

**TEXAS TECH UNIVERSITY HEALTH
SCIENCES CENTER EL PASO**

**INSTITUTIONAL ANIMAL CARE AND
USE COMMITTEE MANUAL**



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CHAPTER 1 ORGANIZATION OF THE TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

1.1 Introduction and Organizational Summary

The Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Institutional Animal Care and Use Committee (IACUC) is dedicated to the humane care and use of animals in activities related to research and teaching conducted at TTUHSC El Paso or by individuals associated with the University. The IACUC is guided by federal and state laws, regulations, and ethical principles, and is responsible for supporting and protecting the officially sanctioned use of animals in research, and teaching and service at TTUHSC El Paso. All research involving live vertebrate animals that is conducted, or authorized, under the jurisdiction of TTUHSC El Paso is subject to review by the IACUC.

This manual describes the policies and procedures of the TTUHSC El Paso IACUC. Its purpose is to communicate comprehensive information about the organization, structure, and function of the animal activities related to teaching and research to the scientific community at TTUHSC El Paso and affiliated institutions. This Manual incorporates in one core document TTUHSC El Paso's dedication to the humane care and use of animals, operating procedures of the Institutional Animal Care and Use Committee (IACUC), and references to TTUHSC El Paso Institution-Wide Operating Policies and Procedures. The document is organized around the elements and standards required by the Association for Assessment and Accreditation of Laboratory Animal Care, International. The Manual describes applicable regulations governing research involving animals, such as the U.S. Department of Agriculture (USDA) under statutory law (Title 7, Section 2131 of the United States Code [7 USC 2131]) and regulations (Title 9 of the Code of Federal Regulations [9 CFR 2.31 et seq.]), Public Health Service (PHS) under statutory law [42 USC 289d], the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the Guide for the Care and Use of Laboratory Animals (The Guide), and the Office of Laboratory Animal Welfare (OLAW).

All members of the TTUHSC El Paso community who are engaged in research involving animals must be knowledgeable about the requirements of the IACUC. All information governing the conduct and review of research involving animals under the purview of the TTUHSC El Paso IACUC may be found at the TTUHSC El Paso Research website.

The IACUC is led by the Vice President for Research (VPR) who has been designated as the Institutional Official (IO) for purposes of executive responsibility for research programs at TTUHSC El Paso. Delegation of day-to-day responsibility of the TTUHSC El Paso IACUC is shared by personnel in the Office of Research Resources (ORR), TTUHSC El Paso IACUC Chair, and IACUC members. Ultimately, however, success of the TTUHSC El Paso IACUC requires commitment from all parties involved in animal research, including institutional administrators, faculty, staff, students and other trainees, sponsors and affiliates.

The VPR/IO, Managing Director, and Sr. Director of the ORR engage in an on-going review of the status of the IACUC via monthly meetings to discuss pertinent issues. An annual written summary of the activities of the TTUHSC El Paso IACUC is prepared by the Sr. Director and is provided to the VPR, usually near the beginning of the fiscal year. This annual summary is used to assess IACUC composition and provides a basis for adjusting membership as needed. The institutional effectiveness process also provides ongoing quality assessment and quality improvement goals for issues related to the efficiency of the TTUHSC El Paso IACUC.

The funds to support the TTUHSC El Paso IACUC, including the salaries of full-time personnel, and the costs of maintenance and operations, are derived from the budget of the ORR. The budget is reviewed at least annually by the Managing Director of the ORR and the VPR; adjustments are made as necessary to cover any unexpected expenses. Initial and continuing review fees of industry-sponsored research provide supplemental funding for the IACUC. These fees are used primarily for education, conference registration, and travel expenses incurred by ORR staff and associated research committee members, and for membership fees and certifications for professional organizations.

1.2 Components of the TTUHSC El Paso IACUC

In order to function effectively, the TTUHSC El Paso IACUC requires commitments and assistance from many areas within and outside of the institution. The major components of the TTUHSC El Paso IACUC include:

The Institutional Official. The Vice President for Research (VPR) serves as the Institutional Official with overall responsibility for the TTUHSC El Paso IACUC. Specific duties and responsibilities of the VPR with regard to the IACUC can be found under Institutional Authority.

Office of Research Resources. The ORR is recognized by the Institutional Official as the point of contact with OLAW and the USDA. ORR staff members exercise operational responsibility on a day-to-day basis for the IACUC. This includes IACUC administration, compliance, and educational components of the TTUHSC El Paso IACUC.

Institutional Animal Care and Use Committee (IACUC). TTUHSC El Paso has one IACUC. The IACUC reviews research involving animals conducted under the oversight of Principal Investigators (PIs) at this campus. The IACUC has the authority to approve, require modifications to secure approval, or disapprove all animal research overseen and conducted by TTUHSC El Paso faculty and staff. The IACUC, or chairperson working on behalf of the IACUC, may also suspend or terminate approval of research not being conducted in accordance with the IACUC's requirements, or that has been associated with unexpected serious harm to animals. The IACUC may observe, or have a third party oversee, the conduct of animal research.

Department Chairpersons/Signatory Authorities. Each project submitted for IACUC review may be electronically signed by a Department Signatory Authority (generally, the Department Chair) attesting to the study's scientific elements of the protocol as they relate to the welfare and use of animals, available resources, and study feasibility, as described in more detail under Principal Investigator Sign-off.

General Counsel. The TTU System Office of General Counsel is available to provide advice upon request of the VPR, IACUC, or other individuals involved with the IACUC. The Office of General Counsel may provide legal guidance and interpretation of TTUHSC El Paso policies, and of State and Federal laws and regulations as they relate to the conduct of research involving animals.

Office of Sponsored Programs (OSP). The TTUHSC El Paso OSP handles grant and clinical trial contract administration. Personnel in this office review sponsor contracts and funding agreements for compliance with Federal and State regulations, and with TTUHSC El Paso and IACUC policies and procedures.

Conflict of Interest in Research Committee (COIRC). Studies in which an investigator has a financial conflict of interest in the research must be reviewed by the COIRC and, if

necessary, have an approved Conflict Management Plan in place prior to approval by a TTUHSC El Paso IACUC. Further details are found in TTUHSC EP OP 73.09.

Investigators and Research staff. Investigators and research staff have a responsibility to follow the IACUC requirements described throughout this Manual and to comply with all determinations of the IACUC and the VPR.

Deans/Department Chairs. These individuals are responsible for “setting the tone” for responsible conduct and oversight of animal research in their department or school, for providing opportunities for education regarding ethical actions and compliance as they relate to research, for fostering support for IACUC members, and for providing adequate resources to conduct animal research at TTUHSC El Paso.

All TTUHSC El Paso faculty, staff and students. Everyone associated with TTUHSC El Paso should have a general idea of animal research protections and should consult the IACUC when faced with uncertainty about whether an activity involves research with animals. Individuals should report allegations of possible research misconduct as outlined in TTUHSC EP OP 73.14, Research Compliance and TTUHSC EP OP 73.07, Honesty in Research and Allegations of Scientific Misconduct.

1.2.1 Communication between components

TTUHSC El Paso uses several mechanisms to communicate information relevant to the IACUC. These may include a general announcements website, which posts all institutional policy changes/updates, as needed. In addition, issues specifically pertinent to animal research (for example: updates to the IACUC manual, template form changes, relevant policy alterations) are communicated to investigators and staff via the iRIS Announcement feature on an as needed basis.

The Managing Director of the ORR serves as a central liaison between the IACUC and other research compliance committees, the IO, and various departments.

The IACUC application form serves as a primary tool for assessment of the institutional requirements to be met to ensure humane care and use in an animal research project. IACUC members and IACUC administrative staff review each submission to verify that these institutional components are adequately described. Examples include appropriate signatory authorization, training and financial disclosures of all study personnel, and the presence of approved conflict management plans when necessary. If the IACUC or IACUC administrative staff determines that any of the institutional requirements necessary to protect animals are lacking, then the principal investigator (PI) will be notified in writing. The PI will be required to address the issue(s) and to provide additional necessary documents and/or information needed to comply with institutional policies and procedures.

1.3 Scope

Only research that involves the use of live vertebrate animals requires review by the TTUHSC El Paso IACUC. Further, TTUHSC El Paso, or an affiliated entity with which TTUHSC El Paso has a written agreement to serve as an IACUC of record, must be engaged in the research project in order to require review by a TTUHSC El Paso IACUC. To determine whether an activity meets the definition of research involving animals, the following definitions should be considered.

Field studies, which are defined as research that involves studying free-living, wild animals in their natural habitat, require IACUC approval when (1) the study is funded by the PHS,

National Science Foundation, or other funding agency that requires review, (2) the animals are warm-blooded and the study has the potential to cause harm or alter the behavior of the animals under study, or (3) state regulations or the respective permitting agency requires IACUC review. The IACUC may accept oversight by another PHS-approved IACUC.

The following activities involving animals do not require IACUC approval:

- The study of animals in their natural habitat without investigator intervention;
- The study of preserved specimens or tissues obtained from recognized vendors of scientific supplies, research institutions or museums;
- The study of tissues obtained from a USDA-approved slaughterhouse or any vendor selling such tissue;
- Any activities not associated with teaching or research.

1.3.1 Definitions

1.3.1.1 Animal Care and Use Program

Activities conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management.

1.3.1.2 Animals

An unqualified use of the term “animal” refers to live vertebrates beyond the fetal stage (mammals) or that have hatched (other vertebrates). The IACUC does not regulate activity associated with non-vertebrate animals or animal carcasses.

1.3.1.3 Engagement

TTUHSC El Paso is considered to be “engaged” in an animal research project if any one or more of the following criteria is met:

- The research is conducted by or under the direction of any employee, student or agent of TTUHSC El Paso in connection with responsibilities to TTUHSC El Paso.
- The research is conducted by or under the direction of any employee, student or agent of an entity with which TTUHSC El Paso has a written agreement to serve as the IACUC of record or as a relying IACUC, if the project falls under the auspices of the agreement.
- The research is conducted in accordance with an assurance filed with OLAW in which a TTUHSC El Paso IACUC is designated as the IACUC of record.

TTUHSC El Paso may also be engaged in the research, and require IACUC approval, if either of the following applies:

- The research takes place at any property or facility of TTUHSC El Paso

OR

- The research is sponsored by TTUHSC El Paso.

Investigators and study personnel who are unsure whether a proposed project meets the criteria for research or whether TTUHSC El Paso is engaged in the project

should contact their local IACUC administrative staff for assistance with making the determination.

1.4 Authority

All research involving animals conducted at or in affiliation with TTUHSC El Paso shall be conducted in accordance with federal regulations and TTUHSC EP OP 73.03, Animal Care and Usage. Applicable federal and state regulations include, but are not limited to:

- Animal Welfare Act
- Health Research Extension Act of 1985
- U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training
- Public Health Service Policy on the Humane Care and Use of Laboratory Animals
- Guide for the Care and Use of Laboratory Animals

Any changes made to these regulations will be immediately adopted by the TTUHSC El Paso IACUC, supplanting anything written in TTUHSC El Paso Policies and Procedures.

1.4.1 U.S. Department of Agriculture

The U.S. Department of Agriculture (USDA), through its division of the Animal and Plant Health Inspection Service (APHIS), administers the Animal Welfare Act of 1966 (AWA) and its amendments, codified at 7 USC 2131 et seq. and 9 CFR 2.31 et seq. The AWA regulates the transportation, purchase, care and treatment of animals used for exhibition, sold as pets, or used in basic and biomedical research, education, and product safety testing. The AWA specifically applies to the use of all warm-blooded vertebrates (Mammalia and Aves), with the exception of mice of the genus *Mus*, rats of the genus *Rattus*, and bird species bred specifically for use in research.

The AWA requires the establishment of an IACUC at all institutions that use animals in research, teaching or testing. The IACUC is responsible for reviewing all activities that involve animals in research, teaching or testing to ensure humane use of animals. The IACUC is also responsible for conducting semiannual assessments of TTUHSC El Paso IACUC Policies and Procedures for animal care and use programs, including inspections of all animal study areas and facilities. As a research facility, TTUHSC El Paso is subject to random inspections by USDA and must file an annual report concerning its IACUC Policies and Procedures, TTUHSC El Paso's compliance with AWA, the location of all facilities where animals are housed or used, and specific animal information as required. Failure to comply with USDA laws and regulations pertaining to the use of live animals can result in civil or criminal prosecution and suspension of animal research activities. TTUHSC El Paso is required to renew its registration every three years.

Every Investigator at TTUHSC El Paso can access a current copy of the AWA and related regulations (included in the TTUHSC El Paso Investigators' Manual for the Care and Use of Animals in Research). In addition, a current copy of the AWA and related regulations are accessible to everyone who works with animals through the APHIS Animal Care Publications website at <https://www.aphis.usda.gov/aphis/resources/lawsandregs>.

1.4.2 Office of Laboratory Animal Welfare at the National Institutes of Health

The *PHS Policy* was created to implement the provisions of the Health Research Extension Act of 1985. The Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) administers the policy. The policy applies to institutions conducting PHS-supported projects involving live vertebrate animals.

The *PHS Policy* requires that such institutions establish an IACUC. In accordance with the policy, the IACUC, using *The Guide*, is responsible for reviewing the use of animals and conducting semiannual assessments of TTUHSC El Paso IACUC Policies and Procedures, including inspections of all animal study areas and facilities.

TTUHSC El Paso is required to file an Animal Welfare Assurance of Compliance Statement (Assurance) every five years with OLAW, providing written documentation of the institution's commitment to animal welfare and detailed information on the TTUHSC El Paso IACUC Policies and Procedures. The Assurance commits TTUHSC El Paso to compliance not only with the *PHS Policy* and *The Guide*, but also with the AWA.

At least once every 12 months, the IACUC, through the IO, shall submit a written report, to include any minority views, to OLAW. The report shall include the following:

- Changes to TTUHSC El Paso's program or facilities that would place it in a different category than specified in our Assurance;
- Changes in the IACUC membership;
- Changes in the description of the TTUHSC El Paso IACUC Policies and Procedures for animal care and use programs as outlined in the Assurance;
- Dates that the IACUC conducted its semiannual evaluations and submitted its reports to the Institutional Official.

If there are no changes, the report shall state that there are no changes and shall inform OLAW of the dates of the semiannual evaluations and submission of semiannual reports to the Institutional Official.

Failure to comply with the *PHS Policy* and/or *The Guide* may lead to various actions, including the termination of PHS funding for all projects at TTUHSC El Paso involving the use of animals.

TTUHSC El Paso has an approved, signed PHS Assurance (D19-01056) filed with the Office of Laboratory Animal Welfare (OLAW). This is TTUHSC El Paso's assurance of compliance that all research involving animals will be conducted in accordance with the policy on Humane Care and Use of Laboratory Animals.

A current copy of the *PHS Policy* and *The Guide* are accessible to everyone who works with animals, from the website at

<https://el Paso.ttuhs.edu/research/committees/iacuc/resources.aspx>.

1.4.3 Institutional Authority

The VPR is the TTUHSC El Paso Institutional Official (IO) with overall responsibility for the TTUHSC El Paso IACUC. Components of the IACUC have been described previously in this document. Additional references include [TTUHSC EP OP 73.03](#), PHS

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Assurance (D19-01056), the [ORR](#), and the TTUHSC El Paso Research Compliance Program.

The VPR/IO responsibilities include but are not limited to, the following areas:

- Ensuring compliance with applicable laws and policies previously identified.
- Appointing IACUC members, in consultation with the administrative staff of the IACUC.
- Develop in consultation with the IACUC and the Institutional Veterinarian, administrative policies and procedures for review and possible adoption by the President, which are necessary to implement this policy.
- Implement this policy with the assistance of the President, the LARC, and the IACUC.
- Serving as the point of contact for correspondence to OLAW, the USDA and other agencies as applicable, including reports to federal agencies.
- Reporting to the appropriate federal governmental and TTUHSC El Paso officials any serious or continuing noncompliance with the laws and policies identified previously and any corrective action taken.
- Subjecting protocols that have been approved by the IACUC to further review and approval, but may not approve an activity that has not been approved by the IACUC.
- Serving as signatory authority for the PHS Assurance.
- Committing TTUHSC El Paso to meet the requirements of PHS policy and the Animal Welfare Act.
- Ensuring that all personnel involved in animal care, treatment, and use are qualified to perform their duties and that adequate training and instruction in specific areas are provided to those personnel.
- Ensuring that training and instruction are made available and that the qualifications of personnel are reviewed with sufficient frequency to fulfill the TTUHSCEP research facility's responsibilities.
- Ensuring that the institution has an attending veterinarian who provides adequate veterinary care to its animals in compliance with federal and state laws, policies and guidelines.
- Suspending or terminating the IACUC membership of any individual for whom it has been determined that membership obligations or responsibilities are not being fulfilled.
- Appointing the IACUC Chair and Vice-Chair.
- Suspending or terminating the appointment of any Chair or Vice-Chair for whom it has been determined that leadership obligations or responsibilities are not being fulfilled.
- Managing and administering funds.
- Ensuring that adequate personnel, space, and other resources are allocated to the IACUC.
- Conducting periodic review of IACUC funds and staffing levels.

- Reviewing and signing Memoranda of Understanding and cooperative agreements between TTUHSC El Paso and other organizations, including those that establish reliance on the TTUHSC El Paso IACUC of record for collaborative research.
- Ensuring that the IACUC functions independently and that the Chair and Members have direct access to the IO if they experience undue influence or if they have concerns about the function of the IACUC.

The VPR/IO has access to the Internet Medical Research Informational Systems (iRIS) program, which contains all documents, correspondence, and deliberations regarding each project reviewed by the TTUHSC El Paso IACUC. This access permits review of all activities of the TTUHSC El Paso IACUC as well all documents submitted. However, the VPR is not permitted to be involved in the day-to-day operations of the IACUC.

Day-to-day operation of the TTUHSC El Paso IACUC is delegated to staff members in the TTUHSC El Paso ORR, specifically the administrative staff of the IACUC, who are assigned to oversee the various components of the TTUHSC El Paso IACUC.

1.4.4 Limitation on Institutional Authority

All animal research conducted by TTUHSC El Paso must be approved by an IACUC. Specifics regarding obtaining IACUC approval can be found in this TTUHSC El Paso IACUC Manual. Research that has been reviewed and approved by a TTUHSC El Paso IACUC may be subject to further review and disapproval by other review bodies or officials (including the VPR); however, no person or group may override the IACUC's disapproval determination and approve research that had been previously disapproved by the IACUC.

1.4.5 IACUC Authority

The TTUHSC El Paso IACUC is an autonomous administrative body that has the authority to approve, disapprove, or require modifications to research activities involving animals. The IACUC also has the authority to require continuing reviews of previously approved research, and to observe or appoint a designee to observe any aspect of the research, inspect research facilities, obtain records and other relevant information relating to the use of animal in research, and take such actions that are in its judgment necessary to ensure compliance with the federal and state regulations, other applicable federal and state laws, TTUHSC El Paso policies, and IACUC procedures established hereunder. This includes authority to suspend or terminate approval of the research if the IACUC determines that there has been serious or continuing noncompliance with any federal regulation or with the requirements or determinations of the IACUC.

The Chair or authorized designee of the TTUHSC El Paso IACUC shall have signatory power for review and actions taken by each local IACUC. Electronic documents found in iRIS--including all finalized IACUC minutes, stamped documents, documents referenced in electronic letters, and official correspondence --have the full approval of the IACUC Chair/designee and have the authority of signed documents. Handwritten signatures of the IACUC Chair/designee are not required under this policy.

1.4.6 State Authority

Compliance with these procedures will not render inapplicable pertinent laws of the State of Texas, any local law, which may bear upon the proposed activity, the [TTUHSC EP policies](#) or [TTU System Regents' Rules](#). In the case of conflicting federal law, state law and institutional policies, federal law will override state laws or institutional policies

and state laws will override institutional policies. The [TTU System Office of General Counsel](#) provides the IACUC and other components of the IACUC with counsel on an as needed basis, primarily on matters related to state laws, cooperative agreements, conflicts of interest, and contractual issues on research involving animals.

1.5 Protection from Undue Influence

IACUC chairs, IACUC members, and IACUC administrative staff who are involved in the IACUC have numerous interactions with investigators and others in the performance of their assigned roles. TTUHSC El Paso will investigate and resolve any reported attempt to inappropriately pressure an IACUC member or other representative of the TTUHSC El Paso IACUC through undue influence. Undue influence includes interference with the normal functioning or decision-making of a TTUHSC El Paso IACUC representative outside of established processes in order to obtain a favorable outcome.

