

Texas Tech University Health Sciences Center

Institutional Review Board (IRB) For the Protection of Human Subjects

IRB #1: Lubbock/Odessa
IRB #2: Amarillo
IRB #3: El Paso



POLICIES AND PROCEDURES MANUAL

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1.0 INTRODUCTION

The Institutional Review Board (“IRB”) Policies and Procedures Manual provides the Texas Tech University Health Sciences Center (“TTUHSC”) research community with an overview of the federal regulations and TTUHSC policies that govern the conduct of research involving human subjects.

There are three registered TTUHSC IRBs:

- IRB #1 Lubbock/Odessa
- IRB #2 Amarillo
- IRB #3 El Paso

These may also be referred to as “local IRB”.

The IRB Policy and Procedures Manual will be reviewed annually each December by the Human Research Protection Office (“HRPO”) with recommendations for revision forwarded to the IRB Chairs and Associate Vice President for Research by February 1.

The Institutional Review Board (IRB) is a committee of the Texas Tech University Health Sciences Center established for the purpose of carrying out requirements governing research involving human subjects under federal law and TTUHSC policies and procedures. The IRB, or any committee thereunder, is a “medical committee” as defined under Texas Health & Safety Code chapter 161, and/or other applicable state and federal statutes. All documents generated by, submitted to, or for the purposes of fulfilling IRB committee duties are confidential and privileged as “medical committee documents.”

Access to Documents

Certain IRB documents are privileged and confidential Medical Committee records, not subject to disclosure except to authorized TTUHSC representatives, including IRB, TTUHSC Compliance personnel, TTUHSC Human Research Protection Office (HRPO), the AVPR, and federal regulatory officials. The IRB Office shall make its records accessible for inspection and copying by the authorized entities named above. Requests for authorization to access IRB records shall be made to the HRPO.

2.0 ABOUT THE INSTITUTIONAL REVIEW BOARDS

2.1 Purpose of the Institutional Review Boards

The TTUHSC mission includes conducting human subjects research in compliance with applicable laws and regulations, including but not limited to U.S. Department of Health and Human Services (“DHHS”) regulations and TTUHSC policy. TTUHSC has signed an Assurance with DHHS. As set forth in this Assurance, TTUHSC has three (3) registered Institutional Review Boards (IRBs) whose purpose is to protect the rights and welfare of human subjects participating in research activities conducted at TTUHSC and any other entity for which TTUHSC has been designated as the IRB of record in an Assurance filed with DHHS, Office for Human Research Protections (“OHRP”) and by written agreement between the parties. These Institutional Review Boards are located at the Lubbock-Odessa, Amarillo, and El Paso campuses and provide initial and continuing review of research applications and protocols involving human subjects.

Each IRB shall uphold the TTUHSC Assurance (Multiple Project Assurance No. 1078 and succeeding Federal Wide Assurance) as filed with the U.S. Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP). As set forth in the Assurance, TTUHSC has three registered Institutional Review Boards:

- TTUHSC IRB #1 – 00000096 (LUBBOCK/ODESSA)
- TTUHSC IRB #2 – 00000097 (AMARILLO)
- TTUHSC IRB #3 – 00000098 (EL PASO)

Designation of additional IRBs under the Assurance requires prior notification of and approval by OHRP.

2.2 Principles Governing the IRB

The TTUHSC IRBs are guided by ethical principles applicable to all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles Guidelines for the Protection of Human Subjects of Research, known as the “Belmont Report”). The ethical principles set forth in the Belmont Report are:

- **Respect for Persons:** recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
- **Beneficence:** obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm; and
- **Justice:** fairness in the distribution of research benefits and burdens.

2.3 IRB Scope and Authority

Research involving human subjects (regardless of sponsorship) and all other activities that involve such research in any way must be reviewed and approved by the IRB if one or more of the following apply:

- The research is sponsored by TTUHSC;
- The research is conducted by or under the direction of any employee or agent of TTUHSC in connection with his or her responsibilities to TTUHSC;
- The research is conducted by or under the direction of any employee or agent of TTUHSC using any property or facility of TTUHSC;
- The research involves the use of non-public information maintained by TTUHSC;
- The research is conducted in accordance with an assurance filed with the Office for Human Research Protections in which a TTUHSC IRB is designated as the IRB of record;
- Any employee of TTUHSC is engaged in research in connection with his or her responsibilities to TTUHSC, but not as PI.

Federal regulations govern IRBs and the conduct of human research, principally found in 45 CFR 46 (the “Common Rule”). All references to this regulation are current through revision date October 1, 2003.

All human research which is exempt under section 45 CFR 46.101(b)(1-6) or 45 CFR 46.101(i) will be conducted in accordance with TTUHSC policies and procedures and the Belmont Report.

Whether research is exempt is an IRB decision. The Principal Investigator (PI) shall promptly contact the local TTUHSC IRB for clarification regarding whether a particular activity meets the criteria for human subjects research prior to beginning any phase of the activity.

The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by federal regulations (45 CFR 46.109a) and TTUHSC policy. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by TTUHSC officials. However, as stated in 45 CFR 46.112, TTUHSC officials may not approve research if it has been disapproved by a TTUHSC IRB.

2.4 Signatory Authority

Except with regard to external reports (see Section 2.7 below), the Chair or authorized designee of each TTUHSC IRB shall have signatory power for review and actions taken by each local IRB.

2.5 Federal Regulations and TTUHSC Policy

All research involving human subjects conducted at or in affiliation with TTUHSC shall be conducted in accordance with federal regulations and TTUHSC Operating Policy (HSC OP 73.06, 10.16) and VA policies and regulations where applicable. Applicable federal regulations (as specified in the Code of Federal Regulations, CFR) include, but are not limited to:

- 45 CFR 46, generally known as the Common Rule,
- 21 CFR 50, Human Subject Protection (Informed Consent)
- 21 CFR 56, Institutional Review Boards,
- 21 CFR 312, Investigational New Drug Application,
- 21 CFR 812, Investigational Device Exemptions,

References are current through revision date October 1, 2003 (45 CFR 46) and April 1, 2003 (21 CFR 50, 56, 312, 812).

2.6 TTUHSC Institutional Official and Reporting Procedures

The Associate Vice President for Research (AVPR) is the TTUHSC Institutional Official with overall responsibility for the TTUHSC Institutional Review Boards (see TTUHSC OP 73, MPA-1078 DHHS); the TTUHSC Research Compliance Program and the Human Research Protection Office (HRPO) (see TTUHSC OP 10.16).

