is the responsibility of the Institutional Veterinarian. The training programs employed are those made available to laboratory animal care technicians by the American Association for Laboratory Animal Science. The technician certification program is administered by either the Managing Director or the Quality Assurance/Compliance Officer with assistance from the Institutional Veterinarian, Vivarium Manager and Veterinary Technician. Classes are held on a regular basis for all animal caretakers. In addition, "hands on" and "on-the-job" training sessions are held for all LARC personnel. Other training is provided as new standard operating procedures and forms are developed.

2. Training of Laboratory Animal Experimenters:

The IACUC-approved training process 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). The day-to-day operation and record keeping necessitated by the training requirement is administered by the LARC staff person. The LARC staff person checks the records to determine if the personnel listed have completed the necessary training. Those who have not completed training are notified that they must complete the training requirement before the item (application/renewal/amendment) can be approved. Once the item is approved personnel are then authorized to use the animals and gain admission to the LARC facility.

The training program has two major elements. The first is a series of online modules which specifically address the training topic requirements currently listed in 9 CFR, Part 2, Subpart C, Section 2.32(c). We currently use an online series offered by the Laboratory Animal Training Association (LATA). Individuals working with animals in laboratories complete a series of modules relating to their proposed use of animals. All complete the module entitled "The Humane Care and Use of Laboratory Animals" which outlines 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 R's (Reduction, Refinement, and Replacement) of animal research. Each person then completes modules relevant to the species which they are using which outlines the principles of husbandry and demonstrating basic experimental procedures. All records of LATA training are maintained in the LARC office and the online iRIS system.

In addition to the training described above, individuals using exotic species or employing new techniques are provided one-on-one instruction and assistance from the LARC professional staff. Training is generally provided in the form of workshops (anesthesia, euthanasia and survival surgery workshops).

Records of participation in the required formal training program are maintained in the LARC staff office and the online iRIS system. Records of participation in training exercises initiated by the LARC are kept by the LARC.

3. Training of Individuals Observing or Participating in Supervised Educational Experiences Involving Laboratory Animals:

The use of animals in the educational mission of the Institution is subject to the oversight of the IACUC. A protocol form must be submitted and approved before animals may be used. The purpose, value and availability of alternatives, as well as 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 i) the use of the animals has been approved by the IACUC; ii) they have a responsibility to contribute to the humane and purposeful use of animals in the educational experience and iii) they are to promptly address any concerns of animal use to the supervising instructor and, if warranted, the IACUC.

4. Training of IACUC Members:

Each IACUC member is provided with an electronic copy (hard copies provided if requested by the member) of the following:

- a) The PHS Policy for the Humane Care and Use of Laboratory Animals;
- b) The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
- c) The ARENA/OLAW IACUC Guidebook;
- d) The AVMA Guidelines on Euthanasia;
- e) A copy of this Assurance.

Orientation of new members is provided by one or a combination of the IACUC Chair, the Institutional Veterinarian, the Training/Information Subcommittee Chair and/or IACUC Staff. A PowerPoint presentation is available and online resources such as URL's to access the AVMA for Euthanasia, OLAW FAQ's, PHS Policy, USDA, the "Guide", etc. are provided.

Regular members of the IACUC are encouraged to attend conferences which focus on the care and use of animals and issues of regulation and compliance. In addition, training conducted during IACUC meetings consists of reports by members who have attended meetings such as PRIM&R, SCAW, etc. IACUC members are provided training opportunities and materials (i.e., webinars, SCAW newsletters, Lab Animals, HSUS Pain and Distress Reports, AWIC Bulletins, etc.) that are documented by the IACUC staff when participation or review is confirmed.

Members are required to complete The Humane Care and Use of Laboratory Animals and the Occupational Health and Safety modules offered by the Laboratory Animal Training Association (LATA) at <http://balsam.forest.net/latanet/ttuhsc/welcome.htm>. They are encouraged to 1) complete the PHS Policy on Humane Care and Use of Laboratory Animals Tutorial located at the OLAW website, <http://grants.nih.gov/grants/olaw/tutorial/index.htm> 2) visit the OLAW website at least annually and (3) familiarize themselves with the other pertinent modules and information, e.g., OLAW FAQs, Policies and Laws, Guidance, Educational and other Resources.

Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting, or similar course will be substituted for any required IACUC training session.

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 six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the 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 "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.

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

V. Record keeping Requirements:

A. This Institution will maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by 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 given or withheld.
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official.
 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 three 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. This Institution's reporting period is January 1 – December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31 of each year. The 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), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this Institution will provide OLAW with written notification that there are no changes.
 2. 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, the Executive Vice President for Research.
- B. The IACUC, through the Institutional Official, will provide OLAW promptly 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 shall include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Douglas M. Stocco, Ph.D.