Any attempt to exercise undue influence over an IACUC Chair, member or IACUC administrative staff member should be reported and investigated as follows:

An IACUC Chair, IACUC member, or IACUC administrative staff member who experiences undue influence should report the occurrence to the Managing Director of ORR who will attempt to mediate or resolve the concern in consultation with the VPR, and/or Research Compliance Officer.

Alternatively, the person(s) experiencing undue influence may report directly to the VPR, acting as the IO.

Any individual who believes that undue influence is being exerted by an official in the above reporting chain, or who believes that the undue influence has not been appropriately or timely resolved, should report to the next higher level in the reporting chain, and ultimately to the Institutional Compliance Office, Human Resources, or the Office of General Counsel.

1.6 Institutional Conflict of Interest

As it relates to research with animals, institutional conflict of interest refers to a situation in which licensing, technology transfer, patents or investments of--or gifts to--Texas Tech University Health Sciences Center El Paso OR the financial interests of TTUHSC El Paso senior administrators (Deans, Vice Presidents or President) might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review or oversight of animal research.

Financial and other interests of senior administrators will be disclosed and reviewed according to processes outlined in [TTUHSC EP OP 10.05 Conflict of Interest and Commitment Policy](#) and TTU System Regents' Rules Other potential sources of institutional conflict of interest (gifts, institutional licensing agreements, etc.) which are not related to a particular individual will be reported to the institution's Conflict of Interest/Commitment Committee (COICC) for review. Representatives from the Office of Research, Office of General Counsel, Purchasing, Development Office, or Office of Research Commercialization are most likely to have knowledge of these institutional level conflicts.

The TTUS Chief Financial Officer will have primary responsibility for reviewing the financial disclosures of TTUHS senior administrators. Any potential conflicts of interest will be referred to the Office of General Counsel as indicated in [TTUHSC EP OP 10.05](#). The COICC will have primary responsibility for reviewing disclosures involving gifts to the institution. Potential institutional conflicts that involve research, including research with animals, will be forwarded by the Office of General Counsel or the COICC for review by the

Conflict of Interest in Research Committee (COIRC) as described in TTUHSC EP OP 73.09 Financial Conflicts of Interest in Research. If the COIRC determines that there is little potential risk to the institution, this information will be documented and shared with the IACUC Chair(s) and Administrator(s) for notification to the IACUC members. If the COIRC determines that there is potential for reputational or other risk to the institution, a plan to manage, reduce, or eliminate the conflict will be developed as described in HSCEP OP 73.09.

1.7 Confidential Medical Committee

The IACUC is a committee of TTUHSC El Paso established for the purpose of carrying out requirements governing research involving animals under federal law and TTUHSC El Paso policies and procedures. The IACUC is a “medical committee” as defined under [Texas Health & Safety Code Chapter Section 161](#), and/or other applicable state and federal statutes. All documents generated by, submitted to, or for the purposes of fulfilling IACUC committee duties are confidential and privileged as “medical committee documents.”

1.8 IACUC Relation to Other Entities

1.8.1 Other TTUHSC El Paso Compliance Committees

The TTUHSC El Paso IACUC functions independently of, but in coordination with other TTUHSC El Paso research committees, including but not limited to:

- [Conflict of Interest Research Committee](#) (COIRC)
- [Institutional Biosafety Committee](#) (IBC)
- [Institutional Review Board \(IRB\)](#)
- [Radiation Safety Committee](#) (RSC)

The IACUC may request that approval be obtained from any of these committees or additional committees prior to TTUHSC El Paso IACUC approval. For more detailed information refer to [TTUHSC EP OP 73.14, Research Compliance](#).

1.8.2 Affiliated Entities

The TTUHSC El Paso IACUC may work cooperatively with the IACUC of other institutions in projects involving multiple sites and/or investigators. The Committee may also agree to function as the IACUC of record (reviewing IACUC) for another institution or to rely on an IACUC from another institution (relying IACUC) when involved in collaborative research. Such agreements will require written contracts through the Office of Sponsored Programs. Templates for contractual agreements between TTUHSC El Paso and other institutions can be obtained through the Managing Director of the TTUHSC El Paso ORR.

Institutions for which the TTUHSC El Paso IACUC is the IACUC of record may reserve the regulatory right to exercise institutional disapproval of research the Committee has approved, but may not approve research that has been disapproved by a TTUHSC El Paso IACUC serving as the IACUC of record.

TTUHSC EP currently has the following types of Agreements in place:

- TTUHSC EP IACUC serves as IACUC of record for a study

1.8.2.1 Cooperative Research Activities Involving Other Entities

When TTUHSC El Paso researchers conduct research at other institutions or are involved in multi-site research, IACUC review may be conducted in one of three ways: single (TTUHSC El Paso) IACUC review, delegation to an external IACUC, or separate review by each institution's designated IACUC. When single (TTUHSC El Paso) IACUC review or delegation to an external IACUC is involved, TTUHSC El Paso must enter into a formal written agreement to define the responsibilities of each entity. No research may begin until an agreement has been formally executed and the designated IACUC has approved the project.

In determining the need for establishing these formal agreements, the TTUHSC El Paso ORR will take into consideration the source of funding for the research activity(ies), federal and state regulations, specific sponsor regulations governing animal research protections and institutional policies.

Institutions which routinely permit collaborations with TTUHSC El Paso researchers may establish agreements with TTUHSC El Paso that allow a single IACUC to review and provide continuing oversight of animal research covered by a single institution's assurance. These agreements define the parameters for single IACUC review, including the conditions under which the review will be considered, each institution's responsibilities and financial commitments. TTUHSC El Paso will enter into agreements with designated reviewing IACUCs as necessary in order to comply with any applicable regulatory requirements.

Collaborative research for which no formal agreement has been executed require review and approval by each institutions IACUC before the research may begin.

Research where the TTUHSC El Paso IACUC is delegating review to an external IACUC, will still require submission through iRIS, for a facilitated review and for documentation purposes.

1.9 **Developing and Maintaining Animal Research Program Policies and Procedures**

ORR staff, including IACUC administrative staff, with input from the IO, IACUC Chairs, IACUC members and research staff have developed written policies and procedures governing the conduct and review of animal research in compliance with federal and state regulations, Texas law, TTUHSC EP Operating Policies, and standards of regulatory, accreditation, and funding agencies that apply to research conducted under the auspices of the TTUHSC El Paso animal research program.

This **TTUHSC El Paso IACUC Program Manual** presents the most current information for reference by IACUC Chairs, IACUC members, IACUC administrative staff, principal investigators (PIs) and research staff. It is not meant to be a static document. The Managing Director of ORR will keep the research community apprised of new information that may affect the TTUHSC El Paso IACUC including laws, regulations, guidance documents, policies, procedures and emerging ethical and scientific issues. The updated information will be included on the TTUHSC El Paso Research website and incorporated, as needed into the **TTUHSC El Paso IACUC Program Manual**. Changes that directly or immediately affect the investigators will be posted as an announcement in iRIS and may also be sent as an email to those involved with research involving animals at TTUHSC El Paso.

The Managing Director of ORR and the Sr. Director will maintain the **TTUHSC El Paso IACUC Program Manual**. When portions of the manual are revised, the Managing Director

of ORR will maintain a historical archive of all previous versions. The entire manual will be reviewed at least once every odd-numbered year by the Managing Director of ORR and the Sr. Director. If no changes are required, the Managing Director of ORR will make and file note to that effect.

CHAPTER 2 INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE STRUCTURE AND FUNCTION

2.1 Organization of the IACUC

2.1.1 There is one registered TTUHSC El Paso IACUC.

IACUC Assurance # D19-01056.

The IACUC may also be referred to as the “local IACUC”.

2.2 IACUC Scope

The TTUHSC El Paso IACUC is responsible for reviewing research that involves animals when TTUHSC El Paso is engaged in the research. Generally, research conducted by TTUHSC El Paso faculty, using TTUHSC El Paso facilities, or research where TTUHSC El Paso receives funds to conduct the research must be reviewed and approved by a TTUHSC El Paso IACUC prior to beginning any research activities.

TTUHSC El Paso also has/may obtain written affiliation agreements with other institutions. Each of those written agreements will spell out the conditions under which TTUHSC El Paso IACUC review and approval is required prior to commencement of the research. Throughout this document, the TTUHSC IACUC policies and processes apply to those affiliated entities when TTUHSC El Paso serves as the IACUC of record.

2.2.1 Research conducted by students/residents with IACUC approval from another institution

In certain cases, TTUHSC El Paso students or residents who are engaging in research projects which have been reviewed and approved by another institution’s IACUC may not require separate review by a TTUHSC El Paso IACUC.

TTUHSC El Paso will not generally require a separate review of a study protocol in which a TTUHSC El Paso student or resident is involved if ALL of the following conditions are met.

- The research is being conducted at an institution with a PHS Assurance.
- All research activity will occur at the other site.
- No research activity will be taking place at TTUHSC El Paso or at an institution affiliated with a TTUHSC El Paso IACUC.
- A PI from the other institution will be responsible for oversight of the project.
- The student/resident is listed as research personnel on the IACUC-approved protocol at the research site.
- TTUHSC El Paso is not the recipient of funding for the research project.

If any of the conditions above are not met, the project will require review and approval by a TTUHSC El Paso IACUC as well as the other institution’s IACUC prior to the student/resident’s involvement in the project.

If all of the conditions are met, the student/resident involved in the project will be responsible for providing a copy of the IACUC approval letter to the TTUHSC El Paso Office of Student Affairs, prior to participation in the project. TTUHSC El Paso reserves the right to limit, suspend or terminate the involvement of TTUHSC El Paso students or residents in studies approved by another institution's IACUC.

2.3 IACUC Responsibilities

The IACUC has general oversight responsibility for TTUHSC EP IACUC Policies and Procedures. Specific responsibilities of the IACUC include the following:

Review of Animal Use:

- Review and approve, require modifications or withhold approval of all new Applications or revisions to existing protocols involving animals;
- Conduct continuing reviews of approved protocols, not less than annually;
- Conduct de novo review (similar to an initial review) of all active protocols at least once every three years;
- Review all animal incident reports and determine whether any additional action is necessary.

Inspection and Review of Animal Facility Standard Operating Procedures:

- Recommend procedures to be followed for the proper care and humane treatment of animals and review them every six months using Title 9 CFR (USDA) and The Guide (OLAW) as a basis of review, providing a written report to the Institutional Official;
- Inspect every six months all of TTUHSC EP's animal facilities using Title 9 CFR and The Guide as a basis of inspection, providing a written report to the Institutional Official;
- Provide recommendations to the Institutional Official regarding any aspect of the animal program, facilities or personnel training.

Compliance Activities:

- Review and investigate noncompliance with the TTUHSC El Paso's IACUC Policies and Procedures, applicable regulations, PHS Policy or The Guide.
- Suspend any activity that is not in compliance with the PHS Policy and The Guide, the USDA regulations, or IACUC guidelines.

Record Keeping:

- Maintain records of IACUC activities as required by regulation or the PHS Policy.

Community Relations:

- Serve as the liaison between the University and the community for matters involving animal research and welfare.

2.4 Attending Veterinarian

The TTUHSC El Paso Attending Veterinarian serves on the IACUC as a voting member and has delegated authority and responsibility to implement the PHS Policy and recommendations of The Guide and the AWA.

The Attending Veterinarian routinely inspects the animal facilities and all animals at TTUHSC El Paso. The Attending Veterinarian is available to make recommendations

concerning preventive health programs for animals, disease treatment, analgesia, anesthesia, post-operative recovery, euthanasia, general animal welfare and technical training. The Attending Veterinarian provides on-call emergency care and consultation for TTUHSC El Paso's animals. The Attending Veterinarian has the authority to immediately suspend any protocol if animal welfare is endangered.

Responsibilities:

- The Attending Veterinarian (or a qualified designee) must be consulted regarding proposed procedures that may cause more than momentary pain or distress (such as surgery, infectious or inflammatory disease models, and food or water restriction).
- The Attending Veterinarian must ensure an adequate system of health records. Note: The USDA requires health records be kept for all animals that are members of covered species.
- The Attending Veterinarian must decide when necropsies (autopsies) of animals should be performed to investigate health problems in the organization.
- When dogs must be exercised, the Attending Veterinarian must determine the frequency, method, and duration of exercise in consultation with and approval by the IACUC.
- The Attending Veterinarian must direct the required environmental enrichment plan for non-human primates.
- The training of the LARC staff.
- Classes are held on a regular basis for all animal caretakers. "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.
- The training programs employed are those made available to laboratory animal care technicians by the American Association for Laboratory Animal Science.
- The AALAS technician certification program is administered by the Attending Veterinarian.

2.5 IACUC Membership

The IACUC at this Institution is properly appointed according to 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.

2.5.1 Composition of IACUC Committee

The membership requirements of the IACUC will be consistent with the requirements indicated in PHS policy IV.A.3.b. The IACUC shall be comprised of at least five members. The IACUC must include at least one Chairperson, Doctor of Veterinary Medicine, one practicing scientist experienced in research involving animals, one member whose primary concerns are in a non-scientific area, and one member who is unaffiliated with TTUHSC El Paso. A single member may fulfill more than one of these characteristics, if requirements are met.

2.5.1.1 Chair

The chairperson will be selected from the faculty and will have experience or familiarity with animal research and animal research regulations, a working knowledge of parliamentary process to conduct IACUC business fairly and efficiently,

maturity and group leadership skills to keep deliberations focused while ensuring all IACUC members participate, and some organizational authority in order to perform duties without concern that IACUC actions may jeopardize the IACUC Chair's position or career.

2.5.1.2 **Vice-Chair**

The IACUC can appoint one person from among its members as Vice Chair. The Vice Chair serves as the IACUC Chair in the temporary absence of the Chair or when the Chair has a conflict of interest with an IACUC review or other activity. The IACUC may, from time to time, consult with other professionals e.g., legal counsel, consultants, in fulfilling its responsibilities.

2.5.1.3 **Veterinarian**

Have a Doctor of Veterinary Medicine degree, be certified by ACLAM or equivalent, have direct or delegated authority for activities involving animals in organization.

2.5.1.4 **Scientific Member**

This member is a person with experience in research involving animals.

2.5.1.5 **Non-Scientific Member**

This member, sometimes termed the lay member, is a person whose primary interests are in non-scientific areas (i.e., ethicist, lawyer, member of the clergy). PHS Policy IV.A.3. states that the nonscientific member should "have a naïve attitude with regard to science and scientific activities."

2.5.1.6 **Unaffiliated Member**

Consistent with the PHS Assurance IACUC member registration guidelines, unaffiliated members may not be employees of TTUHSC El Paso or immediate family members of TTUHSC El Paso employees because TTUHSC El Paso is the organization operating the IACUC. Unaffiliated members represent community interests in the proper care and use of animals and should not be a laboratory animal user (church leader, science or biology teacher, local veterinarian, professor of ethics, business person, etc.).

2.5.1.7 **Alternate**

It is permissible to appoint alternate members to fulfill the role of a member who must be absent for a meeting or a specified period of time. The alternate must fill the same role as the member for whom he/she is substituting (i.e. non-scientist, scientist, community member), but the alternate should vote according to his or her own conscience, not based on how the absent member would have voted.

2.5.1.8 **Diversity**

Consideration must be given to the inclusion of members with diverse backgrounds including experience, gender, professions and ethnic backgrounds. A TTUHSC El Paso IACUC that serves as the IACUC of record for non-TTUHSC El Paso entities may appoint at least one member from each affiliate.

2.5.1.9 **Consultants**

If an IACUC is reviewing a protocol that is outside the level of expertise of IACUC members, an expert consultant may be requested to assess the protocol and present findings, written and/or orally to the IACUC. Generally, the need for a consultant to

assist with a review of a protocol will be triggered by the IACUC member originally assigned to review the protocol. Any member who does not believe him/herself to have adequate knowledge or expertise to conduct an adequate review of an assigned protocol should contact the IACUC Administrative Staff and ask to have the review re-assigned to another (or additional) IACUC member or to an outside consultant. The decision to enlist a consultant for a given protocol will be discussed with the IACUC Chair to determine who could best serve in this capacity for a given protocol.

The consultant is not counted toward quorum and must leave the meeting during the final discussion and vote on the protocol. Consultants must sign a confidentiality agreement and disclose known or potential conflicts of interest prior to review. If a conflict of interest is disclosed, this will be presented to the IACUC members and documented in the minutes.

2.6 IACUC Management

2.6.1 Liability Coverage

IACUC members who act in the course and scope of their role and responsibility(ies) as an IACUC member in good faith without malice and in the reasonable belief that the action or recommendation is warranted by the facts known by that person have civil immunity pursuant to the Texas Tort Claims Act and Sections 160.010 of the Texas Occupations Code and 161.033 of the Texas Health & Safety Code.

2.6.2 IACUC Staff Education

2.6.2.1 Initial Education

Listed below are the web-based courses that are currently REQUIRED to be successfully completed by IACUC staff within the first week of employment. The courses are web-based and available through the Collaborative Institutional Training Initiative (CITI).

- Essentials for IACUC Members- this is the institutionally approved basic course for members.
- Working with the IACUC-this is an institutionally approved basic course.
- Conflict of Interest Course-this is the institutional approved basic course for training in financial conflicts of interest.
- Financial Disclosure-this is the research financial disclosure.

Additional education is conducted by the supervisor or designee during the first month of employment and continues as needed throughout the employee's tenure. In addition, due to the semi-annual inspection duties, IACUC staff must visit the Occupational Health and Safety Nurse for evaluation and clearance, every three years, with annual status updates, as applicable.

The information presented during the first month includes and is designed to provide education on the following topics:

- Use of the iMedris system (iRIS) for processing IACUC submissions;
- TTUHSC El Paso IACUC Policies and Procedures;
- Interaction between the IACUC administrative staff and the Committee;

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- Terms and regulations (OLAW, USDA, the Guide, etc.);
- Meeting basics (quorum, voting procedures, acceptable templates, etc.);

Information provided to new staff members during the first month of employment includes:

- The PHS Policy for the Humane Care and Use of Laboratory Animals.
- The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
- The ARENA/OLAW IACUC Guidebook;
- The AVMA Guidelines for Euthanasia;
- A copy of the Assurance;
- Local IACUC Member Roster and IACUC Administrative Staff Roster.

2.6.2.2 Continuing Education

IACUC staff are encouraged to participate in ongoing continuing education on the protection of animals. Engaging in any of the following is considered evidence of continuing education:

- Attending educational presentations as part of regularly scheduled IACUC meetings, including changes in Federal and State Regulations, IACUC processes, or forms;
- Reviewing relevant books, periodicals, or handouts furnished to IACUC members;
- Attending TTUHSC El Paso training seminars focusing on relevant topics;
- Attending webinars hosted by outside organizations such as The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or Public Responsibility in Medicine and Research (PRIM&R);
- Attending regional or national seminars or conferences which involve discussion of research ethics;
- Certification specific to their position (example: Certified IACUC Professional, etc.) is strongly encouraged.

Required Education: Listed below are the web-based courses that are currently REQUIRED to be successfully completed:

- CITI Essentials for IACUC Members- completed at least once every 3 years.
- CITI Conflict of Interest Course-completed at least once every 4 years.
- Financial Disclosure-completed at least once per year.

All required education is monitored on an on-going basis.

Evaluation of staff performance is an ongoing activity involving each staff member and their supervisor. Completion of training, educational activities and performance improvement is formally evaluated annually as part of the TTUHSC El Paso performance management program. The formal evaluation process includes a self-evaluation and further evaluation by both the direct supervisor and/or next-level

supervisor. Feedback is provided individually by the direct supervisor. Growth plans for the upcoming year will generally be agreed upon by the employee and direct supervisor.

2.6.3 IACUC Member Conflict of Interest

Neither the sponsor, the investigator, nor any individual involved in the design, conduct or reporting of the research activity under review will participate in the IACUC review or conclusions except to provide information. No IACUC member may participate in the IACUC's initial or continuing review of any project in which the member has a conflicting interest, either financial or non-financial, except to provide information requested by the Committee.

2.6.3.1 Definition

IACUC member conflict of interest exists when the member or immediate family (spouse, unmarried domestic partner or dependent children) have a significant interest that could directly and significantly affect or appear to affect the design, conduct or reporting of a project. Significant interests may be financial or non-financial. "Financial interests related to the research" mean financial interest in the sponsor, product, or service being tested. Examples of significant financial interests include a value of over \$5,000 associated with the sponsor or ownership interest in the company sponsoring the research. Examples of non-financial interest include a personal belief system that precludes objective review of a particular project or being a member of the research team.