Human Research Protection Office (HRPO)

The HRPO is responsible for the oversight and direction of the human research protection program at TTUHSC which includes IRB administration, the Research Compliance Program and TTUHSC human research educational requirements.

Reporting Procedures

IRB Chair(s) shall promptly report pertinent information to the AVPR or other designated TTUHSC official through the HRPO as necessary to facilitate compliance with federal regulations and TTUHSC policy, including the IRB Policies and Procedures.

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

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

The AVPR is responsible and has signatory authority for reporting to external organizations and/or governmental agencies as required under Federal Assurance and TTUHSC policy. (TTUHSC OP 73.06)

Correspondence with governmental agencies and/or external organizations will be maintained in the office of the AVPR; copies shall also be maintained in the Human Research Protection Office (HRPO) and local IRB office.

2.7 Composition of IRB

General information

The membership requirements of each IRB will be consistent with the requirements indicated in 45 CFR 46.107. Each IRB shall be comprised of at least five members. The Board must include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area and at least one community member who is not affiliated with TTUHSC (i.e. not a family member or spouse of an employee, not an alumnus). In addition, each TTUHSC IRB shall include at least one member who is an attorney.

The attorney shall serve as a voting member if s/he is not employed by TTUHSC. Attorneys that are employed by TTUHSC shall be non-voting members.

Consideration shall be given to the inclusion of members with diverse backgrounds including experience in areas involving vulnerable subject populations. An IRB that serves as the IRB of record for non-TTUHSC entities may allow representation from each affiliate.

Subcommittee for Primary Review (El Paso)

Membership of El Paso's Subcommittee for Primary Review shall include at least two (2) IRB members; one scientist and one clinically experienced individual. The IRB Chair shall appoint the subcommittee and may serve as one of the members.

Alternates

Formally appointed alternates may vote in place of an absent or excused regularly appointed member. Alternates may attend all meetings; however, their votes are counted only in the absence of the regularly appointed member. Meeting minutes must indicate when an alternate member replaces the appointed member.

Qualifications of IRB Members

As specified in 45 CFR 46.107 IRB membership must be (i) sufficiently qualified through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel; and (ii) able to ascertain the acceptability of proposed research in terms of Institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

Composition of the membership of the IRB must be adequate in light of the anticipated scope of activities, the types of subject populations likely to be involved, and the size and complexity of the entity. Representation in the following areas will be considered:

- Child Representative
An IRB considering a study involving children as subjects shall:
 - a) assess its needs for pediatric medical experience among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities and
 - b) consider inclusion of one or more individuals who are knowledgeable about and have professional medical experience with children. To fulfill this requirement, the IRB may invite non-voting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members.

- Prisoner Advocate
Federal Regulations require that the IRB membership be modified if it is to review research involving prisoners. Therefore, if any IRB will review research involving prisoners, at least one member of the IRB shall be a prisoner, or a prisoner advocate with appropriate background and experience to serve in that capacity.

- Consultants
On a case-by-case basis, and with appropriate confidentiality safeguards, the IRB may request review by an individual with competence in an area not represented by the Board membership.

2.8 Selection of IRB Members

All IRB members, including each Chair, shall be appointed by, serve at the discretion of, and report to the AVPR. Each appointment is for a one year term. In general, the AVPR appoints

members effective September 1 of each year. Appointments during other times of the year are made as necessary to replace members leaving the Board. Unless otherwise specified, terms expire on August 31 of each year. The AVPR shall consult with each IRB Chair on member appointments. (TTUHSC OP 73.06)

2.9 Removal of IRB Members

Appointment to the IRB may be rescinded at the sole discretion of the AVPR. Removal of members will generally be for cause but not, in any case, for purposes of retaliation or for unconstitutional reasons.

2.10 IRB Member Training

New Member Training: New IRB members are required to attend an orientation session prior to participating as a voting member on the IRB. This training is conducted by the IRB Administrator or IRB Research Coordinator. Additionally, new members are encouraged to attend and observe a Board meeting prior to beginning their appointment.

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

- Responsibilities and obligations of IRB members;
- Interaction between the IRB Office and the Board;
- Effective meeting skills;
- Terms and regulations (FDA, OHRP, NIH, TTUHSC, etc.);
- Meeting basics (quorum, voting procedures, acceptable templates, etc.);
- Vulnerable populations;
- Liability issues; and
- The use of the iRIS software system for reviewing IRB submissions.

Reference materials provided to new IRB Members include:

- The Belmont Report;
- 45 CFR 46;
- FDA 21 CFR 50, 56;
- Glossary of Terms;
- Current TTUHSC Assurance;
- IRB Member Roster and IRB Office Roster; and
- Investigator's Handbook; and
- IRB Policies and Procedures Manual.

CITI

New members must also take an on-line course entitled "*Collaborative IRB Training Initiative (CITI) Biomedical Core Course in the Protection of Human Research Subjects*" administered by the University of Miami. Only Member(s) whose primary concerns are in non-scientific areas may take an abbreviated version of the course as approved by the AVPR. This training shall be renewed by all IRB members within the third calendar year from the year of last completion.

HIPAA for Researchers

All IRB members are required to participate in HIPAA for Researchers training (see Section 17.0

for a link to the TTUHSC HIPAA website for more information).

Continuing Education

Each year IRB members are required to receive six (6) hours of continuing education on the protection of human research subjects. The curriculum for all IRB members is determined by the AVPR, and implemented by the HRPO and may include the following elements:

- Educational presentations as a part of regularly scheduled IRB meetings including changes to Federal regulations and to IRB processes or forms;
- Newsletter subscriptions (all IRB members currently receive the “Human Research Report, Protecting Researchers and Research Subjects” published on a monthly basis);
- Training seminars focusing on specific topics;
- Participation in external seminars and conferences.

Each local TTUHSC IRB shall maintain a record of its members’ continuing education requirements and participation. A written annual report shall be prepared by the HRPO for submission to the AVPR, summarizing the continuing education received by IRB members during the previous year. This report shall be submitted to the AVPR by July 1 each year.

2.11 IRB Meetings

A. Quorum

A quorum is present when a majority of the appointed voting members of the IRB are present, including at least one member whose primary concerns are in a non-scientific area, one member who is a physician/clinician, one member who is an attorney, and one community member. One member may fulfill multiple roles.