Title: Executive Vice President for Research

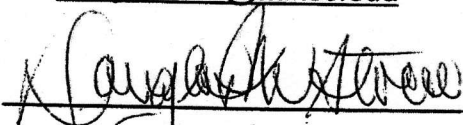
Name of Institution: Texas Tech University Health Sciences Center

Address: 3601 4th Street MS 6252, Lubbock, Texas 79430

Phone: (806) 743-3600

Fax: (806) 743-3615

E-mail Address: doug.stocco@ttuhsc.edu

Signature: 

Date: 2/15/10

B. PHS Approving Official

Eileen M. Morgan
Director, Division of Assurances, OLAW
National Institutes of Health
RKL1, Suite 360-MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Signature: 

Date: 2/24/10

C. Effective Date of Assurance: 2/15/10

D. Expiration Date of Assurance: 2/28/14

ATTACHMENT A**MEMBERSHIP OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

DATE: January 16, 2010

INSTITUTION NAME: Texas Tech University Health Sciences Center

ASSURANCE NUMBER: A-3056-01

| Chairperson Name, Title and Degree/Credentials* | | *Business Address, Phone, Fax and Email of Chairperson | |
|--|------------------------------|--|--|
| Samuel Prien | | 3601 4 th Street | |
| Professor, Dept. of OB/GYN/Lubbock | | Lubbock, TX 79430 | |
| Ph.D., HCLD | | Phone: 806-743-2967 Fax: 806-743-4746 Email: Samuel.prien@ttuhsc.edu | |
| NAME of MEMBER/CODE** | DEGREES / CREDENTIALS | POSITION TITLE (if any) | PHS Policy Membership Requirements*** |
| Gordon Brackee | D.V.M.,M.S., DACLAM | Institutional Veterinarian (LARC Executive Director) Associate Professor | (V) |
| 1◇ | Ph.D. | Associate Professor | (S) Lubbock |
| 2◇ | Ph.D. | Associate Professor | (S) Lubbock |
| 3◇ | RLATG | Unit Coordinator, Animal Facility | Non-voting (ex officio) El Paso |
| 4◇ | | Section Manager, Safety Services | Non-voting (ex officio) Lubbock |
| 5◇ | Ph.D. | Associate Professor | (S) Lubbock |
| 6◇ | Ph.D. | Professor | (S) Lubbock |
| 7◇ | Ph.D. | Professor | (S) Lubbock |
| 8◇ | B.S., CMAR, RLAT | Section Coordinator, Animal Facility | Non-voting (ex officio) Amarillo |
| 9◇ | Ph.D. | Associate Professor | (S) El Paso |
| 10◇ | | Nuclear Safety Specialist, Pantex Plant | (NA) Amarillo |
| 11◇ | RLATG | Unit Manager, Animal Facility | Non-voting (ex officio) Lubbock |
| 12◇ | | Sears Advertising Copy Writer/Accountant (Retired) | (NA & NS) Lubbock |
| 13◇ | Ph.D. | Professor | (S) Lubbock |
| 14◇ | | Sr. Business Assistant Classroom Support | (NS) Lubbock |
| 15◇ | LATg | Managing Director, Animal Facility | Voting (ex officio) Lubbock |
| 16◇ | Ph.D. | Associate Professor | (S) Amarillo |
| 17◇ | Ph.D. | Associate Professor | (S) Amarillo |
| 18◇ | Ph.D. | Assistant Professor | (S) Lubbock |
| 19◇ | M.D. | Professor | (S) Amarillo |

◇ Names of members are available upon request by OLAW or PHS representative.

*This information is mandatory.

**Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the Institution and available to authorized OLAW or other PHS representatives upon request.

***PHS Policy Requirements - identify which IACUC members meet the four criteria below:

- Veterinarian (V) - a veterinarian with direct or delegated program responsibility.
- Scientist (S) - a practicing scientist experienced in research involving animals.
- Nonscientist (NS) - a member whose primary concerns are in non-scientific areas (e.g. ethicist, lawyer, member of the clergy).
- Nonaffiliated (NA) - a member who is not affiliated with the Institution in any way other than as a member of the IACUC, and who is not a member of the immediate family of a person who is affiliated. This member is expected to represent the interests of the general community in the proper care and use of animals and should not be a laboratory animal user. A consulting attending veterinarian may not be considered nonaffiliated.

Notes:

1. All members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Ad hoc or nonvoting members may be listed and identified as such, but are not considered members for the purpose of the PHS Policy, and do not contribute to a quorum.
2. If Alternate members are listed, identify for whom (by name or code number, not specialty) they will serve as Alternates.

OTHER KEY CONTACTS (OPTIONAL)

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

Name: Gayle Ferguson
Title: Unit Manager
Phone & Fax: 806-743-2967 & 806-743-4746
E-mail: gayle.ferguson@ttuhsc.edu

Name:
Title:
Phone & Fax:
E-mail:

ATTACHMENT B**FACILITY AND SPECIES INVENTORY**

INSTITUTION NAME: Texas Tech University Health Sciences Center

ASSURANCE NUMBER: A-3056-01

DATE: February 5, 2010

| LABORATORIES, UNITS or BUILDINGS | GROSS NUMBER OF SQUARE FEET OF FACILITY (INCLUDING SERVICE AREA) | SPECIES HOUSED IN FACILITY | APPROXIMATE AVERAGE DAILY INVENTORY OF SPECIES |
|--|---|--|---|
| TTUHSC Abilene | 3,093 | Mice | 373 |
| TTUHSC Lubbock | 33,980 | Cats Pigs Rabbits Rats Mice Frogs Pigeons Guinea Pigs | <1 <1 8 113 1617 51 23 3 |
| TTUHSC Amarillo 1400 Wallace 411 SOP Coulter Research Bldg | 3,745 | Mice Rats | 312 53 |
| TTUHSC El Paso | 9,176 | Mice Rats | 256 148 |