2.6.3.2 Process

IACUC members are required to complete TTUHSC El Paso conflict of interest training and a financial disclosure form prior to the initial appointment and annually thereafter. A financial conflict of interest (FCOI) is defined in TTUHSC EP Operating Policy [73.09, Financial Conflicts of Interest in Research](#). TTUHSC El Paso's policy regarding non-financial conflicts of interest can be found here: [HSC OP 10.05, Conflict of Interest and Commitment Policy](#).

Financial and non-financial disclosures are reviewed by a representative from the COIRC and any conflicts are indicated in the training section of IRIS. IACUC staff are also notified. The IACUC staff maintain a record of any financial and non-financial disclosures made by IACUC members to preclude assignments for review of conflicted research.

Should an IACUC member receive an assignment and upon review, discover they have an undisclosed conflict or personal belief system that precludes them from providing an objective review of the submission, he/she must notify the IACUC staff regarding the conflict and disqualify themselves from conducting the review or participation in discussion of the submission except to provide information on request. This applies to all assignments and types of review (convened IACUC, designated review, etc.).

Conflicted IACUC members shall leave the meeting during the discussion and may not vote on the research in question. These members are not considered as contributing to the quorum for the discussion and vote on the conflicted research.

Further, the iMedRIS software system used by the TTUHSC El Paso IACUC does not permit any IACUC member who is listed as study personnel on a particular

project to access the IACUC review comments or meeting discussions for that project.

2.6.4 IACUC Member Education

2.6.4.1 Initial Education

New Member Orientation: New IACUC members are required to attend an orientation session prior to participating as a voting member on the IACUC. This session is conducted by the IACUC staff. Additionally, new members are encouraged to attend and observe a Committee meeting prior to beginning their appointment.

The orientation session is designed to provide education on the following topics:

- Responsibilities and obligations of IACUC members;
- Interaction between the member and the Committee;
- Effective meeting skills;
- Terms and regulations (OLAW, USDA, the Guide, etc.);
- Meeting basics (quorum, voting procedures, acceptable templates, etc.);
- Liability issues; and
- The use of the iRIS software system for reviewing IACUC submissions.

Information provided in electronic format to new IACUC members includes:

- The PHS Policy for the Humane Care and Use of Laboratory Animals;
- The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
- The ARENA/OLAW IACUC Guidebook;
- The AVMA Guidelines for Euthanasia;
- A copy of the Assurance;
- Local IACUC Member Roster and IACUC administrative staff Roster.

Required Education: All new IACUC members are required to provide a current copy of their curriculum vitae and successfully complete online courses prior to their appointment as a voting member of the IACUC. The courses are offered through the University of Miami's Collaborative Institutional Training Initiative (CITI) Program.

These include

- Essentials for IACUC Members- this is an institutionally approved basic course for members;
- Working with the IACUC-this is the institutional approved basic course.
- Conflict of Interest Course-this is the institutional approved basic course for training in financial conflicts of interest;
- Financial Disclosure-this is the research financial disclosure.

- Occupational Health and Safety-Due to semi-annual inspection duties, all members must visit the OHS Nurse for evaluation and clearance every three years, with annual status updates, as applicable.

Additional Training for:

- Committee Chairs and Vice-Chairs-Available online through CITI.
- Community Members-Available online through CITI.

All required education is monitored by the IACUC Administrative Staff on an ongoing basis.

2.6.4.2 Continuing Education

IACUC members are encouraged to participate in at least six (6) hours of continuing education annually on the protection of animals. Members will complete renewal training at least once every three years. The VPR will be kept aware of the continuing education opportunities made available to IACUC members during periodic meetings or emails from the IACUC Administrative Staff. Engaging in any of the following is considered evidence of continuing education.

- Attending educational presentations as part of regularly scheduled IACUC meetings, including changes in Federal and State Regulations, IACUC processes, or forms;
- Reviewing relevant books, periodicals, or handouts furnished to IACUC members;
- Attending TTUHSC El Paso training seminars focusing on relevant topics;
- Attending regional or national seminars or conferences that involve discussion of research ethics.

A stipend may be available to IACUC members to help defray costs of attending a regional/national meeting.

Required Education: The following are mandatory educational requirements for IACUC renewal training:

- Essentials for IACUC Members- completed at least once every 3 years;
- Conflict of Interest Course-completed at least once every 4 years;
- Financial Disclosure-completed at least once per year.
- Occupational Health and Safety-Due to semi-inspection duties, all IACUC staff must visit the OHS Nurse for evaluation and clearance every three years, with annual status updates, as applicable.

All required education is monitored by the IACUC staff on an on-going basis.

2.6.5 IACUC Chairperson and Vice-Chairperson

2.6.5.1 Appointment

The VPR, in collaboration with the Sr. Director and Managing Director of ORR, appoints the IACUC Chairperson and Vice-Chairperson for a two-year term. Generally, terms will begin on September 1 of each odd-numbered year. Committee needs will be assessed prior to the appointment, at which time a new chairperson will be appointed or the incumbent will be reappointed. However, the IACUC

Chairperson may be removed or reappointed at any time upon written notice by the VPR or designee.

At the time of appointment/reappointment the IACUC Chairperson and Vice-Chairperson will sign an agreement to serve, a confidentiality agreement and shall have an up to date disclosure of potential conflicts of interest on file.

2.6.5.2 Duties

The chairperson will conduct the IACUC's meetings. In the chairperson's absence the Vice-Chairperson will conduct the meeting. Another IACUC member may also be designated to run the meeting in the event that neither the chairperson nor vice-chairperson can be present. The chairperson and vice-chairperson are considered voting members of the IACUC committee for purposes of establishing the quorum.

The IACUC Chair or designee shall assign each submission requiring full committee review to at least one IACUC member as a primary reviewer and a nonscientific member as a secondary reviewer. The veterinarian will be assigned as a tertiary reviewer. Additional members may be assigned in additional roles. Efforts will be made to make assignments primarily on the basis of reviewer expertise and knowledge of the study population. Non-scientist members will not be assigned as primary reviewers on an initial review.

The chairperson and vice-chairperson have the responsibility to ensure the compliance of their IACUC with all applicable regulations, to manage the matters brought before the IACUC in accordance with applicable procedures and regulations, to provide leadership and offer guidance to all members of the committee to ensure they are fulfilling their roles, to foster a collaborative spirit and resolve issues in a respectful, collegial manner, and to monitor the quorum during the meeting.

Chairpersons and vice-chairpersons will be presented in the Committee roster.

The chairperson will ensure that the VPR and the Managing Director of ORR are notified of pertinent information to facilitate compliance with federal regulations and TTUHSC El Paso policy.

Pertinent information requiring prompt reporting to the VPR includes but is not limited to:

- Injuries, unexpected serious harm to animals or others, or any other unanticipated problem involving risks to animals or others arising from research;
- Any serious or continuing non-compliance with regulations or IACUC policies, procedures, and determinations;
- Any suspension/ termination of IACUC approval of research.

2.6.6 IACUC Members

2.6.6.1 Appointment

Any interested party may recommend new members, including self-referrals. The VPR, in collaboration with the Sr. Director and Managing Director of ORR, appoints the IACUC members for a two-year term. Generally, terms will begin on September 1 of each odd-numbered year. Committee needs will be assessed prior to the appointment, at which time new members will be appointed and/or incumbent members will be reappointed. However, any member may be removed or reappointed at any time upon written notice by the VPR or designee.

At the time of appointment/reappointment the IACUC members will sign an agreement to serve and a confidentiality agreement, and shall disclose any known or potential conflicts of interest.

2.6.6.2 Duties

The agenda, protocols, and other appropriate documents will be available for review for all members prior to regular meetings at which the member is scheduled to attend. Members should review the materials before each meeting, in order to participate fully in the review of each proposed project. Brief additional information may also be provided to attendees during the meeting. Committee members will hold protocols and supporting data in confidence.

The IACUC Chair or designee shall assign each submission requiring full committee review to at least one IACUC member as a primary reviewer and a nonscientific member as a secondary reviewer. The veterinarian will be assigned as a tertiary reviewer. Additional members may be assigned in additional roles. Efforts will be made to make assignments primarily on the basis of reviewer expertise and knowledge of the study population. Non-scientist members will not be assigned as primary reviewers on an initial review. The primary and secondary reviewers conduct an in-depth review of all materials and enter their comments into iRIS. The primary and secondary reviewers shall present an oral summary of the study and their recommendations regarding its disposition.

Primary and/or secondary reviewers are encouraged to contact PIs prior to the IACUC meeting with any questions they have so that these issues may be addressed in advance of the full committee meeting.

Any member may be asked by the chairperson, vice-chairperson or designee to preside over a particular IACUC meeting.

Any experienced IACUC member (has served as an IACUC member for more than 1 year) may be asked to serve as a designated reviewer. Specific duties of designated reviewers can be found under [Duties of the IACUC Member Conducting Designated Review](#).

2.6.6.3 Attendance

The importance of voting IACUC member attendance cannot be overstressed. Member absences may affect the quorum and therefore the ability to conduct business. Notification of an expected absence is required. Members absent more than 3 times in a fiscal year may be contacted by the IACUC administrative staff or IACUC Chairperson to confirm their commitment/ability to continue as an IACUC member.

2.6.7 IACUC Alternate Members

2.6.7.1 Appointment

Any IACUC member may recommend an alternate member who fulfills the same role(s) and has similar qualifications. Alternate member attendance satisfies the attendance requirement for the regularly appointed IACUC member. Self-referrals for alternate positions and other person's recommendations for alternates will also be considered.

The VPR in collaboration with the IACUC Sr. Director and Managing Director of ORR appoints the IACUC alternate members, generally for a two-year term beginning

September 1 of each odd-numbered year. Any alternate member may be removed or reappointed at any time upon written notice by the VPR or designee.

At the time of appointment/reappointment the alternate IACUC members will sign an agreement to serve and a confidentiality agreement, and shall have an up-to-date disclosure of potential conflicts of interest on file.

2.6.7.2 Duties

Alternates may vote in place of an absent or excused regular member.

Any experienced alternate IACUC member (has served as an IACUC member for more than 1 year or in an alternate position with prior IACUC experience) may be asked to serve as a designated reviewer.

2.6.7.3 Attendance

Alternates may attend all meetings; however, their votes are counted only in the absence of the regular member. Meeting minutes must indicate when an alternate member replaces the appointed member.

2.7 IACUC Meeting Minutes

The minutes of all IACUC meetings must be in sufficient detail to demonstrate the following:

- attendance at the meetings and presence of quorum;
- actions taken by the IACUC;
- each action will include separate deliberation;
- the vote on each of these actions including: (a) members present for the vote (located in the IACUC Voting section in iRIS for each submission), (b) the number of members voting for, (c) against, and (d) abstaining;
- the basis for requiring changes in or disapproving initial and continuing research; and
- summary discussion of controverted issues and their resolution.

The IACUC meeting minutes must also reflect the following as applicable:

- for initial and continuing reviews the approval period will be documented;
- alternate member replacement of regular/primary voting member;
- names of IACUC members who abstained from a vote with the reason for abstention; and
- names of IACUC members recused from a discussion/vote due to a conflict of interest.

TTUHSC El Paso IACUC meeting minutes are created through the iRIS system based on the information provided in written reviews of all IACUC submissions since the last convened meeting, as well as from documented discussion that takes place during a convened meeting of the IACUC. Meeting minutes will be distributed for review by the IACUC administrative staff prior to the next convened IACUC meeting. At each convened meeting, members will vote to approve the minutes from the previous review period. Documentation of approval of meeting minutes will be noted on the agenda and in the next review period's meeting minutes.

2.8 IACUC Record Keeping

2.8.1 File Composition

The IACUC files shall be maintained, either electronically or on paper, in a manner that reflects a complete history of all IACUC actions related to review and approval of a research study, including continuing reviews, amendments, and adverse event reports. IACUC files include all submissions to the IACUC, including all attachments to each submission. The submissions and attachments may include, but are not limited to:

- all submitted versions of the IACUC application;
- all submitted versions of the protocol;
- any scientific evaluations provided to the IACUC;
- progress reports;
- continuing review form describing research activities;
- requests to modify or amend the approved research project;
- reports of unexpected events, including protocol deviations, unanticipated problems involving risks to subjects or others, serious adverse events;
- all official study correspondence;
- reports of audit findings, including non-compliance;
- requests to close a study (termination report);
- notices or approval letters from other TTUHSC El Paso Compliance Committees (e.g., IBC, Radiation Safety Committee, etc.);

2.8.2 Record Retention

The IACUC shall retain IACUC paper files, as applicable, for three (3) years after the final closure date of the research study.

Electronic files are maintained in iRIS for a minimum of three (3) years after final closure date of the research study.

Both paper and electronic records will be maintained for after the final closure date of the research study even if the project is cancelled without activity.

2.8.3 Access to Records

The IACUC secures all paper and electronic IACUC records and limits access to the IACUC members, IACUC administrative staff, compliance officer(s), IO and other authorized affiliated institution and TTU System representatives, and officials of federal and state regulatory agencies including representatives from OLAW, USDA, PHS, and AAALAC. IACUC records are accessible for inspection and copying by these representatives at reasonable times and in a reasonable manner.

IACUC administrative staff may grant other TTUHSC El Paso/TTUS personnel access to necessary records on an as-needed basis for official business. Investigators or their authorized study personnel have reasonable access to files related to their research activities. Access to IACUC files is limited to those who have legitimate need for them, as determined by the IACUC administrative staff, the Sr. Director, the Managing Director of ORR, or IO.

2.9 IACUC Submission Process

2.9.1 Submission Mechanism

All information relative to animal research projects must be submitted using the proprietary software program, Internet Medical Research Informational Systems (iRIS). Assigned privileges within iRIS provide all IACUC members access to all study documents for all studies submitted for review at the local IACUC unless a particular IACUC member is included as study personnel on the project. In those cases, the conflicted IACUC member may not access the IACUC review or deliberation on the study.

Materials for convened meeting of the IACUC must be received by the established deadline (see [IACUC Submission Deadlines](#)).

Information is communicated between the IACUC and investigators via iRIS. All correspondence generated by IACUC administrative staff and iRIS, and sent to research personnel is considered official and does not require the handwritten signature of an IACUC Chairperson or designee.

2.9.2 Documents

The following documents, as applicable to the study and type of submission, must be submitted through iRIS for IACUC review:

- completed electronic IACUC study application form;
- completed iRIS submission form relevant to the type of submission (i.e., Initial Review form; Annual Status Report form; Amendment form; Adverse Event form, etc.);
- full protocol;
- If a TTUHSC El Paso PI is one of the primary investigators for a multisite study, documentation regarding communication between all site IACUCs (for example: unanticipated problems, amendments, etc.);
- documentation of review/approval by required TTUHSC El Paso compliance committees (example: Institutional Biosafety Committee, Conflict of Interest in Research Committee, etc.);
- CV of Investigators and/or others as requested;
- other materials necessary to allow the IACUC to effectively review the proposal.

2.9.3 Attending Veterinarian Pre-Review

The Institutional Veterinarian is a helpful resource for investigators who are preparing protocols. The IACUC strongly recommends contacting the AV early in the process of preparing applications, renewals, or amendments to provide advice on the appropriate and optimal species-specific uses of procedures, anesthesia, analgesia, and euthanasia.

2.9.4 Scientific Review of Proposed Research

In order to approve research, the IACUC must determine that risks to animals are minimized by using procedures that are consistent with sound scientific design. The IACUC may utilize any of several alternatives for ensuring that sound scientific design. All initial reviews may be reviewed and approved by a Departmental Signatory Authority

prior to submission for IACUC review as noted [here](#). The Departmental Signatory Authority may review the proposal and attest that it is consistent with TTUHSC El Paso's research mission, is based on sound scientific principles and that the study design is adequate to address the proposed research question. At the discretion of the IACUC, scientific review beyond the attestation of the signatory authority *may* be required.

The following types of protocols will generally be considered to have received a scientific review prior to IACUC submission and will not require a scientific review by the IACUC, though the IACUC retains the discretion to request clarification or changes to the research design prior to approving the research:

- Grant-funded projects which have received full peer review (e.g., review by a study section or grant committee);
- Multi-site clinical trials;
- Internally sponsored (investigator-initiated) research which is submitted through a School/ Department which provides documentation of a formal scientific review process.

Studies for which no scientific review outside of the Signatory Authority's signature has taken place will receive a scientific review by the primary reviewer and/or IACUC Chairperson or designee as part of the initial review process. The scientific review will address the following issues:

- Are the Specific Aims and hypotheses clearly stated?
- Are the outcomes clearly stated and defined?
- Has a literature search supporting study rationale been conducted?
- Will testing the hypothesis provide important knowledge for the field?
- Is the study design appropriate?
- Will the proposed tests/measurements address the hypotheses?
- Are the validity/reliability of measures established?
- Are all of the proposed tests/measurements required/related to at least one proposed outcome?
- Are the proposed statistical methods clearly stated/correlate with study design?
- Is the proposed sample size adequately justified?
- Is the PI appropriately qualified, knowledgeable and experienced to perform the procedures?

If the IACUC does not feel that they have adequate knowledge to conduct a scientific review, a consultant with the appropriate knowledge may be asked to perform the scientific review, or an *ad hoc* committee may be formed to conduct the scientific review. Further IACUC review of the project will be [Tabled/Deferred](#) until the scientific review has been conducted. The VPR and/or IACUC Chairperson will determine an appropriate consultant or committee member(s) to conduct the scientific review.

2.9.5 Principal Investigator (PI) Sign-off

Initial and continuing review submissions must be signed by the PI electronically in iRIS prior to the IACUC receiving the submission. In signing the submissions, the PI is

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indicating that s/he has reviewed the information in the submission. Prior to submitting an initial review, the signature of the PI indicates an understanding and agreement with the following:

- PI will comply with the regulations of the TTUHSC EP, USDA and OLAW for the protection of animals with respect to the conduct of this study;
- the experiments do not, to the best of the PI's knowledge, unnecessarily duplicate any previous experiments as required by the Code of Federal Regulations, Chapter. 9, Part 24;
- the proposed research project will be conducted by the PI or under his/her close supervision at the location(s) designated in the protocol;
- the proposed research project will be conducted in accordance with the protocol submitted to and approved by the IACUC;
- changes or modifications in the research project during the period for which IACUC approval has been granted shall not be initiated without prior IACUC review and approval;
- PI agrees to accept responsibility for providing all laboratory personnel (including students and volunteers) who will work with the live animals on this study with appropriate training in proper laboratory practices and techniques; PI also assures that personnel who will work with live animals on this study will complete the TTUHSC EP IACUC training requirements prior to working with any animal;
- personnel who will work with live animals on this study will be enrolled in the Occupational Health and Safety Program prior to working with any animal;
- a copy of the approved protocol application will be provided to all research personnel involved in the study.
- PI will report progress of approved research project to the IACUC, as often as requested.
- PI will notify the IACUC upon completion of the research project and submit a final report.
- PI will abide by all institutional rules regarding purchase and transfer of animals.
- PI understands that the TTUHSC EP IACUC has the authority to monitor this research project for compliance with federal regulations and TTUHSC EP policies. The TTUHSC EP Office of Research Resources has the authority to conduct compliance monitoring on behalf of the TTUHSC EP IACUC and TTUHSC EP. PI agree to make all research records available for review or audit upon request of the IACUC, Office of Research Resources or other authorized TTUHSC EP or TTU System officials.
- PI understand that the TTUHSC EP IACUC has the authority to suspend/terminate approval of this research project if it is not being conducted in accordance with the approved protocol, TTUHSC EP policies, or federal regulations. The IACUC is required to report any decisions to suspend or terminate the research project, as well as any unanticipated problems involving risks to animals or others to the Vice President for Research. Notification of other TTUHSC EP administrators, and outside agencies (such as USDA and OLAW) may also be required.

- Significant financial interests have been reported and financial conflicts have been managed as required by regulations and internal policies;
- PI understand that grant funds, equipment, and research records (including data/specimens) are the property of TTUHSC El Paso and shall not be transferred to another institution upon leaving TTUHSC El Paso, whether or not moving to another institution, without prior approval of the VPR.
- Before approval or during the course of conduct of any project, the IACUC may ask for verification from the PI that any of these requirements is, in fact, being met.

Routine audits of ongoing research may be conducted in order to assess compliance with these and other requirements. See the [Research Compliance](#) section of this manual for more information.