The IRB may only review proposed research at convened meetings at which a quorum is present, except when an expedited or exempt review procedure is used. No official action may be taken at a meeting where a quorum is not present.

Failure of Quorum during Meeting

Should the quorum fail during a meeting (e.g., those with conflicts recused, early departures, loss of a non-scientist), no further votes can take place until the quorum is restored.

B. Conflict of Interest

An IRB member may not participate in the initial or continuing review of a project in which the member has an actual conflicting interest or the appearance of a conflict exists, except to provide information requested by the IRB.

An IRB member shall be recused from the meeting during discussion and voting on research in which a conflict exists, and such shall be noted in the IRB meeting minutes. Prior to leaving the room, the member may be asked to give a brief overview of the study, if requested to do so by any member of the IRB. A conflict may include, but is not limited to:

- A financial conflict of interest through ownership of stock of the sponsor of the research or by an equity position of unknown value.

- The board member is involved in the research as PI, sub-investigator, consultant, etc.
- The board member has a personal relationship with the PI (such as a spouse) or strong positive or negative interactions that may be perceived as a possible conflict.
- A personal belief system that would preclude acceptance of any research in that area even though permitted under existing regulations or policies.

C. Meeting Attendance

Absences

IRB members will be required to notify the IRB Administrator at least 24 hours prior to a scheduled meeting if they will be unable to attend; this constitutes an excused absence. An attendance record will be maintained on all Board members and membership may be revoked if a member has three (3) unexcused absences within a fiscal year.

PI Presence During Meeting

The IRB may request that the PI be present during discussion at a convened meeting to address the IRB and/or provide answers to IRB inquiries.

IRB and TTUHSC Administrative staff members

These individuals who attend the IRB meeting do not have voting privileges.

Guests or consultants to the IRB may attend the meeting only with advance notice and approval by the Chair and with appropriate confidentiality safeguards.

D. Meeting Schedule

IRB members may request that the regularly scheduled meeting date be changed due to conflicts with holidays, faculty meetings, conferences, etc. IRB members will be notified of the meeting location each month via the full Board agenda. Subject to change, the meeting schedules of the TTUHSC IRBs are:

- Lubbock/Odessa IRB – fourth Wednesday of each month at 2:00 p.m.
- Amarillo IRB – first and third Thursdays of each month at 4:00 p.m.
- El Paso IRB – first Tuesday of each month at noon
- El Paso Subcommittee—second Tuesday of each month at noon

IRB members and others in regular attendance shall be notified in a timely manner regarding changes to the regularly scheduled meeting time and/or location.

E. Meeting Minutes

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

- Attendance at the meetings and presence of quorum;
- Actions taken by the IRB;
- The vote on these actions including the number of members voting for, against, and abstaining;
- The basis for requiring changes in or disapproving research; and

- Thorough discussion of research issues and resolution.

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

- For research involving pregnant women or and/or fetuses - documentation of IRB findings required under 45 CFR 46 Subpart B;
- For research involving prisoners – presence of appropriate prisoner representative; documentation of IRB findings required under 45 CFR 46 Subpart C;
- For research involving children – documentation of IRB findings in accordance with 45 CFR 46 Subpart D;
- Consideration of additional safeguards for vulnerable subjects;
- Names of IRB members who abstained from a vote with the reason for abstention; and
- Names of IRB members who were recused from a discussion/vote due to a conflict of interest and a description of the conflict of interest.

2.12 IRB Office Records

File Composition

The IRB Office files shall be maintained in a manner that reflects a complete history of all IRB actions related to review and approval of a research study, including continuing reviews, amendments and adverse event reports.

Document Retention

The IRB Office shall retain all records regarding IRB activity for five (5) years after closure of the research study at the TTUHSC approved site. Records maintained will include files for individual studies as well as minutes of each IRB meeting.

3.0 PRINCIPAL INVESTIGATOR REQUIREMENTS

3.1 Faculty Status

Principal Investigator Eligibility

TTUHSC Principal Investigators

TTUHSC Principal Investigators (“PI”) must have a TTUHSC faculty appointment (full or part time). TTUHSC employees who do not have faculty status (including residents, students, assistants, fellows or other individuals receiving training at TTUHSC) can not be named as PI for a research study involving human subjects. These individuals may participate in research as sub-investigators or study personnel. However, the PI has ultimate responsibility for conducting and overseeing the research (see 3.6). Human subjects research conducted by TTUHSC faculty must be reviewed by a TTUHSC IRB and must use the TTUHSC approved informed consent template.

Principal Investigators from Affiliated Entities

Employees of entities affiliated with TTUHSC may be named as PI in a research study under all of the following conditions:

- Affiliated entity has a Federalwide Assurance (FWA) approved by DHHS;
- Affiliated entity has designated the TTUHSC IRB on its FWA;
- Affiliated entity has a current IRB Agreement with TTUHSC;
- PI possesses a terminal degree, with professional qualifications appropriate for the conduct of the proposed research;
- PI submits professional qualifications for review and approval first to the authorized official at affiliated entity as designated in the IRB Agreement and then to TTUHSC;
- PI submits application and protocol in accordance with federal regulations and TTUHSC policy with signature of authorized official from other entity.

Principal Investigators who are self-employed or are not employed by an affiliated entity

Persons in this category may only be considered a PI and use the TTUHSC IRB under all of the following conditions:

- PI has a current Unaffiliated Investigator Agreement with TTUHSC;
- PI agrees to grant TTUHSC Research Compliance Office access upon request to research project records for audit and compliance purposes;
- Possess a terminal degree, with professional qualifications appropriate for the conduct of the proposed research; and
- Submits professional qualifications for review and approval to the TTUHSC AVPR prior to submission to an IRB.

Persons in this category may not use the TTUHSC approved informed consent document. Any modified informed consent must be approved by the TTUHSC IRB. These investigators may not use TTUHSC facilities for conduct of the research. Malpractice coverage is the responsibility of the PI and/or the employing entity. PI shall submit documentation of coverage to HRPO at the request of the IRB or TTUHSC.

Verification of Faculty Status

For clinical trials which are currently active, the PI's faculty status will be verified at the time of continuing review. For new IRB submissions, faculty status will be verified upon submission to IRB.