2.9.6 Department Signatory Sign-off

In addition to the Principal Investigator, a Departmental designated authority may be required to electronically sign an initial review prior to the IACUC receiving the submission. In providing an electronic signature, the designated authority is attesting that:

- the project is based on sound scientific principles and the study design is adequate to address the proposed research question(s);
- the project's goals are consistent with TTUHSC El Paso's research mission;
- the PI is qualified to conduct the research project;
- there is adequate time for the researchers to conduct and complete the research;
- an adequate number of qualified staff are available;
- adequate facilities to conduct the research will be provided;
- grant funds, equipment, and research records (including data/specimens) are the property of TTUHSC El Paso and shall not be transferred to another institution upon the PI leaving TTUHSC El Paso, whether or not moving to another institution, without prior approval of the VPR.
- The IACUC may request documentation from the Department Signatory authority regarding review and approval of any of these requirements.

In cases where the PI is the department chair/dean, sign off by the President or designated alternate will be required. If the department chair/dean is related to the PI, sign off by a designated alternate will be required.

2.9.7 Submission Screening

IACUC administrative staff will prescreen all IACUC submissions. If the submission is incomplete or otherwise not fully prepared for review, it will be returned to the PI for completion. When the submission is adequately prepared and resubmitted, it will be assigned to an IACUC member or members for review.

2.9.8 Agenda

The IACUC agenda consists of all IACUC submissions that have been prescreened by IACUC administrative staff, and acknowledged or assigned for review. IACUC staff, in

consultation with the IACUC Chair as necessary, make assignments based on an initial assessment of whether the submission requires full committee review. Because reviews of submissions that are to be acknowledged or that may receive designated review take place on a continual basis, the agenda is an evolving document until finalized at the time of the convened meeting.

New and existing studies are assigned to the agenda by IACUC administrative staff.

The agenda serves as the working document to inform IACUC members of all submissions that have been acknowledged or have received designated member review (DMR) since the last convened meeting of the IACUC. The agenda provides an up-to-date reference of the review status of each submission.

2.9.9 Notifications to Investigators

All IACUC decisions are communicated to the PI and designated research team members via the iRIS system. This includes but is not limited to approval, disapproval, clarifications, or modifications to secure approval. Generally, IACUC decisions will be communicated within three business days of the IACUC's determination.

For multisite research studies, the TTUHSC EP PI and research team members will be responsible for communicating all IACUC decisions to and from other sites.

2.10 IACUC Actions

2.10.1 Approval

In conducting the review of proposed research, each IACUC must obtain information in sufficient detail to make the determinations required under federal and state regulations and institutional policies. This review may be conducted through designated review if requested by the PI for projects that meet regulatory criteria or subsequent to full committee review.

2.10.1.1 Approval Requirements

The IACUC must determine that the following requirements are satisfied before it approves a proposed research project. These requirements are delineated by the Animal Welfare Act, the Guide, and the Institution's Assurance.

- Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design;
- 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;
- 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;
- 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;

- Medical care for animals will be available and provided as necessary by a qualified veterinarian;
- Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;
- Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

2.10.1.2 **Determination of review cycle**

IACUC review cycles are every 12 months with a full renewal at 3 years.

2.10.1.3 **IACUC Approval and Expiration Dates**

Approval date-If IACUC approval is required, the approval date is the date all approval requirements have been met and the PI is formally notified in writing that the project has received IACUC approval. No research may be conducted prior to the approval date(s) or after the expiration date(s) for ongoing research.

Expiration date-The expiration date for research required to be approved at a convened meeting is determined by the date of the convened meeting, or by the date of approval if referred for DMR. For example, a research project may require minor modification prior to formal approval and is assigned for final review through DMR. The date of approval will be assigned when the minor modification has been adequately addressed.

The expiration date is assigned at the time of recommendation to approve the research by either DMR or at a convened meeting. The research always expires one day less than the assigned review interval. For example, research project approved for annual review on 01/27/2021 will expire on 01/26/2022. Research activities are allowed to take place on 01/26/2022 (the day of expiration).

2.10.2 **Modifications required to secure approval (Additional Information Required)**

The IACUC (for research reviewed at a convened meeting) or experienced IACUC member (for research reviewed by DMR) may request additional information prior to approval of a submission in order to make all of the determinations required for approval.

The IACUC/experienced IACUC member may request clarifications, protocol modifications, or other supporting documentation. In iRIS, these requests are titled "Stipulations." Stipulations must be satisfactorily addressed before approval is effective.

The IACUC will classify modifications of submissions requiring review at a convened meeting as minor (a change that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study), or as significant. Investigator response(s) to minor modifications may be reviewed by IACUC Administrative personnel if approved by DMR or by unanimous vote at a committee meeting. Significant modifications are considered substantive and must be reviewed at a subsequent convened IACUC meeting.

Responses to stipulations in iRIS are due within 60 days of the date of the request for additional information unless otherwise specified. If no response has been received after 60 days, the study will be administratively closed by the IACUC and further review of the study will require a new application to be submitted to the IACUC.

2.10.3 Withhold Approval

When the IACUC disapproves new research, it is rejecting oversight of the project as submitted, and the research is not allowed to go forward.

When the IACUC disapproves a change in research, the change cannot be implemented, and it is expected the research will continue as previously approved by the Committee.

Disapproval may occur for a variety of reasons, most of which involve animal safety and/or scientific validity.

The IACUC cannot disapprove a submission that has previously been approved. Disapproval is only valid when the Committee is considering an item that is not yet approved.

The IACUC shall provide the PI with written notification of the reasons for its decision to disapprove. The PI may request reconsideration of the IACUC's decision in writing within ten (10) days of the date of notice. The PI shall provide a rationale for the request to reconsider and any other relevant supporting documentation. The PI may also address the IACUC in person. The IACUC shall notify the PI in writing of its final decision after reconsideration and the reason(s) for its decision. No further request for reconsideration by the PI is permitted following the final decision by the IACUC. TTUHSC El Paso officials cannot approve research if it is disapproved by the IACUC.

2.10.4 Table/Defer

To table or defer means to remove an item from committee consideration at a convened meeting. The IACUC may decide to table a submission for the following reason(s):

- Numerous changes are required;
- Incomplete submission;
- IACUC member/consultants not available for review;
- Loss of quorum;
- Necessary documentation from other pertinent TTUHSC El Paso committees (e.g. Conflict of Interest Committee) has not been provided.

NOTE: All studies that are tabled at a full committee meeting will require subsequent full committee review unless the changes indicated allow for review through DMR.

IACUC administrative staff will send a written notice to the investigator to describe the reason(s) for table/deferral. If additional information is required, stipulations will be stated. Responses to stipulations in iRIS are generally due within 60 days of the date of the request for additional information unless otherwise specified. If no response has been received after 60 days, the study may be administratively closed by the IACUC and further review of the study will require a new application to be submitted to the IACUC.

2.10.5 Suspension

This action may be used as a response to alleged or known non-compliance.

2.10.6 Suspend Research Activity

When the IACUC suspends activity the investigator is required to cease all research activities. Research activity can only be suspended by the full committee at a convened

meeting. This is true for studies that had qualified for DMR as well as those that were originally approved by FCR at a convened meeting. A majority vote of the voting members present is required to formalize a decision to suspend research activity.

This action is used when research-related activity must cease, but the IACUC has requirements the investigator is expected to fulfill in order to resume research activity.

This includes ceasing research activities for animals in the study, unless the PI provides information in writing to the IACUC indicating that failure to perform study-related procedures on animals would be detrimental to their health or welfare. All data analyses must halt at the time of suspension.

Suspension may occur as a result of the need:

- for a response to serious or recurring non-compliance with the regulations or TTUHSC El Paso IACUC requirements;
- to protect the safety and welfare of animals; or
- other situations, as the IACUC deems appropriate.

2.10.6.1 IACUC Considerations

The IACUC will notify the PI in writing of suspension of IACUC approval along with the reasons for the suspension.

The IACUC will notify the Managing Director of ORR and the VPR of a decision to suspend within 2 business days of the decision. The VPR, serving as the IO, will promptly (within 30 days) notify other TTUHSC El Paso officials or outside entities (OLAW, USDA, etc.) as required to comply with our Assurance.

IACUC oversight continues, so the research is considered active for the purposes of continuing review. Investigators must continue to follow the IACUC's requirements for reporting unanticipated problems, changes in research, and so forth.

The PI will be required to submit a written corrective action plan for review and approval by the IACUC before any research activities can resume. More detail can be found regarding corrective action plans in the [Research Compliance Section](#) of this manual.

2.10.6.2 Suspension by Institutional Official or IACUC Chairperson

In urgent situations the VPR acting in the role as IO or IACUC Chairperson acting on behalf of the IACUC may determine that research activity must be suspended immediately. If this action occurs, the VPR/IACUC Chairperson must provide a written report of this action to the IACUC for review at the next convened meeting. The report shall include any actions taken to protect the rights, welfare, and safety of animals and others, and whether they have been notified of the suspension.

2.10.6.3 Appeal of Suspension

The PI may appeal the decision of the IACUC or VPR by submitting a written request to the IACUC and providing a rationale for the appeal and any other supporting documentation. The PI must submit an appeal within five business days of the date of notification of suspension.

Within 14 days of the appeal of termination, a request by the PI for reconsideration shall be reviewed by a subcommittee, consisting of the IACUC chair and two IACUC members, who were jointly selected by the IACUC Chair and IACUC Sr. Director.

The subcommittee may also invite individuals with expertise in that area of research to assist the subcommittee in its review of the issues. The IACUC Sr. Director, research compliance officer, and Managing Director of ORR will provide assistance to the subcommittee as needed, although they will not be considered to be members of the subcommittee. Individuals assisting the subcommittee shall maintain confidentiality of the IACUC proceedings.

This subcommittee shall review the PI's documentation, the research, and suspension documentation, and may speak with the PI. The subcommittee shall submit findings and a recommendation to the full IACUC at its next regularly scheduled meeting, if possible. At the discretion and invitation of the subcommittee, the PI may address the IACUC in person at its next regularly scheduled meeting.

The full committee shall consider the subcommittee's recommendation(s) and make a ruling to accept, reject, or revise its recommendation(s). If the subcommittee recommends that suspension be upheld and the IACUC accepts this recommendation, then a formal plan of correction must be submitted to and approved at a convened meeting of the IACUC in order for the research to resume.

The post-appeal decision by the full IACUC to suspend a research project is final, and may not be reversed by the VPR or any other officer/agency of TTUHSC El Paso or affiliated entities.

2.10.7 **Terminate Research Activity**

When the IACUC terminates approval the PI is required to permanently cease all research activities, including data analysis, for the terminated study(ies). A research study may be terminated only by the full IACUC at a convened meeting. This is true for studies that had qualified for DMR, as well as for those that were originally approved by the FCR at a convened meeting. A majority vote of the voting members present is required to formalize a decision to terminate a research study. Termination will occur as a result of 1) the need to protect the safety and welfare of animals, 2) serious or continued non-compliance and/or 3) other situations, as the Committee deems appropriate.

2.10.7.1 **IACUC Considerations**

IACUC deliberations will include consideration of:

- the actions to protect the rights and welfare of animals;
- any adverse event or outcome reported to the IACUC.

The IACUC will notify the PI in writing of termination of IACUC approval along with the reasons for the termination.

The IACUC administrative staff will notify the Managing Director of ORR and the VPR of decision to terminate approval within 2 business days of the decision. The VPR, serving as the IO, will promptly (within 30 days) notify other TTUHSC El Paso officials or outside entities (OLAW, USDA, affiliated institutions, etc.) as required to comply with our Assurance.

2.10.7.2 **Termination by Institutional Official or IACUC Chairperson**

In urgent situations the VPR acting in the role of IO or the IACUC Chairperson acting on behalf of the IACUC may determine that research activity must be terminated immediately. If this action occurs, the VPR/IACUC Chairperson must provide a

written report of this action to the IACUC for review at the next convened meeting. The report shall include any actions taken to protect rights, welfare and safety of currently enrolled participants and whether they have been notified of the suspension.

2.10.7.3 Appeal of Termination

The PI may appeal the decision of the IACUC or VPR by submitting a written request to the IACUC and providing a rationale for the appeal and any other supporting documentation. The PI must submit an appeal within five business days of the date of notification of termination.

Within 14 days of the appeal of termination, the request for reconsideration shall be reviewed by a subcommittee consisting of the IACUC Chair and two IACUC members, jointly selected by the IACUC Chair and IACUC Director. The subcommittee may also invite individuals with expertise in that area of research to assist the subcommittee in its review of the issues. The IACUC Sr. Director, research compliance officer, and Managing Director of ORR will provide assistance to the subcommittee as needed, although they will not be considered members of the subcommittee. Individuals assisting the subcommittee shall maintain confidentiality of the IACUC proceedings.

This subcommittee shall review the PI's documentation, the research, the termination documentation, and may speak with the PI. The subcommittee shall submit findings and recommendation to the full board at its next regularly scheduled meeting, if possible.

At the discretion and invitation of the subcommittee, the PI may address the IACUC in person at its next regularly scheduled meeting.

The full IACUC shall consider the subcommittee's recommendation(s) and make a ruling to accept, reject, or revise the subcommittee's recommendation(s).

If the subcommittee recommends that termination be upheld and the IACUC accepts this recommendation and votes accordingly, there is no further appeal within TTUHSC El Paso.

The post-appeal decision by the full IACUC to terminate a research project is final and may not be reversed by the VPR or any other officer/agency of TTUHSC El Paso or affiliated entities.

2.11 Categories of Animal Use

Each protocol submitted to the IACUC is assigned one of the following pain categories, which are based on the column headings from APHIS Form 7023a United States Department of Agriculture (USDA) Annual Report of Research Facility. There is no Category A.

2.11.1 CATEGORY B

Definition - Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. This category is automatically assigned to breeding and holding protocols.

2.11.2 CATEGORY C

Definition - Teaching, research, experiments, or tests involving no pain, distress, or requirement for pain-relieving drugs.

Examples:

- Non-dangerous procedures such as injections of small amounts of nonionic substances or blood sampling.
- Observation of natural behavior.
- Behavioral testing without significant restraint or noxious stimuli.
- Standard methods of euthanasia that induce rapid unconsciousness, such as an anesthetic overdose.

2.11.3 CATEGORY D

Definition - Experiments, teaching, research, surgery, or tests that result in pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs are used.

Examples:

- Experiments on completely anesthetized animals that do not regain consciousness.
- Survival surgery with appropriate anesthetic, analgesic, or tranquilizing drugs.

2.11.4 CATEGORY E

Definition - Experiments, teaching, research, surgery, or tests that result in pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs cannot be used, because such use would adversely affect the procedures, results, or interpretation of the outcome.

Protocols in Category E may receive scrutiny from external sources; therefore, the protocol must include (A) an explanation of the procedures producing pain or distress in these animals and (B) the reasons palliative drugs cannot be used.

2.12 Review Criteria

Federal requirements state that the IACUC review proposals for animal use must be based on the following criteria:

- **Potential Value of the Study** – Activities involving live animals are designed and performed with the reasonable expectation that such use of animals will contribute to the enhancement of human or animal health, the advancement of knowledge or the good of society (*PHS Policy*).
- **Selection of Animal Species** – The animals selected are of an appropriate species and the number of animals requested is the minimum number needed to obtain valid results (*PHS Policy*).
- **Minimization of Pain and Distress:**

Procedures with animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design [9 CFR 2.31(d) (1) (i) and *PHS Policy*, Section IV.C.1.a].

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 Principal Investigator justifies, in writing, the scientific reasons that the procedure must be performed without such treatments [9 CFR 2.31(d) (1) (iv) (A) and *PHS Policy*, Section IV.C.1.b].

The Principal Investigator has consulted with the Attending Veterinarian or his/her designee in planning procedures that may cause more than momentary or slight pain or distress to the animals [9 CFR 2.31(d) (1) (iv) (B)].

Procedures that cause more than momentary or slight pain and/or distress to the animals will not include the use of paralytics without anesthesia [9 CFR 2.31(d) (1) (iv) (C)].

Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be humanely euthanized at the end of the procedure, or if appropriate, during the procedure [9 CFR 2.31(d) (1) (v) and *PHS Policy*, Section IV.C.1.c].

- **Alternatives** – The Principal Investigator has considered alternatives to procedures that may cause more than momentary or slight pain and has provided a written narrative description of the methods and sources used to determine that alternatives are not available [9 CFR 2.31(d) (1) (ii)].
- **Duplication** – The Principal Investigator has provided written assurance that proposed activities involving animals does not unnecessarily duplicate previous experiments [9 CFR 2.31(d) (1) (iii)].
- **Living Conditions and Housing** – Animal living conditions and housing are appropriate for the species and contribute to the health and comfort of the animals [9 CFR 2.31(d) (1) (vi) and *PHS Policy*, Section IV.C.1.d].
- **Personnel** – Personnel conducting procedures will be appropriately qualified and trained in those procedures [9 CFR 2.31(d) (1) (viii) and *PHS Policy*, Section IV.C.1.f].
- **Surgery**-Activities that involve surgery include appropriate provision for pre- and post-operative care of the animals in accordance with established veterinary medical and nursing practices [9 CFR 2.31(d) (1) (ix)].

No animal will be used in more than one major operative procedure from which it is allowed to recover unless it is:

- Justified for scientific reasons in writing by the Principal Investigator, or
- Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the Attending Veterinarian [9 CFR 2.31(d) (1) (x)].
- **Euthanasia** – Methods of euthanasia must be consistent with the most recent Report of the *American Veterinary Medical Association Guidelines on Euthanasia*, unless a deviation is justified for scientific reasons in writing by the Principal Investigator [9 CFR 2.31(d) (1) (xi) and *PHS Policy*, Section IV.C.1.g].

2.13 Grant Congruency Review

TTUHSC EP is required by the *PHS Policy* to verify that the IACUC has reviewed any procedure in a PHS grant proposal that involves the care and use of animals. In order for TTUHSC El Paso to provide the required verification, the grant proposal must be compared with one or more IACUC-approved animal use protocols.

At the time of grant proposal submission, the Office of Sponsored Programs (OSP) will request that the PI identify the IACUC-approved animal use protocol(s) that contain the procedures in the grant proposal. The title of the protocol(s) does not have to match that of the grant proposal; however, all research that involves animals must be included in the approved IACUC protocol(s). The OSP will instruct the PI to submit the grant proposal and the protocol numbers(s) to the IACUC, along with the information indicated below. The assigned reviewers will be responsible for reviewing the description provided in the "Vertebrate Animals" (or its equivalent) section of the grant proposal and compare it to the approved IACUC protocol(s) for consistency in:

- overall scope of the animal work;
- proposed animal models (including species and strain);
- estimated number of animals; and
- procedures performed on live animals.

If the "Vertebrate Animals" (or its equivalent) section of the grant proposal and the approved IACUC protocol(s) are consistent, the IACUC will document this in the meeting minutes, and will inform OSP, as applicable. OSP will communicate the verification to the federal granting agency. If the grant proposal and protocol(s) are not consistent, the PI must resolve the discrepancy.

2.14 Types of Review

The IACUC uses two mechanisms for reviewing Protocols. These are Full Committee Review (FCR) and Designated Member Review (DMR). Expedited or special reviews are handled via DMR and no other review processes are possible.

2.14.1 Full Committee Review

Generally, the FCR process is used. The agenda is available to all committee members. As previously described, each protocol is assigned to two or more members for review.

2.14.1.1 Deadlines

Materials for convened committee meetings will be submitted to the IACUC through iRIS by pre-established deadlines. Submission deadline dates and IACUC meeting dates and times are found in iRIS and on the TTUHSC El Paso IACUC's [webpage](#). Deadlines for submissions of materials for convened committee meetings are generally a month prior to the meeting date.

When a submission is placed on the agenda, the submission and all documents are immediately available for review by IACUC members. The only exception to such availability is for IACUC members who are listed as study personnel on a project—those members are blocked by the iRIS system from viewing the submission. Reviewer assignments for submissions to be reviewed at a convened meeting are made within three days of the published deadline as described in the next section.

The IACUC reserves the right to limit the number of submissions at a convened meeting in spite of the deadline. If, in the opinion of the IACUC Chair or Sr. Director, more items have been submitted than can be effectively reviewed during the meeting, items will be prioritized. Submissions related to previously approved research will have priority over new projects (e.g., continuing reviews, amendments, etc.). Extra submissions will be assigned for review at the next convened meeting.

2.14.1.2 Conduct of the Meeting

TTUHSC EP IACUC meetings are conducted using the iRIS software program. Generally, each member will have an institutionally provided laptop to allow access to the agenda and all information included with each submission. IACUC meetings are primarily conducted in person, however, TTUHSC EP technology exists to allow non-local members and guests to participate in the meetings via auditory and/or visual access to the meeting materials and each other, as needed.

In addition, during times when in-person meetings are not able to take place, all members have access to the documents and technology needed to conduct a meeting. This forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e. members can actively and equally participate and there is simultaneous communication).

Votes are taken for each full committee agenda item and recorded in iRIS documenting each members vote including recusals, abstentions, or not present as stated elsewhere in this document.

2.14.1.3 Duties of IACUC Member Reviewers

Each submission to be reviewed at a convened meeting will be assigned to a primary and secondary reviewer. Each protocol is presented by the primary reviewer and any outstanding issues are thoroughly discussed. Efforts will be made to make assignments primarily on the basis of reviewer expertise or knowledge of the proposed research. Non-scientist members will not be assigned as primary reviewers. All study materials are routinely available to all IACUC members for review through the iRIS system. Reviews are to be written in the “member comments” section of iRIS prior to the meeting, or through a reviewer checklist, if available.

If needed, a consultant or the investigator may be asked to assist by presenting the IACUC with written or verbal information about the protocol. Clarification and discussion by the full committee then takes place.

The primary and secondary reviewers are responsible for making formal recommendation for IACUC action (approval, require modifications, disapproval) as appropriate to the submission. A majority vote of the voting members present is required to formalize IACUC decisions.

2.14.1.4 Quorum

A quorum is present when a simple majority (i.e. half plus one) of the appointed voting members (or their alternates) of the IACUC are present. Quorum for convened meetings may include video or teleconferencing, provided that the members participating from remote sites have access to all necessary materials required for review. The IACUC may only review proposed research at convened meetings at which a quorum is present. A quorum is not present when a sitting member must recuse him/herself for any reason. No official action may be taken at a meeting where a quorum is not present. Despite the presence of a quorum, no action should be taken at an IACUC where assembled members do not have the expertise to review the proposed research. Individuals who are not appointed to the IACUC, but attend IACUC meetings by virtue of their institutional status may not be counted toward the quorum and do not have voting privileges.

There is no requirement that the Attending Veterinarian attend every meeting. However, a veterinary consult is required before the IACUC may approve a protocol involving procedures that may cause more than momentary or slight pain or distress. If the consult has not occurred prior to the IACUC meeting, then it would seem desirable that the Attending Veterinarian be present at the meeting to give advice to the IACUC before a vote is taken.

2.14.1.5 Investigator Presence During Meetings

PIs may request to attend an IACUC meeting in order to provide information and clarification. PIs who wish to attend a meeting must contact the IACUC administrative staff to make arrangements. The IACUC may specifically request that the PI be present during discussion at a meeting to address the IACUC and/or provide answers to IACUC inquiries. The PI will always be dismissed prior to the main discussion and vote.

2.14.2 Designated Member Review

For DMR, at least one member of the IACUC shall review those protocols and have the authority to approve, require modifications (to secure approval) or request FCR. DMR may be used to secure approval for (1) new or renewing full protocols and amendments that require immediate evaluation, (2) Annual Status Reports (ASR), (3) simple strain changes that do not affect the intent of the protocol or animal welfare, or (4) protocols that have first undergone FCR. The IACUC may also use DMR in special circumstances, indicated below.

2.14.3 DMR Request by the PI

The DMR process may be applied to submissions of either full protocols or amendments that require immediate evaluation. The use of this process must be justified.

2.14.3.1 DMR Concurrence

Members will be polled to obtain concurrence to use the DMR method, or concurrence by silent assent after three full business days. 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.

2.14.4 DMR for Annual Status Reports

The Annual Status Report (ASR) is a crucial element of the Institutional Animal Care and Use Committee's (IACUC) assessment of the handling of animals. The ASR provides the Committee with a status report on animal usage within the previous twelve-month period, and a plan for animal research during the next twelve-month period. In addition, in order to remain compliant with USDA rules, those protocols using USDA-regulated species must have the ASR submitted and approved by the one-year anniversary date of the last approval.

The TTUHSC El Paso IACUC goes one step further and requires all protocols to submit an ASR whether they have USDA-regulated species or not, as a method of Post Approval Monitoring (PAM).

In order to facilitate this process, the IACUC will routinely review ASRs without amendments by DMR.

2.14.5 **DMR for Simple Animal Strain Changes**

In certain circumstances, the PI may wish to change the animal strain used in an IACUC protocol in a manner that does not change the purpose of the study, or impact animal welfare. Examples include changes between “wild-type” mouse or rat strains with a different genetic background (such as changing C57BL/6 to BALB/c), or the use of a different strain with the same gene knocked out.

2.14.6 **FCR to DMR**

Following the presentation and associated discussion of a protocol, amendment or ASR at FCR, the IACUC members who are present will vote to either a) approve, b) require modifications to secure approval, or c) withhold approval. Modifications of these items may be designated as either minor (modifications that do not involve animal health or welfare) or major (modifications that do involve animal health or welfare). Minor modifications will be confirmed by DMR and processed administratively (see Policy #13). Approval of required major modifications will be delayed until appropriate changes are approved via DMR. Specifically, the DMR will occur subsequent to FCR, if approved unanimously by members at the convened meeting in which the matter is discussed, and with the approval vote of a majority of the quorum present.

2.14.6.1 **Deadlines**

Submissions that appear to meet the criteria for DMR are reviewed in the order in which they are received. As such, there are no specific deadlines for these types of submissions. In general, these submissions are reviewed by an experienced IACUC member within one week of the assignment.

2.14.6.2 **Documents**

The information required for review using DMR is identical to those required for review at a convened IACUC meeting ([see Documents list](#)).

2.14.7 **DMR in Special Circumstances**

While the TTUHSC El Paso IACUC prefers that protocol reviews be conducted at a full committee meeting, the IACUC administrative staff may, during times of extended shut downs of the university under special situations, including pandemic, war and inclement weather, when the committee cannot make quorum, or other circumstances when FCR is impractical, switch to full DMR review of all protocols, at the discretion of the IACUC chair. This review would occur according to the procedure specified for expedited review. Full committee review would commence on the normal schedule when the special circumstance has passed.

2.14.8 **Duties of the IACUC Member Conducting DMR**

At least one member, designated and qualified to conduct the review, is assigned to these protocols and has the authority to approve, require modifications in (to secure approval), or request FCR of those protocols.

DMR actions include approval, require modifications (to secure approval), and referral for FCR. “Withhold approval” is not a possible outcome of DMR. If the project meets all

criteria for DMR and approval, all documents and reviewer's comments will be included in the agenda provided to the full IACUC for reference at the next convened meeting.

If the project DOES NOT meet all criteria for DMR and/or at the discretion of the IACUC member, it will be placed on the agenda for consideration at the next convened meeting.

2.14.9 **Standard Extension During Emergencies**

Based on the guidelines provided by OLAW during the pandemic COVID-19, the TTUHSC El Paso IACUC has created a new procedure for handling a standard extension.

Under certain special circumstances, due to an emergency affecting the PI or the institution, including but not limited to a medical emergency, personal emergency, natural disaster, war or pandemic, practical issues may prevent the timely submission of the 3-year renewal application, or ASR. In these circumstances, a standard extension of 6 months may be requested for a previously approved protocol, which will be processed via assigned member review (AMR). The request for an extension must be submitted three business days before the three-year renewal expires or ASR is due. Standard extension cannot be granted for a protocol that has already expired.

2.15 **IACUC Submission Categories**

2.15.1 **Initial Reviews**

In conducting initial reviews, the IACUC will consider all regulations applicable to the research and that must be met prior to initial IACUC approval of a research project. No research involving animals that falls under the scope or authority of the TTUHSC El Paso IACUC may commence prior to IACUC approval of the project. In no case, will a TTUHSC El Paso IACUC grant "retroactive" approval to a research project where research activities have begun prior to IACUC approval.

2.15.2 **Continuing reviews**

Continuing review of all research approved by the IACUC ensures that the protocol is being conducted in accordance with current policies and regulations and, also serves as an ongoing post-approval monitoring tool.

2.15.2.1 **Continuing Review Requirements**

Each previously approved, ongoing activity covered by PHS Policy will require continuing review at intervals determined by the IACUC, including a complete review at least once every 3 years.

2.15.2.2 **Frequency**

Protocols will be assigned to annual continuing review, as well as a three-year 'de novo' review.

2.15.2.3 **Deadlines**

In order to provide timely review and approval of each study, the PI shall submit an annual status report with required documentation at least 21 days prior to the full board meeting preceding the study expiration date. Although automatic reminders are sent, the PI is responsible for submitting continuing review materials in a timely manner.

2.15.2.4 **Required Information**

Information included on the “Annual Status Report” in iRIS and which is required for continuing review includes:

- the status of funding;
- number of animals used in the last 12 months, listed by species and/or experiment;
- a status report on the progress of the research and interim findings;
- a summary of the goals for the next 12 months.
- any information, including that from recent literature relevant to the study;
- a summary of any incidents of the following: adverse events, unanticipated problems involving the research, and/or complaints about the research since the last IACUC review;
- an updated complete protocol;

2.15.2.5 Submission Screening

Each Annual Status Report will be screened by IACUC administrative staff to assure all necessary information is provided. After prescreening, if there are no changes indicated, the submission will be reviewed by DMR. If there are changes, the submission will be assigned to reviewers for FCR.

2.15.2.6 Duties of IACUC Members

All study materials are routinely available to all IACUC members for review through the iRIS system. Based on its review, the IACUC may require that the research be modified, restricted, suspended/terminated, or administratively closed. Alternatively, previously imposed restrictions by the IACUC may be lifted.

In order to approve an Annual Status Report with changes, the IACUC member(s) will review all the materials and/or information (see [Documents](#)) including any protocol modifications and unanticipated problems. All this information, study materials and past submissions are accessible through the iRIS program to the reviewer(s). This review will be based on the same criteria as was used at the time of initial review (see [Approval Requirements](#)).

2.15.2.7 Expiration of IACUC Approval

The expiration date is assigned at the time of recommendation to approve the research at a convened meeting. The research expires one day less than the assigned review interval. For example, a research project approved for annual review on 12/18/2020 will expire on 12/17/2021; research activities are allowed to take place on the day of expiration.

2.15.2.8 Continuing review – FCR

This includes protocols that were originally approved by the IACUC through FCR and the annual review includes changes.

PI responses to IACUC stipulations regarding continuing reviews conducted at a convened meeting may be reviewed by DMR if agreed to by unanimous vote.

2.15.2.9 Continuing review – DMR

This includes protocols where there are no changes being submitted. It may also include a PI's request for DMR, subsequent to FCR, and polling of members provides assent with this process.

2.15.2.10 **Failure to Provide Continuing Review Information**

If a PI has failed to provide continuing review information to the IACUC or the IACUC has not reviewed and approved the research study by the expiration date specified by the IACUC, all research activity, data collection and analysis, shall stop unless the IACUC finds that it is in the best interest of the animals to continue participating in the research interventions or interactions. No new research activities may occur after the expiration of IACUC approval until such time as the IACUC has re-approved the research.

2.15.2.11 **Submission of Continuing Review Materials after Expiration Date**

Once IACUC approval expires, all research activity, data collection and analysis must stop. However, the IACUC will not immediately inactivate the study, pending continuing review, if the PI submits the continuing review materials to the IACUC within 30 calendar days after the expiration date. Extensions to the 30-day deadline will be made on a case-by-case basis. Research activity shall resume only after IACUC approval of continuing review. If the PI fails to submit the continuing review materials within 30 days after the expiration date and has not communicated with the IACUC regarding extenuating circumstances, the study will be closed administratively by the IACUC. Studies that are administratively closed by the IACUC are no longer approved for any research activity. An investigator who wishes to reinstate a research protocol that has been inactivated must submit the project as an initial application.

2.15.3 **Amendments (proposed modifications) to previously approved protocols**

For previously approved projects, all planned changes in the conduct of a study must be approved by the IACUC prior to initiation of these changes, unless the change is required immediately to prevent immediate hazards to animals. The changes are submitted electronically through iRIS on an amendment form with a revised study application and protocol attached.

The IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed changes 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 AWA insofar as it applies to the activity, and that the protocol is consistent with the Guide, unless acceptable justification for a departure is presented. Furthermore, the IACUC shall determine that the protocol conforms to the Institution's PHS Assurance:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- b. 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.

- c. 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.
- d. 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.
- e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. 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 investigator.

2.15.3.1 Non-significant Changes

A non-significant change is defined as a change that would not affect animal welfare or does not substantially change the specific aims or design of the study. Examples of non-significant changes include:

- add, delete or change the title of a study;
- add, delete or change personnel, other than the PI;
- add and/or delete locations;
- Increase the number of animals on the protocol when the increase is no greater than 10% of the original approved number (rats and mice only);
- correction of typographical errors;
- correction of grammar;
- contact information updates;

The IACUC administrative staff will review and acknowledge non-significant changes.

Modifications of any study document (IACUC Application, protocol) require submission of an updated copy of the proposed revised document with changes clearly identified. All minor modifications, which have been approved or acknowledged, will be immediately available on the IACUC agenda for review by all IACUC members at any time.

2.15.3.2 Significant Changes

A significant change is defined as changes that have, or have the potential to have, a negative impact on animal welfare. In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant. Examples of significant changes include, but are not limited to:

- from nonsurvival to survival surgery;
- resulting in greater pain, distress, or degree of invasiveness;
- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;

- in species;
- in strain;
- in study objectives;
- in PI;
- that impact personnel safety substances;
- euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals;
- duration, frequency, type, or number of procedures performed on an animal.

Modifications of any study document (IACUC Application, protocol) require submission of an updated copy of the proposed revised document with changes clearly identified.

All significant changes will be reviewed through FCR or DMR. All members (including alternate members) have immediate access to all modification requests and associated documents via iRIS. The IACUC will use the same criteria as initially used to approve the research for review/approval of the amendment.

2.15.3.3 **Veterinary Verification Consultation**

In some instances, specific significant changes in approved research may be handled in consultation with a veterinarian authorized by the IACUC. This is called veterinary verification consultation (VVC). The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies.

Examples of changes that **can** be approved by VVC include:

- Anesthesia, analgesia, or sedation, provided that animal welfare is not compromised;
- Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals;
- Duration, frequency, type, or number of procedures to be performed on an animal as long as those procedures are already approved in the protocol.

Examples of changes that **cannot** be approved by VVC include:

- Change a surgery from a non-survival to a survival
- Increase pain, distress, or degree of invasiveness
- Change housing or use of animals to a non-LARC location
- Change species
- Change study objectives
- Change Primary Investigator
- Make changes that will impact personnel safety.
- Add new procedures to a protocol.

Consultation with the Veterinarian will be documented through iRIS study correspondence by having the Veterinarian approving the change send the correspondence to the PI, IACUC Chair, and IACUC Lead Analyst through the protocol in iRIS. The PI must submit an amendment with revised protocol, through iRIS, within five business days of the consultation. The IACUC Lead Analyst will assign the protocol amendment to the IVET for review and approval.

2.15.3.4 Notification to the PI

The decisions by the IACUC will be promptly conveyed to the PI in writing by the IACUC administrative staff. All correspondence is sent electronically through the iRIS system.

2.15.4 Unanticipated Event Reporting

The IACUC is under federal mandate to monitor all research activities related to unapproved activities or unexpected events that may compromise animal welfare. All suspected Unanticipated Events (UE) should be reported promptly, without delay. The mechanism for reporting these events to the IACUC is the Unanticipated Event Form found in iRIS. Questions about whether or not to report any particular event may be directed to the respective IACUC administrator or Chair. If uncertainty remains, the event should be reported to the IACUC.

2.15.4.1 Definition

The occurrence of an unforeseen event that negatively impacts the welfare of research animal(s), involving pain, distress, and/or death of the animal. By definition, UEs are not identified as potential risks or outcomes in the approved IACUC protocol.

2.15.4.2 Reportable UEs

Examples of reportable situations include:

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- conduct of animal-related activities without appropriate IACUC review and approval;
- failure to adhere to IACUC-approved protocols;
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;

- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

2.15.4.3 Non-Reportable AEs

Examples of situations *not* normally required to be reported include:

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
- animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, *must* be reported promptly along with corrective plans and schedules).

2.15.4.4 Reporting to IACUC

Reports must be submitted through iRIS within 72 hours of the event. Any report of an unexpected or atypical event that is submitted to the IACUC must contain the following information:

- a detailed description of the situation, including what happened, when and where, the species of the animal(s) involved, and the category of individuals involved (e.g. PI or Co-I, technician, animal caretaker, student, veterinarian, etc.)
- an explanation of the basis for determining that the incident represents an adverse event;
- Relevant grant or contract number, if the situation is related to an activity directly supported by PHS;
- a description of any changes to the conduct of the study or other corrective actions that have been taken or are proposed.

Assessment/Review

The purpose of reporting these occurrences is to help in the IACUC assessment of overall study conduct.

IACUC administrative staff prescreens UE submissions for completeness. If adequate, the submission is assigned to the IACUC Chair and/or designated IACUC member for review.

The IACUC Chair and/or designated member review may include acknowledgment, request for additional information, or a determination to initiate a compliance audit.

2.15.4.5 Reporting to Regulatory Agencies

If the IACUC determines that there is

- serious or continuing noncompliance with PHS policy;
- serious deviation from the provisions of the Guide;
- or any suspension of an activity by the IACUC

the IACUC Chair or IACUC administrative staff will notify the IO's office. The IO will notify OLAW and/or USDA promptly, without delay, in compliance with the TTUHSC El Paso Assurance. Since IV.F.3 requires a full explanation of circumstances and actions taken, and the time required to fully investigate and devise a corrective action plan may be lengthy, a preliminary report will be provided to OLAW as soon as possible and a follow-up with a thorough report once action has been taken.

Failure to report an animal incident within 72 hours may result in corrective action by the IACUC.

2.15.5 Study Closures

Studies that have been approved by the IACUC may be closed by the investigator, the sponsor, the IACUC, TTUHSC El Paso, or by an affiliated entity. When the decision to permanently or temporarily close a study is made by the investigator, an affiliated entity, or the study sponsor, the PI must promptly notify the IACUC through iRIS and include a summary of findings to date.

2.15.5.1 Study Status - Completed

Studies that have been completed and are closed at the local research site will be designated as "Completed" in iRIS. The PI shall submit the "Termination Request" to the IACUC, which will include the total number of animals used, any major problems, and a summary of the findings. A manuscript may be substituted for the summary of the findings. Prior to the study being designated "Completed" all data must be stored on a designated drive. Study materials must be stored by the PI, or PI's department in the event the PI leaves the institution, for a minimum of 3 years, and must be stored as long as additional applicable federal or contractual regulations stipulate.

Once the IACUC has sent a written acknowledgment that the study is designated "Completed", no further actions are necessary by the PI. No further research activity is permitted for studies which are completed. Any further activity on such studies will require the submission of a new application to the IACUC.

2.15.5.2 Study Status - Cancelled

If, after IACUC approval, a study is permanently closed by the PI or sponsor for any reason prior to its completion, it will be designated as "Cancelled" in iRIS. The PI shall submit the "Termination Request" to the IACUC, which will include the total number of animals used, any major problems, and a summary of the reasons for not completing the study as approved. All data must be stored on a designated drive.

Once the IACUC has sent a written acknowledgment that the study is “Cancelled,” no further actions are necessary by the PI. No further research activity is permitted for studies which are cancelled. Any further activity on such studies will require the submission of a new application to the IACUC.

2.15.5.3 Study Status - Administratively Closed

Studies may be “Administratively Closed” by written notice to the PI by the IACUC for reasons including, but not limited to:

- non-responsiveness to requests for information from the investigator, or
- no study activity at the local site for a period of three or more years.

No further research activity is permitted for studies that are administratively closed. Any further activity on such studies will require the submission of a new application to the IACUC.

2.16 Semiannual Reviews

Twice each year, the IACUC reviews the TTUHSC El Paso IACUC Policies and Procedures for animal care and use programs and inspects all TTUHSC El Paso facilities where animals are housed and/or used. The IACUC uses The Guide and the AWA regulations as the principal reference documents in conducting these reviews.

2.16.1 Types of Semiannual Review

The IACUC is required to semiannually evaluate the TTUHSC EP IACUC Policies and Procedures for animal care and use programs. This semiannual evaluation includes the following:

- IACUC membership and functions, including protocol review practices;
- IACUC records and reporting requirements;
- Veterinary care, to include:
 - Preventive medicine, animal procurement, and animal transportation,
 - Surgery,
 - Pain, distress, analgesia, and anesthesia,
 - Euthanasia,
 - Drug storage and control;
- Personnel qualifications and training;
- Occupational health and safety of personnel;
- Disaster Plan.