3.2 Additional Requirements for Industry Sponsored Research:

The following categories of faculty (and affiliated others) in all HSC schools have specific responsibilities when conducting clinical research that is funded by industry sponsors (See TTUHSC OP 73.08):

Full-time TTUHSC faculty employees (where research is considered part of the faculty member's job duties):

- Must use the TTUHSC IRB
- Must pay IRB review fees **IF** the study is funded by an industry sponsor
- Must use the TTUHSC Division of Clinical Research Office to process Confidential Disclosure Agreements and Clinical Trials Agreements
- School of Medicine faculty physicians are covered under the TTUHSC Professional Liability Self-Insurance Plan; other HSC schools shall check their malpractice policies
- Employees are covered by the Texas Torts Claims Act if actions are in the course and scope of employment and in good faith

Part-time (any amount less than 100%) TTUHSC faculty employees (where research may be considered part of the faculty member's job duties):

- Must use the TTUHSC IRB
- Must pay IRB review fees **IF** the study is funded by an industry sponsor
- Must use the TTUHSC Division of Clinical Research Office to process Confidential Disclosure Agreements and Clinical Trials Agreements
- School of Medicine Faculty shall check with the Professional Liability Office for malpractice coverage on a case by case basis; other HSC schools shall check their malpractice policies
- Employees are covered by the Texas Torts Claims Act if actions are in the course and scope of employment and in good faith

Faculty member with a TTUHSC faculty appointment (usually clinical), who is self-employed or employed by another entity (not a TTUHSC-compensated employee):

- Must use the TTUHSC IRB if using staff, facilities, or resources of TTUHSC
- Outside entity must have an executed IRB Agreement or Unaffiliated Investigator Agreement in place to use the IRB
- Must pay IRB review fees, **IF** the study is funded by an industry sponsor
- Professional Liability coverage by the TTUHSC Self-Insurance Plan is **not** provided by the TTUHSC Self-Insurance Plan, but the faculty member shall check with their own Professional Liability Plan to confirm coverage
- Texas Torts Claims Act does not apply (because not an employee, but **may** apply if performing services under a contract).

Self-employed or employed by another entity without a TTUHSC faculty appointment:

- Can use the TTUHSC IRB only if individual or employing entity:
 1. Have a Federal-wide Assurance approved by DHHS or an Unaffiliated Investigator Agreement;
 2. Have designated a TTUHSC IRB by executing an IRB Agreement with TTUHSC as applicable;
 3. Have agreed that the TTUHSC Research Compliance Office shall have access upon request to research project records for audit and compliance purposes;
- Must pay IRB review fees and iRIS use fee upon receipt of invoice, **IF** the study is funded by an industry sponsor.
- Cannot use TTUHSC consent form. Any modified consent form must be approved by the TTUHSC IRB;
- Cannot use TTUHSC facilities for conduct of the research;
- Malpractice coverage is the responsibility of the PI and/or the employing entity.

3.3 Good Clinical Practice

Good Clinical Practice (GCP)

PIs, regardless of their affiliation, shall follow Good Clinical Practice Guidelines as defined by the FDA, and found at www.fda.gov/oc/gcp/guidance.html, in designing and conducting clinical trials.

3.4 Notice of Absence

A PI is required to notify the IRB in writing at least two (2) months prior to any extended absence or faculty development leave during which the PI will be engaged in research. (See TTUHSC OP 60.02) PI shall submit information and/or an amendment to the IRB designating an Investigator responsible for any active research study during PI's absence. Notice and/or amendments shall be made in accordance with local IRB submission requirements.

3.5 Conflict of Interest

Investigators shall provide written notice to the IRB with each application, sponsored or not, stating whether or not they, or any other person responsible for the design, conduct, or reporting of the research, has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research. If a conflict of interest is indicated, the IRB shall send refer the matter to the TTUHSC Conflict of Interest Committee for review and resolution pursuant to TTUHSC policy.

3.6 Responsibility for Submission of Research Documents

The PI retains ultimate responsibility for the conduct of all research activities as specified in the IRB-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 IRB Policies and Procedures.

3.7 Principal Investigator and Research Staff Education Requirements

Principal Investigators, Co-Investigators, and all research staff are required to receive initial and continuing training regarding the rights and protection of human subjects in research. The course currently approved by TTUHSC is the web based **Biomedical Core Course** in the Protection of Human Subjects administered by the University of Miami through the Collaborative IRB Training Initiative (CITI). The CITI course consists of an on-line tutorial and certification examination which replaces the online NIH course and GCP video. PIs are responsible to monitor that all personnel associated with human subject research completes the initial training program **prior** to beginning work on any study.

Initial TTUHSC Training Program

Consists of both the CITI and TTUHSC HIPAA for Researchers courses.

1. The CITI course (entitled *Collaborative IRB Training Initiative (CITI) Biomedical Core Course in the Protection of Human Research Subjects*): a web based tutorial, administered by the University of Miami. Registration through the following website is required before beginning the on-line course: www.miami.edu/citireg.
2. TTUHSC HIPAA for Researchers: TTUHSC training related to HIPAA compliance in research must be completed by PIs and research staff. Information regarding this research training is located at www.ttuhs.edu/hipaa (see *HIPAA for Researchers*).

The HRPO is responsible to verify that all PIs and research staff have received CITI and HIPAA training and have passed the examination at initial and continuing review. Investigators and research staff that have not completed the required training and obtained a passing score cannot be involved in any part of the study until all training requirements have been fulfilled. The Education Coordinator in the HRPO can verify training status for PIs and research staff.

Continuing Education

Investigators and research staff are required to receive continuing education on the protection of human research subjects every three years. The approved course for continuing education is the "*Collaborative IRB Training Initiative (CITI) Biomedical Core Course in the Protection of Human Research Subjects*" administered by the University of Miami. This is the same course approved for initial training. The course is updated regularly to reflect changes in the regulatory and research environments. The CITI course replaces the online NIH course and GCP video. Questions about continuing education requirements shall be directed to the Education Coordinator in the HRPO.

Additional Educational Resources

The IRB website and iRIS Home Page provide links to additional resources, including TTUHSC's Assurance, IRB Policy and Procedure Manual, Investigator's Handbook, CITI training, and the Internet Research Information System (iRIS). Books, periodicals and other relevant educational materials are available at the IRB office.

External Investigators

In cases where a co-investigator or other key study personnel are not associated with TTUHSC, other forms of human research training may be approved at the recommendation of HRPO and final discretion of the AVPR. A description of the training and a copy of a completion certificate shall be provided by the Investigator to the Education Coordinator at the HRPO.

4.0 INITIAL IRB REVIEW

Types of Review

Three categories of review are recognized by federal regulations.