2.16.2 Review and Inspection of Animal Facilities

The IACUC will 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. The IACUC procedures for conducting semiannual facility inspections are as follows:

- At least once every six months at least two members of the IACUC will visit all of the institution's facilities and any surgical areas where vertebrate animals are maintained for more than 12 hours. Areas also inspected may include holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals will also be inspected.

- The IACUC uses the Guide and other pertinent resources, e.g., the PHS Policy, as a basis for the inspection. To facilitate the inspection, the IACUC will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
- If deficiencies are noted during the inspection, they will be categorized as significant or minor and the IACUC 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.
- Subcommittees may be used to conduct all or part of the inspections. However, no member will be involuntarily excluded from participating in any portion of the inspections.

2.16.2.1 Significant Deficiencies

Definition: One that is or may be a threat to the health and safety of the animals or personnel.

Examples:

- Failures in heating, ventilating, and air conditioning systems (HVAC)
- Inoperative watering systems
- General power failures of sufficient duration to affect critical areas
- Inadequate veterinary medical or post-surgical care for animals

2.16.2.2 Minor Deficiencies

Definition: An area of situation that is not in compliance with the AWR or PHS Policy, but does not pose a threat to animal health and safety

Examples

- Infrequent findings of peeling or chipped paint
- Burnt-out light bulbs
- Warped floor drain covers
- Similar problems for which immediate solutions generally are not necessary to protect life or prevent distress

2.16.3 Semiannual Review Subcommittee and Reports

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

- The Inspection Team Leaders collect individual comments and concerns from their team members and prepare reports which are submitted to the IACUC Administrator who in-turn will draft the reports and make them available for the IACUC, using the sample OLAW Semiannual Report to the IO format from the OLAW website.
- The reports will identify specifically any IACUC approved departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. If there are no departures the reports will so state.

- In cases where departures from the Guide and PHS Policy have not been approved via protocol or policy, the IACUC will consider such departures deficiencies and will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.
- 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.
- 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 so state.
- Following completion of each evaluation, the completed report will be submitted to the IO in a timely manner.
- Continuing deficiencies will be tracked by the IACUC staff and be discussed as a standing report at monthly IACUC meetings for appropriate action until resolved.
- In compliance with PHS Policy IV.B.3., the IACUC files through the IO, at least annually, a certification to OLAW that the reviews and inspections 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.

2.16.4 Monitoring Corrective Action Plans

The IACUC administrative staff shall monitor compliance with required corrective actions, as identified in the final semiannual report, and shall provide updates to the IACUC. If any deficiencies are not remedied within the time period set forth in the final semiannual report, the IACUC shall take appropriate corrective action.

2.17 Protocol Post-Approval Monitoring

Post-approval monitoring of protocols is permitted to provide assurance to regulatory agencies and to the IACUC that animal experiments are performed in accordance with approved protocols. The Animal Vivarium can perform post-approval monitoring on behalf of the IACUC. The Animal Vivarium confirms consistent and accurate performance of the IACUC-approved protocols, standard operating procedures and practices.

2.17.1 Post-approval monitoring may be performed as a “For Cause” investigation or routinely as a “Not for Cause” review.

The Animal Vivarium conducts “For Cause” Investigations at the request of the IACUC for a variety of reasons including:

- Receipt of an internal complaint (i.e. anonymous report) or internal concern of possible protocol violation or regulatory noncompliance;
- Receipt of an external complaint (the FDA, Sponsor, OLAW, or USDA) of potential protocol violation or regulatory noncompliance; or
- Investigator history of poor adherence to TTUHSC EP policies/procedures or regulatory requirements.

The “Not for Cause” or routine post-approval monitoring may include:

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- Review of IACUC records and activities to ensure that the IACUC policies and procedures are consistent with regulatory requirements and federal assurances;
- Review of risk areas identified during periodic risk assessments of research at TTUHSC EP;
- Protocols randomly selected for on-site review.

In post-approval monitoring:

- All active and approved protocols and modifications are available for review;
- All allegations of misuse, neglect or inappropriate protocol performance will be investigated;
- In general, the monitoring reviews will be scheduled with the PI or other laboratory personnel in advance. Follow-up audits for the purpose of confirming PI reported resolutions may be unscheduled;
- “For Cause” monitoring may be conducted at any time, with or without advance notice (i.e., unannounced) to the PI;
- During a monitoring visit, the Animal Vivarium will compare procedures conducted in the laboratory with those listed in the approved protocol;
- The Animal Vivarium will provide a description of any discrepancies between the procedures performed in the lab and those listed in the protocol to the PI;
- The Animal Vivarium will provide information to the IACUC by means of a written report. The report may include identification of:
 - Unapproved personnel who are performing procedures in the protocol,
 - Outdated cage cards, incorrect cage cards, or improperly labeled cage card,
 - Location of the procedure that does not match the location specified in the protocol,
 - Anesthetics/analgesics: unapproved regimen or route of administration, expired date, improper use,
 - Minor unapproved modifications to approved procedures that are performed,
- Other procedural deviations that can be corrected by submission of a minor change request, and
- Incidents of animal distress that were not anticipated;
- The Animal Vivarium will discuss monitoring/auditing results with the PI to confirm the observations for accuracy, and to assure a complete understanding of issues;
- The Animal Vivarium shall refer issues that pose an immediate threat to animal welfare to the Attending Veterinarian, and the IACUC;
- The Animal Vivarium will send a final written report of the monitoring results to the research compliance officer, PI, and the IACUC;
- As the Animal Vivarium determines necessary, he/she may recommend further training/ retraining or modifications, and may perform a follow-up monitoring/audit visit to check for compliance and to assure the welfare of the animals and the integrity of the IACUC protocol process.

2.18 Sudden Departure of a PI

During certain circumstances, a PI may suddenly leave the institution without terminating the IACUC protocol or amending the protocol to list a new PI. These circumstances may include, but are not limited to termination of employment, or death of the PI. In these circumstances, the IACUC must take steps to ensure the immediate welfare of any animals on that protocol. These steps are intended as a stop-gap measure. Beyond the immediate timeframe, it is the responsibility of the department chair and any grant-awarding agencies supporting the study, to identify a potential new PI or request termination of the protocol.

2.19 Research Non-Compliance

The TTUHSC El Paso IACUC is authorized to monitor research involving animals approved by the IACUC pursuant to the responsibilities and assurances made by TTUHSC El Paso under its assurance (D19-01056) and TTUHSC El Paso Policy [TTUHSC EP OP 73.03 Animal Care and Usage](#) and [TTUHSC EP OP 73.14 Research Compliance](#).

The IACUC has the authority to inspect research facilities, obtain records and other relevant information relating to the use of animals in research. The IACUC investigates concerns involving the care and use of animals raised by complaints or reports of noncompliance received from the public or from research personnel or employees [9 CFR 2.31(c) (4)]. The IACUC takes such actions that are in its judgment necessary to enforce compliance with applicable federal and state law, regulations, or guidelines, including action to suspend/terminate approval of research that is not being conducted in accordance with IACUC requirements or that has been associated with unexpected serious harm to animals. TTUHSC El Paso is required to report results of some investigations to OLAW and the USDA.

2.19.1 Identification of Compliance Issues

Anyone who has a concern or question about animal care and use at TTUHSC EP including protocol noncompliance or animal treatment, is expected to report the complaint either orally or in writing, to any member of the IACUC, to call 1-866-294-9352 or through [ethicspoint](#), to report anonymously. The Attending Veterinarian, animal care staff and individual IACUC members must also report any suspected incidence of noncompliance. Reports are made to the IACUC and assigned for investigation by the Chair. Strict confidentiality will be maintained to the extent possible and allowable by law. TTUHSC EP prohibits retaliation against any employee who makes a good faith report of known or suspected noncompliance in the care and use of animals at TTUHSC EP.

Concerns include situations or activities in which animals are in immediate jeopardy and those in which violations of the Federal Animal Welfare Regulations or the Assurance are alleged but animals are not in apparent danger. They may also be past violations of the IACUC Policies and Procedures or protocol noncompliance.

2.19.2 Investigation of Animal Care and Use Concerns

2.19.2.1 Initial Evaluation and Actions

The response of the IACUC to a concern about animal use is driven by the urgency of the situation. Conditions that jeopardize the health or well-being of animals are evaluated immediately. The Attending Veterinarian is authorized to halt procedures if he or she has reason to believe that animal welfare is being compromised until the IACUC can be convened to consider the matter formally. Situations that involve

potential criminal activity or human safety are reported promptly to TTUHSC El Paso's Security or human resources officials. Allegations concerning less urgent policy or procedural matters are handled as promptly as practicable.

An emergency meeting of the IACUC may be necessary to ensure prompt consideration. Upon receipt of a concern, the IACUC Chair or the Chair's designee(s) will convene a meeting of the IACUC to determine whether the concern requires further investigation and immediate action, further investigation but no immediate action, or no action. Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately. If immediate action is warranted to protect animal or human welfare, the IACUC notifies the Institutional Official or the Institutional Official's designee(s). Any suspension of activity is reported to regulatory agencies.

2.19.2.2 Investigation

If further investigation is required, the Chair or a subcommittee appointed by the Chair conducts the investigation and reports its findings to the IACUC by an assigned completion date. To avoid actual or perceived conflicts of interest in the investigation process, no person with an unresolved personal, professional or financial conflict of interest with the affected investigator or personnel is involved in the investigation.

The investigation may involve:

- interviewing complainants, any persons against whom allegations were directed, and pertinent program officials;
- observing the animals and their environment;
- reviewing pertinent records, (e.g., animal health records, protocol).

The report to the IACUC summarizes:

- the concern(s),
- the results of interviews,
- the condition of animals and their environment,
- the results of document reviews.

The report must also contain:

- any supporting documentation such as correspondence, reports, and animal records,
- conclusions regarding the substance of the concerns;
- recommended actions.

2.19.2.3 Outcomes and Final Actions

Upon receipt and evaluation of the report, the IACUC may request further information or find that:

- there was no evidence to support the concern or complaint,
- the concern or complaint was not sustained, but
 - related aspects of the animal care and use program require further review,*or*
 - other institutional programs may require review, *or*
- the concern or complaint is valid.

Actions of the IACUC may include:

- notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, institutional attorneys, etc.);
- implementing measures to prevent recurrence;
- notifying the Institutional Official;
- notifying funding or regulatory agencies.

2.19.3 Noncompliance with IACUC Policies

Failure to comply with IACUC policies or to adhere to the procedures of an approved protocol constitutes noncompliance. Examples of noncompliance are performing unauthorized surgery, unauthorized persons participating in a research project, or injecting drugs that the IACUC has not approved.

The IACUC's first goal when non-compliance is found is to restore compliance. In determining its response to a finding of non-compliance, the IACUC may consider:

- self-reporting by the Principal Investigator or staff,
- proactive corrective action(s) taken in response,
- the extent to which the incident(s) represent a continuing, or repeated violation and the length of time between incidents of noncompliance,
- the extent to which harm to an animal resulted from the incident(s).

The response of the IACUC may include:

- counseling,
- mandating specific training aimed at preventing future incidents,
- monitoring by the IACUC or IACUC-appointed individuals of activities that involve animals.

2.19.4 Consequences of Noncompliance

If, in the opinion of the IACUC, sanctions are not appropriate, they need not be applied. If the IACUC finds that sanctions are appropriate, they may include;

- requiring the Principal Investigator to present plans for corrective action to the IACUC;
- issuing letters of reprimand;
- notification to the Principal Investigator's Departmental chair;
- a letter to the Principal Investigator from the Institutional Official outlining the problem and requesting a detailed plan of corrective action;

- suspension of protocol and or loss of animal use privileges;

2.19.5 Suspension of a Protocol

The IACUC may suspend activities on a protocol if it finds violations of the Institutional Policy, PHS Policy, the Assurance, and/or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the affirmative vote of a majority of the quorum present. Further, the IACUC must consult with the Institutional Official regarding the reasons for the suspension. The Institutional Official is required to take appropriate corrective action and report the action to regulatory agencies (Section 8.6).

The Attending Veterinarian has authority to immediately suspend IACUC approval if he or she has reason to believe that animal welfare is being compromised. The Attending Veterinarian immediately notifies the affected Principal Investigator and the IACUC Chair in writing. The circumstances that led to suspension shall be investigated as quickly as possible and the IACUC Chair shall call an emergency meeting of the IACUC to review the suspension.

2.19.6 Programmatic Deficiencies and Corrective Actions

The IACUC semiannual evaluations are tools for institutional self-identification and correction of facility and program deficiencies. Program deficiencies include:

- failure to correct situations identified as significant deficiencies in a timely manner,
- shortcomings in the programs of veterinary care, occupational health, training, or with the IACUC,
- conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals.

Programmatic deficiencies must be categorized as acceptable, minor, or significant. The corrective action for a significant deficiency must include a reasonable plan to correct the issues as well as a date by which the issue will be corrected. Significant programmatic deficiencies must be reported to the applicable regulatory agencies if the deficiency jeopardizes the health and welfare of the animals, or if TTUHSC EP is unable to make the correction by the specified date.

2.19.7 Reporting Requirements

2.19.7.1 AAALAC

Each year in mid-December, the AAALAC International office makes available the online Annual Report form. There are no specific due dates for submitting an Annual Report. However, AAALAC International's Rules of Accreditation require that an Annual Report be submitted in order to maintain accreditation. An institution may choose from a variety of reporting periods (e.g., University fiscal year, calendar year, federal government fiscal year, government oversight body reporting period, etc.) as the AAALAC International reporting period as long as the period covered is continuous with previous reports (i.e., there are no gaps and all periods are covered by a report).

Annual Reports should provide notification of any:

- Protocol violations
- Animal use not approved by IACUC
- Protocol suspensions
- Changes in facility size, location, name
- Changes in IACUC composition or members
- Other changes in the animal care and use program
- Animal numbers

The same animal numbers reported to the USDA may be used, but must also include animal numbers for species not regulated by the USDA.

2.19.7.2 **OLAW**

The Institutional reporting period is the fiscal year (October 1 – September 30). The IACUC, through the IO, will submit an annual report to OLAW by December 1 of each year. The annual report will include:

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

Any change in the IACUC membership

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, [Insert name or title of the Institutional Official signing the Assurance].

Any minority views filed by members of the IACUC

The IACUC, through the IO, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

Any serious or continuing noncompliance with the PHS Policy

Any serious deviations from the provisions of the Guide

Any suspension of an activity by the IACUC

Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

In addition, the IACUC, through the IO or the IO's designee, must report within 15 days any failure to correct a significant deficiency to the USDA and any federal agency funding the activity in which the significant deficiency was found.

Examples of reportable incidents include:

conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;

conduct of animal-related activities without appropriate IACUC review and approval;

failure to adhere to IACUC-approved protocols;

implementation of any significant change to IACUC-approved protocols without prior IACUC approval;

conduct of animal-related activities beyond the expiration date established by the IACUC;

conduct of official IACUC business requiring a quorum in the absence of a quorum;

conduct of official IACUC business during a period of time that the IACUC is improperly constituted;

failure to correct deficiencies identified during the semiannual evaluation in a timely manner;

chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;

participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained;

failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);

failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);

failure to ensure death of animals after euthanasia procedures;

failure of animal care and use personnel to carry out veterinary orders (e.g., treatments);

IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the PHS Policy, Animal Welfare Act, the Guide, or the University's Animal Welfare Assurance.

2.19.7.3 **USDA**

Animal Welfare Act Regulations (AWARs) require each USDA-registered reporting facility to submit an annual report to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) on or before December 1st of each calendar year. The report documents its use of animals for research, testing, teaching, experimentation, and/or surgery.

The annual report will include:

Only vertebrate species. In this document, the words "use" or "used" refer to the incorporation of vertebrate animals in teaching, testing, experiments, or research protocols.

Regulated species are the only species included in this report and they are all live, warm-blooded species acquired or bred specifically for use.

A summary of any IACUC-approved exceptions to the regulations or standards must be submitted in hard copy to USDA as part of the Annual Report.

CHAPTER 3 RESEARCHER AND RESEARCH STAFF INFORMATION

3.1 Introduction

The purpose of this chapter is to provide guidance to research investigators and personnel on the protection of animals in accordance with applicable laws, regulations and TTUHSC El Paso policies and procedures.

All research involving animal subjects conducted at or in affiliation with TTUHSC El Paso must be reviewed and approved by the TTUHSC El Paso IACUC prior to beginning the study.

The Office of Research Resources (ORR) provides administrative support to the TTUHSC El Paso IACUC, provides education regarding the protection of animals, and monitors animal research approved by the IACUC.

In addition to the information found in this Manual, investigators and research staff or those who wish to learn more about the TTUHSC El Paso IACUC can find more information at the TTUHSC El Paso [IACUC Website](#). Specific policies, contact information for IACUC administrative staff, IACUC deadlines and meeting dates, as well as links to other helpful information can be found at the site.

3.2 Applicable Regulations

Applicable regulations include, but are not limited to:

- Animal Welfare Act;
- The Health Research Extension Act of 1985;
- The U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research and Training;
- The Public Health Services Policy on the Humane Care and Use of Laboratory Animals;
- The Guide for Care and Use of Laboratory Animals

3.3 Prerequisites for all personnel involved in animal research

3.3.1 Education Requirements

All PIs and research personnel working with animals must complete the training topic requirements currently listed in 9 CFR, Part 2, Subpart C, Section 2.32(c) 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, the 3 R's (Reduction, Refinement, and Replacement) of animal research, and disclose financial conflicts of interests prior to beginning any animal research-related activities.

The IACUC-approved training process is initiated prior to or at the time of requesting an iRIS account. Training is also verified at 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). In addition, approval of IACUC Annual Status Reports and Three-Year Renewals will be withheld until all research personnel have been verified as having completed/updated training and financial disclosure reports on file.

3.3.1.1 Animal Training and Financial Conflict of Interest Training

Each person conducting or assisting in the conduct of a research project that involves animals is first required to complete training on ethical and regulatory issues administered by the University of Miami through the Collaborative IACUC Training Initiative (CITI). The web-based courses currently required by TTUHSC El Paso are the following:

- Working with the IACUC Course
- Reducing Pain and Distress in Laboratory Mice and Rats Course
- Working with (Specie) in Research Settings Course (species will vary i.e. mice, rats, ferrets, fish, etc.)
- Conflict of Interest Course

Additional web-based courses, as applicable:

- Antibody Production in Animals
- Aseptic Surgery
- Responsible Conduct of Research Course

Additional training components that are required:

- Occupational Health and Safety (OHS)
- Research Financial Disclosure

Procedural and task-specific training is provided to individuals by their lab supervisors. Additional training needs for PIs and research personnel, including students, is determined by the Attending Veterinarian and the IACUC during protocol review.

Safety Services administers introductory safety training following its Chemical Hygiene plan. Additional training needs are also identified during introductory safety training. Training can be conducted by experienced persons listed on the protocol, the Attending Veterinarian, other faculty, or outside experts as is indicated. If requested the Veterinary staff can also provide species and bi methodology training. Animal-specific training is provided to the animal technicians by expert researchers as necessary.

3.3.1.1.1 Occupational Health and Safety Program

Medical Evaluation and Preventive Medicine for Personnel/Health Questionnaire and Evaluations

- The Risk Assessment Health Questionnaire is used by the OHS professional to gather starting information. Health histories are collected by the OHS professional for evaluation and follow-up. Compliance with HIPAA regulations are maintained by direct action of the OHS professional. Likewise, all medical records are maintained by the OHS professional in a HIPAA-compliant manner.
- The Risk Assessment Health Questionnaire and instructions, and Employee Health for Animal Users information are available on the IACUC website at: <https://elpaso.ttuhsu.edu/research/committees/iacuc/training-requirements.aspx> and in iRIS under the 'Help' section. They may also be

Chapter 3 Researcher and Research Staff

requested from the IACUC Lead Analyst. New animal users should be directed to these sites to obtain the required forms.

- The employee schedules an appointment with the OHS professional for evaluation of the completed (or declined) Risk Assessment Health Questionnaire, 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 the OHS professional in a HIPAA compliant manner.
- On the 3-year anniversary of their enrollment, individuals still active in the Program will complete an updated Risk Assessment Health Questionnaire and submit it to the OHS professional for additional evaluation/recommendations. PI's are responsible for ensuring that this is taken care of.

Immunizations

- Immunizations at TTUHSC El Paso are suggested, but not required. However, un-vaccinated personnel may be excluded from participation in studies. The decision for exclusion is risk-based and upon recommendation by OHS and Safety Services.
- Available vaccines are provided by OHS personnel when indicated.

Precautions taken during pregnancy, illness or decreased immunocompetence.

- During the health history evaluation the OHS professional may identify those who are pregnant, or have illness/decrease immunocompetence. The OHS professional will provide information and training pertinent to their individual situation.
- Personnel are advised 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. Likewise, all personnel are advised to contact the OHS professional should they experience any change in health status and require additional training.

Personnel who are not involved with animal care and/or use, but need to enter areas when animals are housed or used are identified by the OHS program

- Personnel from the Physical Plant and Texas Tech Police personnel are given a tour of the facility including PPE available and PPE required in certain areas.
- Physical plant personnel who have exposure to vivarium ductwork and/or maintenance of HVAC filters may wear eye and respiratory protection and have additional training upon request.
- Visitors that are authorized by the LARC Director to access the vivarium support areas are also required to sign-in/out. Any visitors are escorted by LARC staff or laboratory staff.

Availability and procedures for treatment of bites, scratches, illness or injury.

- In the event of injury or exposure, incidents 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 by the OHS professional and/or Emergency Room.

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 OHS professional.
- When seeking medical attention for an illness or injury, a complete description of exposure to animals is provided to medical personnel. Any spills or potential hazards are reported to Safety Services.

3.3.1.2 **New CITI Account Instructions**

Registration

To set up a new CITI account, go the [CITI website](#) and select "Register". After selecting “Texas Tech University Health Sciences Center El Paso” as your organization affiliation continue through the multiple step process to establish your Username and Password. An eRaider is not required to complete the training. On the CITI curriculum page, select the modules indicated above. This will provide you access to the required modules. TTUHSC El Paso personnel must use their TTUHSC El Paso email address for registration. More information on CITI Training can be found at the [CITI Program Support Center or on the TTUHSC El Paso Research Website](#).

Course Completion

Upon successful completion of the course, you will be able to download a course transcript (for your records). TTUHSC El Paso is also notified of your successful completion of the courses. You will be required to achieve an overall score of at least 80% to successfully complete the courses.

3.3.1.3 **CITI Renewal Training**

All investigators and research staff are required to renew their animal research training at least once every three years; the Conflict of Interest training is every four years. Initial approval of IACUC submissions will be withheld until all study personnel have been verified as having completed/updated training and financial disclosure reports. Additionally, approval of continuing reviews may be delayed if training of any study personnel has lapsed. Renewal training is identical to the initial CITI course.

3.3.2 **Research Financial Disclosure**

All research staff must have a current Research Financial Disclosure statement on file with the ORR in accordance with [TTUHSC EP OP 73.09 Financial Conflicts of Interest in Research](#). The annual disclosure form may be accessed through iRIS via the Conflict of Interest Module under "My Workspaces" at the top left of the iRIS dashboard.

3.3.3 Investigator Conflicts of Interest

All TTUHSC El Paso investigators and study personnel are bound to the policies set forth in [TTUHSC EP OP 52.06 Standards of Conduct and Ethics](#), [TTUHSC EP OP 10.05 Conflicts of Interest and Commitment](#) and [TTUHSC EP OP 73.09 Financial Conflicts of Interest in Research](#). Unaffiliated investigators may also be bound to these policies if their own institutions do not have internal conflict of interest policies. Failure of any PI and associated research personnel to comply with these policies may result in suspension of submission privileges. In accordance with the TTUHSC EP Conflict of Interest in Research Policy, all research personnel are required to disclose any financial conflicts of interest as outlined in the policy. These disclosures are to be made at least annually, and are to be updated more frequently as circumstances change.

If a project is submitted for IACUC review and it is determined that a financial conflict of interest exists, the issue must be referred to the Conflict of Interest in Research Committee (COIRC) established by [TTUHSC EP OP 73.09 Financial Conflicts of Interest in Research](#). The IACUC will not continue the review of a submission until the COIRC has met and made its recommendations, and the investigator has adequately addressed these. The IACUC must also approve the CMP prior to beginning research work. Affiliated entities should submit documentation to the IACUC specifying how the identified conflict of interest will be managed.

Non-financial conflicts of interest (conflicts of commitment, nepotism, etc.) may also interfere with objective conduct of research activities. Such conflicts will be addressed as indicated in [TTUHSC EP OP 10.05 Conflicts of Interest and Commitment](#) and [TTU System Regents' Rules, Chapter 10](#).

3.3.4 iRIS Access

All submissions to the TTUHSC El Paso IACUC must be submitted using the Internet Medical Research Information System (iRIS) software. In order to gain access to the system, all users must first complete the minimum required training consisting of online modules through CITI. The iRIS access request is web-based and can be found at the following website: <https://ttuep.imedris.net>.

INSTRUCTIONS: Click on the “Request New Account” link underneath the login area, and complete the request, including phone numbers, and TTUHSC El Paso email address. Enter ‘N/A’ or ‘NONE’ in fields that do not apply (i.e. Outside collaborators may not have an eRaider). Please add a note detailing the reason for needing access to iRIS (i.e. to participate on an animal research project).

3.4 Who can be a TTUHSC El Paso PI?

Faculty status is required for all PIs. Exceptions may be granted on a case-by-case basis by the VPR. Details may be found in TTUHSC EP OP 73.08 Requirements for PI Status.

3.5 Who can be a PI from an affiliated entity?

Employees of entities affiliated with TTUHSC El Paso may not be designated as a PI in a research study. Collaborators from institutions may be listed in other roles, and must comply with all TTUHSC El Paso policies and procedures.

3.6 Non-Salaried Appointments

Personnel with a Non-Salaried faculty appointment may not be PIs on TTUHSC El Paso IACUC applications, but may be listed as coinvestigators. If listed as participants in a project, non-salaried faculty must comply with all TTUHSC El Paso policies and procedures.

3.7 Non-TTUHSC EP Research Personnel

Non-TTUHSC EP personnel who will be conducting research activities on campus will first need to submit an application to be processed as a research volunteer. This is done through the ORR and includes completion of safety training courses, HIPAA training, a criminal background check, orientation, and an immunization review. Additional information can be found at: <http://el Paso.ttuhs c.edu/research/orr/volunteer.aspx>. Successful completion of the prerequisites will allow the personnel to obtain an iRIS account, once research training has been completed, and to be listed as approved research personnel on protocols. Approved research activities may be limited.

Non-TTUHSC EP personnel who will be collaborating on a research project and will not be physically present on campus will not be processed as a research volunteer and do not obtain an iRIS account. Typically, personnel in this position are considered to be consultants, may only be involved in the analysis of deidentified data, and/or they may have their own institutional IACUC approval to collaborate on the project.

3.8 PI Responsibility for Research Activities

The PI retains ultimate responsibility for the conduct of **all** research activities as specified in the IACUC-approved protocol and for submission of all required documents including the application, protocol, forms, responses to stipulations, revisions, reports, and any other documentation, including those made by authorized research personnel in accordance with TTUHSC El Paso IACUC Policies and Procedures. While duties related to the conduct of the research may be delegated to other members of the research team, the authority for and conduct of research remain with the PI.

3.8.1 Notice of Absence

PIs shall notify the IACUC in writing as soon as possible prior to any employment change, extended absence, or faculty development leave during which the PI will be engaged in research (See [TTUHSC EP OP 60.02 Faculty Development Leaves of Absence](#)). The PI shall submit information and/or an amendment to the IACUC designating an investigator responsible for any active research study during PI's absence. Notice and/or amendments shall be made in accordance with local IACUC submission requirements.

3.9 Preparing the IACUC Submission

The TTUHSC El Paso IACUC uses the web-based iRIS program to review and track research study information. PIs and research personnel **must use** this software to submit study-related information to the IACUC. The iRIS site is located at <https://ttuep.imedris.net>. In order to obtain access to iRIS, you must first complete required training (stated previously) and then "Request a New Account" by clicking on the button on the iRIS home page. After your account is activated, you will return to this website to enter your assigned user ID and password.

Delays in the approval of initial applications include the absence of adequate detail for the IACUC to evaluate the study's purpose and/or procedures. Investigators are required to

provide specific information detailing the list of all research procedures. There is never too much detail when describing study procedures. The more complete the initial description, the less likely that time will be spent with correspondence back and forth between the PI and the IACUC. IACUC administrative staff is available to respond to questions by email or telephone.

In addition, the Attending Veterinarian is a helpful resource for investigators who are preparing protocols. The IACUC strongly recommends contacting the AV early in the process of preparing applications, renewals, or amendments to provide advice on the appropriate and optimal species-specific uses of procedures, anesthesia, analgesia, and euthanasia.

The following should be submitted to the IACUC during the initial review process:

- Complete IACUC application form;
- Full protocol;
- Copies of letters of assurance or cooperation with research sites (as applicable);
- Documentation of approval by other TTUHSC EP institutional committees as applicable;
- Ensure that a current Curriculum Vitae of the PI is uploaded under 'My Profile' in iRIS.

Materials for initial review shall be submitted by the established deadlines (see the IACUC website for current deadlines at <https://el Paso.ttuhs.c.edu/research/committees/iacuc/submission-deadlines.aspx>).

3.9.1 Relation to Other Committees

The TTUHSC El Paso IACUC functions independently of, but in coordination with other TTUHSC EP research committees, including but not limited to:

- [Conflict of Interest Research Committee](#) (COIRC)
- [Institutional Biosafety Committee](#) (IBC)
- [Institutional Review Board](#) (IRB)
- [Radiation Safety Committee](#) (RSC)

The IACUC may request that approval from any of these, or additional, committees be obtained prior to TTUHSC El Paso IACUC approval. For detailed information refer to [TTUHSC EP OP 73.14 Research Compliance](#).

3.10 Storage, Handling, and Dispensing of Chemical Agents or Controlled Substances

The PI is directly responsible for the accounting of all chemicals and/or controlled substances and should maintain internal controls to ensure guideline compliance.

The PI must designate a single, centralized location as custodian to receive and manage the chemical agents or controlled substances.

Regardless of where these are retained, the PI, or other designated individual, will maintain records of the product's delivery to the trial site, the inventory at the site, the appropriate storage requirements are met (for example: refrigerator temperature logs, locked cabinet site, locked safe site), the use by each animal, and the disposition of unused products. These records will include dates, quantities, batch/serial numbers, and expiration dates (if

applicable). Researchers should maintain records that document adequately that the animals are provided the doses specified by the protocol.

All controlled substances must be stored in a designated, locked safe and dispensed by trained, approved and authorized study personnel.

3.11 Packaging and Shipment of Infectious Materials

The PI is responsible for overseeing training of all study personnel and ensuring that all specimens packaged and shipped from TTUHSC El Paso comply with [TTUHSC EP OP 75.13 Shipment of Hazardous or Infectious Materials](#). A PI will also be required to have an approved Institutional Biosafety Committee License with designated study personnel listed.

3.12 Recordkeeping and Confidentiality

3.12.1 Recordkeeping

Every PI is required by TTUHSC El Paso and federal regulations to maintain paper and/or electronic records relating to the use of animals in research. Correspondence with the IACUC, notices of approval, other applicable documents must be maintained in the PI's records.

3.12.2 Surgery Recordkeeping

All surgeries on non-rodent mammals require detailed Standard Operating Procedures on file with IACUC in the approved protocol. The health records and protocol are kept with the animal at all times along with records of pre-operative, operative and post-operative care. These forms must be complete and available to all project personnel, the Animal Vivarium, and the Attending Veterinarian so the investigator can be quickly contacted and appropriate treatment decisions can be made. Animal incident reports are required for all unexpected and serious complications including, but not limited to death.

Surgery and recovery in rodents should be documented according to the requirements including post-procedure care and health alert cards.

All records of animal research are subject to inspection by federal authorities, TTUHSC El Paso officials, including but not limited to ORR and Compliance Officers, VPR and the IACUC. Research records (including data/specimens) are the property of TTUHSC El Paso and shall not be transferred to another entity without prior approval of the VPR. All research records must be kept for a minimum of three years after the close of the study at the local research site, by the PI or PI's department.

3.12.3 Confidentiality

An issue of primary importance is confidentiality. The PI must have sound plans to protect the confidentiality of the research records.

Care should be taken to explain the mechanisms that have been devised to protect confidentiality, for example, the use of encrypted data coding systems or safely locked files in private offices. Furthermore, the PI should describe who has access to the data and under what circumstances a code system may be broken. Without appropriate safeguards, problems may arise from long-term retention of records.

The conditions for maintaining confidentiality of the research records are required for the life of the data. These rules apply equally to any and all research conducted by faculty, staff, and students.

3.12.4 Recording Research Animals

To ensure that TTUHSC El Paso's dedication to animal welfare is appropriately represented, the production and use of photos or videos of animal research must be approved prior to production.

The Principal Investigator (PI) must make a request in the appropriate IACUC protocol. The IACUC reviews and, if appropriate, approves the request. Photography or videotaping may proceed only after review and approval by the IACUC. Photos and videos must not contain any identifying information (such as building, room number, and PI names) and should be stripped of location information prior to release. GPS information must also be stripped prior to release.

3.13 Useful Tools for Investigators

3.13.1 PI Responsibilities

The PI promotes good clinical practices in the conduct of investigations by assuring adherence to protocol requirements, protecting the welfare of animals, assuring the integrity of data generated at the site, and directing the conduct of the investigation according to federal and state regulations and guidance documents.

PROVIDES INVESTIGATOR QUALIFICATIONS AND AGREEMENTS BY:

- maintaining a current, up-to-date, signed and dated curriculum vitae
- maintaining current licensure to practice, if applicable
- providing the sponsor, as applicable, and IACUC with documentation of credentials as requested
- demonstrating the proper education, training and experience to conduct the investigation
- assuming responsibility for the conduct of the investigation
- signing the Form FDA 1572 or Investigator agreement, as appropriate
- signing the protocol as required
- documenting the financial aspects of the trial as appropriate
- disclosing conflicts of interest as described in the regulations
- complete institutional mandated research training as required

ASSURES PROTOCOL COMPLIANCE BY:

- possessing a thorough understanding of the requirements of each protocol
- assessing overall protocol feasibility
- not implementing any protocol deviation or changes without prior review and approval by the IACUC

ASSURES INITIAL AND ONGOING IACUC REVIEW BY:

- providing the IACUC with adequate information to initially review the study (i.e., protocol, grant application, etc.)
- providing the IACUC with documents for ongoing review (i.e., amendments to the protocol, unanticipated events, violations or new information)
- securing written IACUC approval prior to initiating the study or instituting any changes to the protocol as approved
- providing written summaries of the trial status to the IACUC annually, or as requested
- providing written information of premature termination or suspension of a trial
- providing the IACUC with all documents subject to their review

DETERMINES ADEQUATE RESOURCES ARE AVAILABLE TO CONDUCT THE STUDY BY:

- having adequate number of qualified staff to conduct the study
- having adequate facilities to conduct the study
- assuring he/she has adequate time to conduct and supervise the study

ASSURES DOCUMENTATION OF STUDY-RELATED PROCEDURES, PROCESSES AND EVENTS BY:

- documenting deviations from the approved protocol
- documenting adverse experiences
- providing study reports as requested by the sponsor, IACUC and regulatory authority(ies)

ASSURES THE PROPER USE AND STORAGE OF CHEMICAL AGENTS AND/OR CONTROLLED SUBSTANCES BY:

- being thoroughly familiar with the use of the product(s)
- ensuring the proper use, storage and documentation of the storage environment of the product(s) at the site

DIRECTS SITE OPERATIONS BY:

- communicating effectively with research team, IACUC and sponsor, when applicable
- meeting regularly with the research team to discuss protocol progress
- assuring that all research staff are informed about the protocol
- being knowledgeable about regulatory requirements and applicable\ GCP standards
- participating in monitoring visits and inspections as appropriate
- permitting monitoring, auditing, and inspection by the sponsor, institution, and regulatory authorities
- making available to monitors, auditors, IACUC and regulatory authority(ies) all requested research records
- delegating authority at the site appropriately
- assuring that all research staff are informed about their duties and functions
- maintaining a list of qualified persons and their corresponding delegated duties

MAINTAINS PROFESSIONAL AND TECHNICAL KNOWLEDGE BY:

- attending educational workshops
- reviewing professional publications
- participating in professional societies

3.13.2 **Regulatory Files Binder Items**

The following items are maintained in a regulatory binder(s), as needed, for individual projects.

Binder Cover

This cover helps identify a binder without having to open the binder. The binder cover should include the PI name, protocol title, IACUC number.

Table of Contents

To organize the binder so that documents can be found quickly.

Study Team Contact Information (optional)

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This includes a 24-hour contact person/number. This is meant to provide contact information for all the study team members and the sponsor, if applicable.

Delegation of Authority Log

This document helps identify the study team members and their roles, responsibilities, signature and initials, and the dates that they worked on the study.

Protocol Forms

A copy of the complete final protocol for the study. If required, ensure that the protocol has been signed and dated by the PI and research personnel.

Protocol Amendments

Retain copies of any amendments to the original final protocol made by the investigator. Modifications may be in the form of new pages to be inserted in the protocol, an addendum to the protocol in the form of a letter, or contained in the body of an amended protocol. Note that all protocol amendments must be reported to the IACUC.

Investigator CVs and Licenses

Copies of the current CVs for all personnel listed on the study.

Training Records

Maintain a training log in order to document that all the personnel involved with the clinical trial are adequately trained and informed about the protocol and their trial-related functions.

Financial Disclosure Forms

To document for the sponsor and TTUHSC EP, potential conflicts of interest or lack thereof. If the sponsor or TTUHSC EP determines that a COI exists, a management plan must accompany the disclosure forms.

IACUC Membership Rosters (optional)

To document IACUC compliance with applicable regulatory requirements.

Ancillary Approvals

Retain all approvals to conduct the study at locations outside of TTUHSC EP. Maintain all approvals and additional reviews from ancillary committees such as IBC.

Laboratory Certification (if applicable)

Obtain a copy of the most recent certificate issued showing the expiration date. CAP and CLIA should be retained to certify that the lab has valid credentials.

Unanticipated Event Reports

All unanticipated events must be reported promptly to the IACUC.

CHAPTER 4 GLOSSARY

ACTIVE The status of an open protocol under which work is being conducted and/or animals are being held.

ADMINISTRATIVELY CLOSED STATUS Decision of the IACUC based on PI non-responsiveness to IACUC requests or no study activity at the local site for a period of three or more years. This can occur prior to initial IACUC approval or any time following IACUC approval. No further activity is permitted for studies which are administratively closed. Any further activity on such studies will require the submission of a new application to the IACUC.

ALCOA This refers to the attributes that should be demonstrated in all source documents.
Attributable-It should be clear who has documented the data.
Legible-Readable and signature lines identifiable.
Contemporaneous-The information should be documented in the correct time frame along with the flow of events. If a clinical observation cannot be entered when made, chronology should be recorded. Acceptable amount of delay should be defined and justified.
Original-Original, if not original should be exact copy; the first record made by the appropriate person. The investigator should have the original source document.
Accurate-Accurate, consistent and real representation of facts.

ANIMAL Refers to live vertebrates beyond the fetal stage (mammals) or that have hatched (other vertebrates). The IACUC does not regulate activity associated with non-vertebrate animals or animal carcasses.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS) A multi-faceted agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities.

ANIMAL BIOSECURITY All measures to control known or unknown infections in laboratory animals.

ANIMAL CARE AND USE PROGRAM The policies, procedures, standards, organizational structure, staffing, facilities, and practices put into place by an institution to achieve humane care and use of animals in the laboratory and throughout the institution. It includes the establishment and support of an IACUC or equivalent ethical oversight committee and the maintenance of an environment in which the IACUC can function successfully to carry out its responsibilities under the Guide and applicable laws and policies.

ANIMAL CARE PERSONNEL Refers to those that are caring for animals and are appropriately trained (i.e. animal husbandry, administration, veterinary medical technology, etc.)

ANIMAL FACILITY Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation, and where vertebrates are kept for more than 12 hours. Also referred to as Study Area.

ANIMAL USE Any contact with live vertebrates, including the proper care, use, and humane treatment, used in research, testing, or teaching.

ANIMAL WELFARE ACT OF 1966 (AWA) This term is normally used for both the Act itself and the resulting regulations. The AWA is a federal law that regulates the treatment of animals (all mammals and birds except mice, rats and birds bred for research purposes) in research, exhibition, transport, and by dealers.