- Full Board Review is conducted at a convened meeting of the IRB.
- Expedited Review allows for the Chair or his/her designee to perform the review.
- Exempt studies may be reviewed by the Chair or his/her designee using an abbreviated application form.

4.1 Full Board Review

Review of research by the full Board may occur only at convened meetings of the IRB at which a quorum is present. Studies are determined to require full Board review based on the potential level of risk (none, minimal, moderate or high) to human subjects as determined by the Chair. In El Paso, the Primary Review Subcommittee performs this function.

The full Board review process includes the following components:

- a) IRB Chair or designee shall assign two or more IRB members to review each proposed research study. In El Paso, the Subcommittee for Primary Review, consisting of two or more IRB members shall review each study. Reviewers conduct an in-depth review of all materials set forth in Section 5. A summary of the study and recommendations regarding the disposition of the study shall be presented to the full Board. Clarification and discussion by the full Board then takes place.
- b) Existence of quorum and a majority vote of the voting members are required to formalize IRB decisions. IRB review will result in one of the following actions:
 - (i.) Approval
The IRB may only approve an application when the requirements for approval stated in 45 CFR 46.111 are satisfied. These requirements are summarized as follows:
 - Risks to subjects are minimized.
 - Risks to subjects are reasonable in relation to anticipated benefits.
 - Selection of subjects is equitable.
 - Informed consent will be sought from each prospective subject or authorized representative.
 - Informed consent will be appropriately documented as required by federal regulation. Plans for data monitoring are included when appropriate.
 - Adequate provisions are in place to protect the privacy of subjects and the confidentiality of data.
 - Additional safeguards have been included to protect the rights and welfare of vulnerable subjects when necessary.

When a study is approved by the IRB, information regarding the risk level assigned by the Board and the frequency and method of continuing review will be provided in writing to the Principal Investigator. The Investigator will also be informed that s/he is required to promptly report to the IRB any changes in research activity and any unanticipated problems involving risks to subjects or others. (See Section 5.4)

(ii.) Request Additional Information or Modifications from PI

The IRB may request clarifications, protocol modifications, revisions to the informed consent document, or other supporting documentation. The request for additional information shall be made in writing to the Principal Investigator in a timely manner following the Board's decision. Replies are due within 30 days of the date of the written notice to the PI unless otherwise specified. If no response has been received after 30 days, the study will be administratively closed by the IRB and further review of the study will require a new application to be submitted to the IRB. Once the modifications have been received, the study will be scheduled for discussion at a subsequent full Board meeting.

The IRB may determine at the original Board meeting that full Board review of the requested changes is not necessary. Under these circumstances, the IRB Chair or designee may review and approve the research on behalf of the IRB.

(iii.) Tabling the study

a) Extensive changes required

The IRB has reviewed the study and determined that extensive changes are necessary before the study can be effectively reviewed. The PI will be notified of the decision and of the corrective action(s) needed before further review can take place. The investigator will have 30 days from the date of notice to respond to the written request for changes. If no response has been received from the PI after 30 days, the study will be administratively closed and removed from the IRB agenda. Further review of the study will require a new application to be submitted to the IRB.

b) IRB members or consultants not available for review

The study was unable to be reviewed by the Board for reasons unrelated to the PI. Such reasons may include loss of quorum, availability of required member for a thorough review ;or the need for outside consultation to assist the IRB.

All studies which are tabled at a full Board meeting will require subsequent full Board review.

(iv.) Study Disapproved

The IRB votes to disapprove a study and determines that there will be no further review of this application.

The IRB shall provide the PI with written notification of the reasons for its decision. The PI may request reconsideration of the IRB'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. At the discretion of the Chair, the PI may also address the IRB in person. The IRB shall notify the PI in writing of its decision after reconsideration and the reasons for its decision. No further request for reconsideration by the PI is permitted following the final decision by the IRB. Pursuant to the regulations in 45 CFR 46.112, TTUHSC officials can **not** approve research if it is disapproved by the IRB.

4.2 Expedited Review

Federal regulations allow the IRB to review certain applications on an expedited basis if they meet specified criteria. An expedited review procedure consists of a review of research involving human subjects by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB or by the IRB Primary Review Subcommittee in El Paso.

In reviewing the research, the reviewer may exercise all of the authorities of the full Board except that the reviewer may not disapprove the research. Additionally, the reviewer has the discretion to refer the application for review at a convened meeting of the full Board.

Federal regulations limit the use of expedited review procedures to specific research categories published in the Federal Register. Research activities that (A) present no more than minimal risk to human subjects, and (B) involve only procedures that are listed in one or more of the research categories published in the Federal Register at 63FR 60364-60367 (Nov. 9, 1998) may be reviewed by the IRB using the expedited review procedures found in 45CFR 46.110 and 21 CFR56.110

Approval

In conducting the expedited review, the designated reviewers must review materials in sufficient detail to make the same determinations as specified in the full Board review section above (4.1(b) (i)).

Notification of Full Board

A summary of the application must be documented in the agenda provided to the full Board for the next convened meeting to allow for member comments. This documentation must cite the specific permissible category or categories justifying the expedited review.

4.3 Exempt Status

Determination of Exempt Status

Determination of “exempt” status is made by the IRB, not the PI. The IRB Chair or designee will review an Exempt Application and accept or decline the researcher’s claim for exemption. To be exempt, an application must meet one of six specific categories of activities summarized below. Exempt approval will be provided to the PI in writing and shall include the citation of the specific category justifying the exemption (45 CFR 46.101(b) (1-6)). PIs do **not** have authority to make an independent determination that research involving human subjects is exempt, but rather submit an exempt application to the IRB for its determination.

Federal regulations 45 CFR 46.101(b) provide for six specific categories of activities that may qualify as exempt. Exempt status does **not** apply to research involving prisoners. The categories are summarized below:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- Research involving the use of educational tests, surveys or questionnaires, provided that human subjects cannot be identified and that responses by the subjects will not place them at risk of liability or be damaging to financial standing or reputation.
- Research involving the use of educational tests or observation of public behavior that is not exempt under the previous category if (1) the human subjects are elected or appointed public officials or candidates for public office or (2) the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the PI in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads in order to review public service programs; procedures for obtaining benefits under those programs; possible changes to those programs or possible changes in methods or levels of payment for benefits under those programs.
- Taste and food quality evaluation and consumer acceptance studies.