ANIMAL WELFARE ASSURANCE A key document that defines the relationship of the institution with PHS. It sets forth the responsibilities and procedures of the institution regarding the care and use of laboratory animals.

ANNUAL STATUS REPORT Periodic review of a research study by an IACUC to evaluate whether risks to animals are reasonable and to verify that the study continues to meet regulatory and institutional requirements. Annual status review shall be conducted once per year.

APPROVED The IACUC has reviewed the study and made a determination that the study has met all requirements.

ATTENDING VETERINARIAN The TTUHSC El Paso veterinarian serves on the IACUC, has delegated authority for all protocols, animal facilities and all animals at the institution. The Attending Veterinarian is available to make recommendations and provides veterinary care.

AUDIT A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

AUTHORIZED OFFICIAL An officer of an entity with the authority to speak for and legally commit the entity to comply with requirements of the federal regulations regarding the involvement of animal subjects in research.

BASELINE 1. Information gathered at the beginning of a study from which variations found in the study are measured. 2. A known value or quantity with which an unknown is compared when measured or assessed.

BENEFIT A valued or desired outcome; an advantage.

BIOLOGIC Any therapeutic serum, toxin, anti-toxin or analogous microbial produce applicable to the prevention, treatment, or cure of diseases or injuries.

BLINDING (OR MASKING) A clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned which interventions.

CANCELLED Study status assigned to a research project the investigator or study sponsor decided to stop prior to study completion as outlined in the approved protocol.

CASE REPORT FORM (CRF) A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

CLINICAL RESEARCH ASSOCIATE (CRA) Person employed by the study sponsor or CRO to monitor a clinical study at all participating sites. See also, monitor.

CLINICAL RESEARCH COORDINATOR (CRC) Site administrator for the clinical study. Duties are delegated by the investigator. Also called research, study or healthcare coordinator, and data manager, research nurse or protocol nurse.

CLOSED The status of a protocol that was approved, but has either expired or been terminated at the request of the Principal Investigator or by IACUC action.

CLOSED TO ACCRUAL Investigator or sponsor initiated decision to stop enrollment. This may be permanent or temporary. *Note:* Study interventions will continue as needed for animals currently enrolled and ongoing continuing review is also required.

CLOSURE Study approved by the IACUC that may be closed by the investigator, the sponsor, the IACUC, TTUHSC El Paso, or by an affiliated entity. No research activities may occur after the closure date.

COLLABORATIVE RESEARCH is defined as research conducted in cooperation with an institution or faculty that is not affiliated with TTUHSC EP. When two or more institutions are engaged in research, multiple IACUCs are responsible for providing oversight. As such, separate applications may be necessary; however, to avoid duplicate review an IACUC Reliance Agreement may be arranged to establish one IACUC as the designated IACUC of Record.

COMPLETED Study status assigned to projects that have been closed by the PI after completion of all research related interventions and collection of animal data.

COMPLIANCE Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory and institutional requirements.

COMPLIANCE OFFICER Responsible for monitoring compliance and corrective actions and works with the IACUC Chair in submission of IACUC reports.

CONFIDENTIALITY The treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure; refers

also to the agreement between the investigator and participant in how data will be managed and used ensuring that information is accessible only to those authorized to have access.

CONFLICT OF INTEREST A conflict of interest refers to a situation in which an Employee's financial, professional, or other personal considerations may directly or indirectly affect, or have the appearance of affecting, the Employee's judgment in exercising any duty or responsibility, including the conduct or reporting of research, owed to the Institution.

CONFLICT OF INTEREST IN RESEARCH COMMITTEE The Conflict of Interest Committee is appointed by the VPR to review and oversee the management of financial conflicts of interest in research. See [TTUHSC EP OP 73.09 Financial Conflicts of Interest in Research](#).

CONTINUING NON-COMPLIANCE A pattern of repeated non-compliance which continues:

- after initial discovery and after IACUC approval of corrective action plan and suggests that non-compliance will continue if there is no intervention, or
- increases the risk of serious non-compliance, or
- if continued, could significantly increase risks to, or jeopardize the safety, welfare, and/or rights of subjects or others, or
- if continued, could decrease potential benefits (the scientific integrity of the research).

CONTRACT An agreement; as used here, an agreement that a specific research activity will be performed at the request, and under the direction, of an entity providing funds. Research performed under the contract is more closely controlled by the entity than research performed under a grant.

CONTRACT RESEARCH ORGANIZATION (CRO) A person or an organization (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's study-related duties and functions.

CORRECTIVE AND PREVENTIVE ACTION (CAPA) An effective CAPA program will include incident identification, investigation of incident causality, development of an action plan based on root cause analysis, action plan verification and validation, action plan implementation, effectiveness checks and closure.

DATA SAFETY MONITORING BOARD A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial. Also referred to as a data monitoring committee (DMC).

DATA USE AGREEMENT (DUA) is an agreement between Texas Tech University Health Sciences Center El Paso and an outside party (e.g., contractor, private industry, academic institution, federal or state agency), when the outside party requests the use of non-public data that is subject to some restrictions on its use. Specifically, DUAs address important issues such as limitations on use of the data, obligations to safeguard the data, and privacy rights that are associated with transfers of confidential or protected data.

DECLINED Study status assigned to projects submitted to the IACUC for review and assessed to be not acceptable for IACUC review. The most common reason is the project does not meet the definition of animal research as designed and therefore does not require IACUC review.

DE-IDENTIFIED No information is linked to the specimen that would allow the investigator to identify the donor **and** no attempts will be made by the investigator to identify the donor using genetic analysis technology, detailed demographic/clinical parameter matching or other means.

DESIGNATED REVIEWER An individual or individuals granted the authority by the IACUC Chair or IACUC to perform the activities set forth in Section 2.9.

DEVICE (MEDICAL) A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices may include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

DISAPPROVED The IACUC has reviewed the study and determined that it is not approved and may not receive further review. This only applies to studies that have not previously been approved. See section on disapproval for request to reconsider requirements and timeframes.

DOCUMENTATION All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

DOUBLE-BLIND The design of a study in which neither the investigator nor the subject knows which medication (or placebo) the subject is receiving.

DRAFT Status of a research project that has not been submitted to the IACUC.

DRUG Any chemical compound that may be used on or administered to animals as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

ENDPOINT Overall outcome that the protocol is designed to evaluate. Common endpoints are severe toxicity, disease progression, or death.

ENGAGEMENT IN A RESEARCH PROJECT Includes *any one or more* of the following conditions:

- The research is conducted by or under the direction of any employee, student or agent of TTUHSC El Paso in connection with responsibilities to TTUHSC El Paso.
- The research is conducted by or under the direction of any employee, student or agent of an entity with which TTUHSC El Paso has a written agreement to serve as the IACUC of record, if the project falls under the auspices of the agreement.
- The research involves non-public information maintained by TTUHSC El Paso or an affiliated entity.
- The research is conducted in accordance with an assurance filed with the DHHS Office of Animal Research Protection in which a TTUHSC El Paso IACUC is designated as the IACUC of record.

ENGINEERING STANDARD A standard guideline that specifies in detail a method, technology, or technique for achieving a desired outcome; it does not provide for modification in the event that acceptable alternative methods are available or unusual circumstances arise.

ENTITY An organization, institution or being that has its own existence for legal or tax purposes, is legally separate from TTUHSC El Paso, and possess OHRP-approved Assurances and IACUC Agreements with TTUHSC El Paso.

EXISTING Data or specimens already have been collected and stored at the time the research is proposed to the IACUC for a determination of whether the research is exempt. Material collected after the date of the initial submission to IACUC is not “existing” for purposes of this policy.

EXPEDITED REVIEW Review of proposed research by the IACUC Chair or a designated voting member or group of voting members rather than by the entire IACUC. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

EXPERIMENTAL Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness.

EXPERIMENTAL ENDPOINT When the scientific aims and objectives have been reached.

FOLLOW-UP Status assigned when either: **A)** study involving interventions/treatment/procedures have been completed and procedures for all locally enrolled subjects are the same as for patients managed off study or **B)** identifiable research data continue to be maintained pending further analysis. *NOTE:* Continuing reviews are required.

FOOD DRUG AND COSMETIC ACT (FD & C Act) States only drugs, biologics and devices proven safe and effective can be marketed.

FULL COMMITTEE REVIEW Review of proposed research at a convened meeting, at which a majority of the voting membership of the IACUC is present, including at least one member whose primary concerns are in non-scientific areas. For the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

GOOD CLINICAL PRACTICE (GCP) is an international quality standard that is provided by ICH, an international body that defines standards, which governments can transpose into regulations for clinical trials involving animal subjects.

GRANT Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

HUMANE CARE Those actions taken to ensure that laboratory animals are treated according to high ethical and scientific standards.

HUMANE ENDPOINT The point at which pain or distress in an experimental animal is prevented, terminated, or relieved.

INCLUSION CRITERIA A list of criteria that must be met by all study subjects.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) A specially constituted review body established or designated by an entity, responsible for the assessment and oversight of the institution's program components and facilities. At TTUHSC El Paso, the IACUC is deemed to be a medical committee.

INSTITUTIONAL OFFICIAL The individual who, as a representative of senior administration, bears ultimate responsibility for the program and is responsible for resource planning and ensuring alignment of program goals with the institution's mission.

INSTITUTIONAL REVIEW BOARD (IRB) A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. At TTUHSC El Paso, the IRB is deemed to be a medical committee.

INSTITUTIONAL VETERINARIAN (iVet) The iVet is the individual responsible for the health and well-being of all animals used in the TTUHSC El Paso ACUP. The iVet directly oversees all aspects of animal care and use to ensure compliance with Federal, state, and local regulations as well as contemporary Standards of Veterinary Care. The iVet serves as the primary Attending Veterinarian (AV). The iVet reports directly to the IO.

INTERNET MEDICAL RESEARCH INFORMATION SYSTEM (IRIS) Internet Medical Research Information System—the software through which all IACUC applications, reviews and approvals are submitted and through which information is communicated between investigators and the IACUC.

INVESTIGATOR Any faculty member using animals (live vertebrates) in research or teaching is classified as an Investigator for IACUC purposes. In addition, any other person serving as Principal Investigator on a research grant is also considered an Investigator, regardless of whether or not they will have physical contact with animals.

INVESTIGATOR'S BROCHURE A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in animal subjects.

IACUC RECORDS IACUC records include but are not limited to: all minutes of IACUC meetings, a copy of all proposals reviewed including all amendments, investigator brochures, and any supplemental information including recruitment and informational materials, consent forms, information submitted for continuing review, all correspondence, and IACUC membership with a resume for each member.

LABORATORY ANIMALS Any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research testing, or teaching.

MACROENVIRONMENT The physical environment of the secondary enclosure i.e. room, barn, or an outdoor habitat.

MICROENVIRONMENT The immediate physical environment surrounding the animal i.e. cage, pen or stall.

MINIMAL RISK The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the participant's daily life or during the performance of routine physical or psychological examinations or tests.

MINOR DEFICIENCY An area or situation that is not in compliance with the AWR or PHS Policy, but does not pose a threat to animal health and safety.

MONITOR Person employed by the sponsor or CRO who reviews study records to determine that a study is being conducted in accordance with the protocol. A monitor's duties may include, but are not limited to, helping to plan and initiate a study, and assessing the conduct of studies. Monitors work with the clinical research coordinator to check all data and documentation from the study. See also CRA.

MONITORING Overseeing the progress of a study and ensuring that it is conducted, recorded, and reported in accordance with the protocol and applicable regulatory requirements.

NATIONAL INSTITUTES OF HEALTH (NIH) Agency within DHHS that provides funding for research, conducts studies and funds multi-site national studies.

NATIONAL RESEARCH COUNCIL (NRC) To bring into cooperation government, educational, industrial, and other research organizations with the object of encouraging the investigation of natural phenomena, and increased use of scientific research in the development of American industries, the employment of scientific methods in strengthening the national defense, and such other applications of science as will promote the national security and welfare.

NON-COMPLIANCE A situation, event or process in research involving animals that does not follow the procedures or design specified in an approved protocol, and/or that violates animal welfare regulations under the jurisdiction of the TTUHSC El Paso IACUC or TTUHSC EP IACUC Policies and Procedures.

NONAFFILIATED MEMBER Member of an IACUC who has no ties to the parent entity, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker, or others).

OFFICE OF LABORATORY ANIMAL WELFARE (OLAW) Provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

OFFICE OF RESEARCH RESOURCES (ORR) Office responsible for the oversight and direction of the animal research protection program at TTUHSC El Paso, which includes administrative oversight of the IACUC, the TTUHSC El Paso Research Compliance Program, and TTUHSC El Paso educational requirements for animal research.

OPEN Status of an IACUC approved research project that has not yet expired or been closed.

PENDING–SUBMITTED FOR INITIAL REVIEW Status of a research project that has been submitted to the IACUC for review. This status label remains until a final decision regarding the project is made by the IACUC. Decisions by the IACUC may include a request for additional information, or may be approved, declined, or disapproved.

PERFORMANCE STANDARD A standard or guideline that, while describing a desired outcome, provides flexibility in achieving the outcome by granting discretion to those responsible for managing the animal care and use program, the researcher, and the IACUC.

PERSONAL PROTECTIVE EQUIPMENT (PPE) Suitable attire for use in the animal facility and laboratories in which animals are used i.e. gloves, masks, face shields, head covers, coats, coveralls, shoes or shoe covers).

PERSONAL SUPERVISION The supervisor is present in the room with the person being supervised while animals are being used.

PHASE Food and Drug Administration (FDA) descriptions of the clinical trial of a drug based on the study's characteristics, such as the objective and number of participants. There are five phases [1]:

- Phase 0: Exploratory study involving very limited animal exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies)
- Phase 1: Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.
- Phase 2: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance, called a placebo, or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.
- Phase 3: Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.
- Phase 4: Studies occurring after FDA has approved a drug for marketing. These including postmarket requirement and commitment studies that are required of or agreed to by the study sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.

PRACTICE STANDARD The application of professional judgment by qualified, experienced individuals to a task or process over time, an approach that has been demonstrated to benefit or enhance animal care and use.

PRINCIPAL INVESTIGATOR (PI) A single individual who has overall responsibility on a Protocol Application for Animal Use. In the case of projects funded by government sources, this individual must be the same as the Principal Investigator on the grant. The Principal Investigator on a protocol is required to be a TTUHSC EP faculty member. Any other Investigators involved with the project must be listed on the Protocol Application as Co-Investigators. The PI has ultimate responsibility for the design and conduct of a research project.

PROJECT All components of an animal research submission to the IACUC. Used interchangeably with the term STUDY.

PROTOCOL The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IACUC for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. Normally refers specifically to a protocol that has been approved by the IACUC, as opposed to an Application submitted for review.

PROTOCOL AMENDMENT Changes or clarifications made in writing to the original protocol.

PUBLIC HEALTH SERVICE (PHS) The agency that serves the office of the Surgeon General, includes agencies whose mission is to improve the public health.

PUBLIC HEALTH SERVICE POLICY This Policy is applicable to all PHS-conducted or supported activities involving animals, whether the activities are performed at a PHS agency, an awardee institution, or any other institution and conducted in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals shall comply with this Policy, or provide evidence to the PHS that acceptable standards for the humane care and use of the animals in PHS-conducted or supported activities will be met.

QUARANTINE The separation of newly received animals from those already in the facility, in a way that prevents potential spread of contaminants, until the health and possibly the microbial status of the newly received animals have been determined.

QUORUM A majority of the voting members appointed to the IACUC membership. A quorum must include at least one member whose primary concerns are in non-scientific areas. A quorum must be established, recorded, and maintained for the deliberation and vote on all matters requiring a vote.

RECRUITMENT Act of enrolling subjects with the proper inclusion criteria.

REDUCTION Involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information.

REFINEMENT Modifications of husbandry or experimental procedures to enhance animal well-being and minimize or eliminate pain and distress.

RELIANCE AGREEMENT A formal, written document that provides a mechanism for an institution or individual engaged in research to delegate institutional review board (IACUC) review to an independent IACUC or an IACUC of another institution. Institutions may use other descriptive terms, e.g. authorization agreement, reciprocity agreement, memorandum of understanding, etc.

RELYING IACUC The IACUC of the institution where the research will take place and which will rely on an external IACUC which will serve as the IACUC for a multi-center study.

REPLACEMENT Methods that avoid using animals.

REPRESENTATIVE A person who makes decisions on behalf of another person. In animal subjects' research, an individual or judicial or other body may be authorized to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

REQUEST FOR ADDITIONAL INFORMATION A request made by the IACUC for changes or clarifications to studies it has reviewed.

RESEARCH A systematic or clinical investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge. ([45 CFR 46.102\[d\]](#); [21 CFR 56.102\[c\]](#)).

REVIEW (OF RESEARCH) The oversight of research on a periodic basis by the IACUC. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis.

REVIEWING IACUC The IACUC that is responsible for the review, approval and regulatory oversight of a multi-center research study and serving more than one site. Sometimes referred to as the IACUC of Record.

RISK The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk".

SERIOUS NON-COMPLIANCE Non-compliance, which could significantly:

- Increase risks to; or
- jeopardize the safety, welfare, and/or rights of subjects or others; or
- decrease potential benefits (the scientific integrity of the research).

SIGNIFICANT DEFICIENCY One that is or may be a threat to the health and safety of the animals or personnel.

SOURCE DATA/DOCUMENTS All information in original records of clinical findings, observations, or other activities in a study necessary for the reconstruction of that study. Source data are contained in source documents, which may include, but are not limited to hospital records, laboratory notes, subject evaluation checklists, x-rays, subjects' files, or pharmacy records.

SPECIMEN Any biological material obtained from or derived from patients or animal research subjects. This includes, but is not limited to: fixed, frozen or fresh pathology or autopsy specimens; blood; urine; saliva; CSF; semen; breast milk; and any purified DNA, RNA, proteins, cell lines or clones.

SPONSOR A person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used

involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator) and the employees are considered to be investigators.

SPONSOR MONITORING REPORT a report submitted by a sponsor to the PI and/or research team after each monitoring visit. Each report summarizes what the monitor reviewed during the visit, what findings were noted, and what actions were recommended or taken to ensure compliance.

STANDARD TREATMENT The currently accepted treatment or intervention considered to be effective in the treatment of a specific disease or condition.

STANDARDS OF CARE Treatment regimen or medical management based on state of the art participant care.

STUDY All components of an animal research submission to the IACUC. Used interchangeably with the term PROJECT.

STUDY APPLICATION The application submitted for Animal Use.

STUDY CLOSURE Study approved by the IACUC that may be closed by the investigator, the sponsor, the IACUC, TTUHSC El Paso, or by an affiliated entity. No research activities involving interaction with participants or use of their identifiable information may occur after the closure date.

STUDY STATUS Label assigned to a study signifying subject enrollment, treatment and/or activity. Labels include: Draft, Pending-Submitted for Initial Review, Open, Exempt, Closed to Accrual, Follow-up, Cancelled, Completed, Declined, Disapproved, Suspended, Terminated, and Withdrawn.

SUB-INVESTIGATOR Helps design and conduct investigation at a study site.

SUSPENDED Study status assigned to research projects that have been previously approved and the IACUC has made a determination that approval is suspended. The PI will be instructed regarding the extent of the suspension. Instructions may include ceasing research procedures, ceasing data collection and or cessation of all research activities pending final IACUC determination in writing.

SUSPENSION/TERMINATION IACUC approval is suspended/terminated and all research activity halted as the result of unanticipated problems involving risks to animals or others; Requires prompt reporting to federal regulatory authorities and TTUHSC El Paso.

TABLED Study status assigned when the IACUC has reviewed the research project and determined that extensive changes are necessary. The study will be re-reviewed at a convened meeting of the IACUC once changes have been made.

TERMINATED Study status assigned to projects that have been permanently closed as a result of 1) the need to protect the safety, welfare, and rights of subjects, 2) serious or continued non-compliance and/or 3) other situations, as the Board deems appropriate.

THE GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS (GUIDE) published by the National Academy of Sciences under the auspices of the National Research Council (NRC), and serves as a standard for laboratory animal welfare.

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA) The agency that provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management.

WEAVE Institutional program to provide ongoing, systematic planning and assessment of institutional effectiveness

WITHDRAWN (STUDY STATUS) Study status assigned to a research project that was submitted for IACUC review and for various reasons the PI decides to withdraw the submission from further consideration by the IACUC.