If the research application does not meet the criteria for exemption, the IRB Office will provide written notice to the PI specifying the additional information needed and stating the appropriate category for review (e.g., expedited or full Board).

4.4 IRB Fee Policy for Sponsored Applications

All industry-sponsored applications submitted to the IRB for initial review will be assessed a fee for new applications and continuing review applications requiring full Board review. The IRB fee and payment schedule shall be determined by TTUHSC Operating Policy (OP 73.08) and established during contract negotiations with sponsors and in IRB Agreements with affiliated entities.

If an application is received and is not designated as industry-sponsored by the PI, but is later determined by the IRB to be industry-sponsored, an invoice will be sent to the sponsor. The invoice shall contain a request for billing information and will clearly show a description of the charge and the amount being assessed.

IRB applications supported by State, Federal, non-profit foundation, or internal funds will be excluded from this charge.

Waiver of IRB Fees

There may be extenuating circumstances where charging IRB fees would be unwarranted. PIs may send a written letter requesting waiver of IRB processing fees, by campus or regular mail (not email) to the AVPR, who has discretion and makes the final decision to waive fees.

4.5 IRB Relation to Other University Committees

The TTUHSC IRB functions independently of, but in coordination with other TTUHSC and Texas Tech University Committees, including:

- Institutional Biohazards Committee (IBC)
- Radiation Safety Committee (RSC)
- Recombinant DNA Biosafety Committee
- Conflict of Interest Committee
- Texas Tech University IRB

If required, approval from these other committees shall be obtained prior to approval by the IRB.

4.6 External Review

Studies being conducted by a PI employed at non-TTUHSC entities must submit documentation which verifies that authorized officials and/or the IRB of the affiliated entity have approved the study prior to submission to the TTUHSC IRB.

5.0 SUBMISSION REQUIREMENTS

5.1 Internet Medical Research Information System (“iRIS”) Software through which all IRB applications, reviews and approvals are submitted and through which information is communicated between investigators and the IRB. All studies submitted to TTUHSC IRB #1 (Lubbock/Odessa) and IRB #3 (El Paso) are submitted via iRIS. TTUHSC#2 (Amarillo) is the **only** IRB currently accepting paper submissions. Paper submissions to IRB #2 (Amarillo) will continue to be accepted for IRB review until iRIS implementation is completed at that campus.

5.2 Initial Application

TTUHSC PIs, regardless of duty location, who are compensated in full or in part by TTUHSC or who have a faculty appointment to TTUHSC, shall submit research studies for review to the TTUHSC IRB at the campus of their appointment, either Lubbock/Odessa, Amarillo or El Paso. This will be the designated IRB for the research activity. Submission of research to the TTUHSC IRB shall be made in accordance with TTUHSC policy and federal regulations. (See TTUHSC OP 73.08)

Non-TTUHSC affiliated PI's shall submit study documentation for review by the TTUHSC IRB if TTUHSC is designated as the IRB of record on the entity's Assurance and has executed an IRB agreement with TTUHSC. Investigators who are not affiliated with an Assurance holding entity must have an executed Unaffiliated Investigator Agreement with TTUHSC to submit research for review by a TTUHSC IRB.

If a local IRB does not have the expertise necessary to review a study involving a vulnerable population, the IRB Chair shall request referral of the study to another TTUHSC IRB for appropriate review. Federal guidelines require that when the IRB is geographically removed from the local research context, the IRB must demonstrate that it has obtained necessary information about the local research context through compliance with established standards (see Section 15, Local Research Context).

In conducting the initial review of proposed research, the IRB must obtain information in sufficient detail to make the determinations required under federal regulations.

The following documents shall be submitted by the PI, as applicable to the study for IRB review:

- Completed TTUHSC IRB-approved (exempt or non-exempt) application form;
- Full protocol;
- Investigational New Drug (IND) or Investigational Device Exemption (IDE) number (see Section 13);
- Investigator's Brochure (if external sponsor);
- Proposed informed consent document using TTUHSC IRB-approved format (required for all non-exempt studies – see Section 7);
- Authorization to Use and Disclose PHI for Research (HIPAA authorization) **or** Request to Use and Disclose PHI Without Authorization for Research (see Section 17);
- Department Chair approval (or signature of authorized official designated in entity's IRB Agreement) certifying that the PI is knowledgeable in the area in which s/he is conducting the research and will employ sound scientific methods and that facilities/equipment are sufficient for conduct of the study.

- Copies of letters of assurance or cooperation with research sites;
- Recruitment materials;
- Relevant grant applications;
- Surveys, questionnaires, or videotapes;
- Documentation of review by required TTUHSC institutional committees (see Section 4.5);
- CV of PI (if non TTUHSC faculty)

Materials for initial review shall be submitted to the IRB Office by established deadlines. The deadlines for each TTUHSC IRB, the location of the IRB application forms and other approved form templates can be found on the iRIS homepage and local IRB webpage.

Exempt study: If a PI considers a study to be exempt under 45 CFR 46.101(b) only the Exempt IRB Application, the full protocol, and any other available documentation to help support the application need be submitted. The determination of whether a study qualifies for exempt status will be made by the IRB. If a Non-exempt application is required, the PI will be notified of this decision in writing. Questions about exempt status shall be directed to the IRB Administrator located at each campus.

5.3 Study Screening and Processing

All IRB submissions will be screened by the IRB Office. If the submission is incomplete or otherwise not fully prepared for review, it will be returned to the PI with a request for correction. When the submission is adequately prepared for review, it will be placed on an agenda for IRB review. (See 4.1 for details).

5.4 Amendments to Previously Approved Studies

For previously approved projects (including exempt studies), all planned changes in the conduct of a study and/or changes to the consent document must be approved by the IRB prior to initiation of these changes.

Minor modifications proposed for previously approved studies may be reviewed in an expedited manner. A minor modification is defined as 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. Modifications to the protocol require submission of an updated copy of the protocol highlighting the changes.

Major modifications. The IRB must review and approve major modifications to a research study during a convened meeting before the changes can be implemented. A major modification is defined as any change which materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Modifications to the protocol require submission of an updated copy of the protocol.

Change of Investigators. PI shall notify IRB of any changes in research personnel by amendment. IRB must review and approve changes of research personnel prior to initiation of these changes. The IRB may assume, unless notified otherwise, that when a PI is replaced or a sub-Investigator is removed from a study that it is with his/her assent, or it is because s/he is no longer associated with TTUHSC or its affiliated entities.

The decisions and requirements for modifications by the IRB on previously approved studies will be promptly conveyed to PIs in writing by the IRB Office. Written notification from the IRB Office of decision to disapprove a study will be accompanied by the reasons for the disapproval and an opportunity for the PI to reply, utilizing the Internet Research Information System (iRIS). Replies are due within 30 calendar days of the date of written notice to the PI unless otherwise specified. The IRB shall consider the written response and materials submitted by the PI for its decision on continuing review.

5.5 Continuing Review of Approved Studies

Continuing review of all research, whether funded externally or not, will take place on at least an annual basis. This review must be substantive and meaningful. The IRB meeting minutes and the initial approval letter will indicate the review interval.

The frequency of the continuing review will primarily be based upon the degree of risk involved as determined by the IRB. Factors to be considered by the IRB in determining the appropriate interval for review may include, but are not limited to:

- involvement of vulnerable populations;
- research conducted internationally;
- the involvement of recombinant DNA or other types of gene transfer studies;
- the use of waiver of informed consent procedures, e.g. surrogate consent;
- classified research;
- research for which subjects would be exposed to additional risks, e.g. breach of confidentiality, Phase 1 studies, disproportionate number or severity of serious adverse events;
- previous suspension of the research due to compliance, record-keeping or other concerns;
- recommendations from other institutional committees;
- accrual information

In order to provide timely review and approval of each study, the PI shall submit required documentation no less than 10 days prior to the Full Board meeting preceding the study expiration date. Although reminders will be sent out, the PI is responsible for being aware of upcoming expiration dates in order to submit continuing review materials in a timely manner.

Materials required for continuing review include:

- Number of subjects enrolled, screened, and withdrawn (with reasons for withdrawal);
- A status report on the progress of the research and interim findings;
- Any information, including that from recent literature relevant to the study which might affect the possible risks to the subjects;
- A summary of adverse events and any unanticipated problems involving the research and/or complaints about the research since the last IRB review;
- Verification that informed consent was obtained from all subjects, that all subjects received a signed copy of the informed consent document and that all signed consent forms are on file (unless requirements were waived by the IRB).
- An unstamped copy of the current informed document or any newly proposed consent document with changes from the original consent highlighted;

- A summary of amendments or modifications to the research since the last review unless these have already been documented in iRIS;
- An updated complete protocol (if changes have been made) with changes from the original protocol highlighted;
- Any relevant multi-center trial reports;
- Any other information which may be relevant to making a determination regarding the potential risks, benefits, or scientific merit of the study.

The approved continuing review template is found in the iRIS software system. Based on its review, the IRB may require that the research be modified, restricted, suspended/terminated or administratively closed. Alternatively, previously imposed restrictions by the IRB may be lifted.

Continuing review requiring full Board approval

Documentation received prior to the submission deadline will be reviewed at the next regularly scheduled IRB meeting. The IRB review will include:

- An assessment of risks, benefits, and safeguards for human subjects;
- A determination that the currently approved or proposed informed consent document is accurate and complete; and
- A review of any significant new findings that may relate to the subjects' willingness to continue participation.

Continuing review **NOT** requiring full Board approval

The following types of studies may not require full Board review:

- Exempt and expedited studies;
- Studies in which enrollment has not yet taken place; and
- Research closed to accrual of new subjects. A research study for which no new subjects will be enrolled must be periodically (at least annually) reviewed until such time that there is no need to re-contact enrolled subjects.

No Grace Period.

If a PI has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved the research study by the continuing review date specified by the IRB, **all research activity**, including enrollment, data collection and analysis, **shall stop** unless the IRB finds that it is in the best interest of individual subjects to continue participating in the research interventions or interactions. **Enrollment of new subjects cannot occur after the expiration of IRB approval.**

Submission of Continuing Review Materials after Expiration Date

If IRB approval has expired, **all research activity, including enrollment and accrual, data collection and analysis must stop**. However, the IRB will permit the study to remain on the agenda pending continuing review if the PI submits the continuing review materials to the IRB within 30 calendar days after the expiration date. Exceptions to the 30-day deadline will be made by the IRB Chair on a case-by-case basis. Research activity shall resume only after IRB approval of continuing review. If the PI fails to submit the continuing review materials within the required time frame, the study will be closed administratively by the IRB. Studies that are administratively closed by the IRB require submission of a new research application to the IRB.

Review of studies in fifth year of accrual

Studies which have been actively enrolling subjects for five (5) consecutive years will undergo a more extensive review during the fifth year. The fifth year review will be conducted by the same criteria as an initial review by the IRB and shall require submission of a new application, an updated protocol, investigator's brochure, etc. to the IRB.

5.6 Study Closure

Studies which have been approved by the IRB may be closed by the investigator, the sponsor, the IRB, TTUHSC, 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 IRB in writing and include a summary of findings to date.

If no subjects have been enrolled in a study for a period of three or more years, the IRB may request that a project be closed, unless there are extenuating circumstances for keeping the project open.

Studies which have been completed as approved by the IRB, including data analysis, and finalized at the local research site will be designated as "completed" in iRIS. The PI shall submit a final report to the IRB which will include the number of subjects, any major problems, and a summary of the findings. A manuscript may be substituted for the summary of the findings.

Once the IRB has sent a written acknowledgment of the completed study and its closure, no further data can be collected about any of the subjects in that particular study and no further actions are necessary by the PI.

Studies which have been permanently closed by the PI or Sponsor will be designated as "closed" in iRIS. Once the IRB has acknowledged in writing the closure of a study, no further data shall be collected about any of the subjects in that particular study and no further actions are necessary on the part of the PI.

Studies which are temporarily closed to accrual by the PI, Sponsor, or IRB will remain in "Active" status in iRIS. Continuing reviews of the research by the IRB are required. (See Section 5.5, page 30).

Studies may be closed administratively by the IRB due to non-responsiveness to requests for information from the investigator. No further research activity is permitted for studies which are closed administratively. Any further activity on such studies will require the submission of a new application to the IRB. (See Section 4.1(b) (ii, iii)).

5.7 Suspension/Termination of Approval

The IRB and/or the AVPR have authority to suspend/ terminate research (See Sections 2.6 and 6.1). The term "Suspension/Termination" applies when the IRB withdraws its approval from a study for any of the following reasons:

- unanticipated problems involving risks to subjects or others;
- serious or continuing noncompliance with regulations governing human subjects research (45 CFR Part 46);
- research is not being conducted in accordance with the requirements or

determinations of the IRB.

Notification of suspension/ termination requires immediate cessation of all research activities by the PI and mandatory reporting to federal regulatory agencies by TTUHSC.

The PI shall be immediately notified in writing of suspension/termination of IRB approval along with the reasons for the suspension/termination. The AVPR shall promptly report suspension/termination of research to the appropriate federal agencies in compliance with federal regulations and TTUHSC policy (See Section 2.6)

Studies which have been suspended require submission of a written Correction plan by the PI and approval by the IRB before any research can resume. Suspended studies shall require ongoing continuing review by the IRB.

5.8 Appeal of Suspension/Termination

Request to IRB

The PI shall be immediately notified of the decision in writing, which shall include a statement of the reasons for the suspension/termination.

The PI may appeal the decision of the IRB or AVPR by submitting a written request to the IRB or AVPR, as applicable, and provide a rationale for the appeal and any other supporting documentation. The PI must submit an appeal within five business days of the date of suspension.

Review by Subcommittee and Recommendation to Board

Within 14 days, the PI's request for reconsideration shall be reviewed by a subcommittee consisting of the IRB Chair and two IRB members selected by the IRB at the next full Board Meeting. The IRB may also invite individuals with expertise in that area of research to assist the IRB in its review of the issues (See 21 CFR 56). Individuals assisting the IRB shall maintain confidentiality of the IRB proceedings.

This subcommittee shall review the PI's documentation, the research, the suspension documentation, and may speak with the PI. The subcommittee shall submit findings and a recommendation(s) 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 IRB in person at its next regularly scheduled meeting.

Decision by Board

The Full Board 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 suspension be upheld and the IRB accepts this recommendation, this decision falls under disapproval of research involving human subjects, and there is no further appeal within TTUHSC. (45 CFR 46.112).

A decision by the full IRB to disapprove, suspend/terminate a research project is final and may not be reversed by the AVPR or any other officer/agency of TTUHSC or affiliated entities.

Faculty Grievance Policies Not Applicable

TTUHSC Schools have faculty grievance policies to address grievances of faculty members through and with their supervisors. A school faculty grievance procedure is not available to appeal an IRB decision with respect to research.

6.0 RESEARCH COMPLIANCE

The IRB and AVPR are responsible for overseeing internal and external monitoring and auditing for research compliance with federal regulations and TTUHSC policy and procedures, including this manual. (MPA 1078, TTUHSC OP 73.06, 10.16)

The IRB and AVPR are authorized to monitor human subjects research approved by the IRB pursuant to the responsibilities and assurances made by TTUHSC under federal regulations and TTUHSC policy (TTUHSC OP 73.06). The HRPO shall be responsible for compliance activities on behalf of the IRB and AVPR, including audits and monitoring of IRB approved research.

6.1 IRB Authority

The IRB has the authority to inspect research facilities, obtain records and other relevant information relating to the use of human subjects in research, and take 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 IRB requirements or that has been associated with unexpected serious harm to subjects (TTUHSC OP 73.06).

The IRB has the authority to observe or appoint a designee to observe the informed consent process and IRB approved research activities [(45 CFR 46.109(e))].

The IRB may determine that some research projects require verification from sources other than the PI to confirm that no unapproved changes have occurred since the previous IRB review. The IRB may direct verification through the use of audits of research records, inquiries, and/or observing the informed consent process and conduct of the research. The IRB, AVPR, HRPO, and/or authorized TTUHSC officials have authority to audit research studies reviewed by a TTUHSC IRB. The HRPO shall conduct both routine and special audits for the IRB.

Suspension/Termination For Cause

TTUHSC IRB has the authority to suspend/or terminate approval of research (See Section 5.6).

If a study has been suspended by the IRB for any reason, the PI shall not submit any research proposals for IRB review until the suspension/termination has been remedied.

The IRB shall promptly report any suspension/ termination of research to the AVPR and authorized official of an affiliated entity, if applicable, for reporting to federal regulatory authorities.

6.2 Monitoring and Audits

The AVPR is responsible for the development and implementation of a research compliance program at TTUHSC. (TTUHSC OP 10.16) The Human Research Protection Office has been established by the AVPR to provide administrative oversight to the IRB and to maintain research compliance at TTUHSC with applicable laws, regulations and TTUHSC policy.

The PI shall make available all research records for review or audit upon request of the IRB, the AVPR, and HRPO or authorized designee. Routine compliance audits shall be conducted as

part of the monitoring process. Special audits may also be conducted on behalf of the IRB at the request of the IRB Chair, Director of HRPO and/or the AVPR in response to allegations that research is not being conducted in accordance with IRB requirements or has been associated with unexpected serious harm to subjects or others.

Monitoring and/or auditing activities may include, but are not limited to the following:

- Study file for required elements including the presence of required documentation; protocol and amendments; approved consent forms and IRB documentation
- Subject eligibility
- Informed Consent Documentation
- Unanticipated and Adverse Event reporting
- Accuracy and completeness of Case Report Forms
- Confidentiality of records
- Drug and Device handling and accountability
- Laboratory data
- Concomitant medications/therapy
- Subject history
- Progress reports from PIs
- Contact research subjects
- Audit advertisements and other recruiting materials as deemed appropriate by the IRB
- Other monitoring or auditing activities deemed appropriate by the IRB
- Any additional information determined necessary by the AVPR.

Allegations of Non Compliance or Harm to Subjects

The Human Research Protection Office (HRPO) shall document the receipt of allegations of non-compliance with IRB approved protocol or harm to research subjects or others. Information received by the HRPO shall be reviewed in a timely manner and assigned to a compliance officer for audit pursuant to criteria and procedures established in the TTUHSC Research Compliance Office Procedure Manual. Audit findings and reports will be sent to the PI, IRB Chair, HRPO and AVPR. Department Chairs shall receive notice of IRB action.

The IRB Chair will determine the need for full IRB review. The report may be placed on the agenda of the next regularly scheduled meeting for notification or discussion, as appropriate. The Full Board may vote to suspend/terminate the research if it is found that a human subject has been exposed to unexpected serious harm or that research is not being conducted in accordance with IRB approved protocol. In addition, shall the AVPR conclude that the research does not fully comply with policies or obligations of TTUHSC, the research may be disapproved, or suspended/terminated on behalf of TTUHSC.

Quarterly Compliance reports summarizing all IRB compliance activities including audits shall be submitted to each IRB and AVPR by the HRPO. Quarterly Compliance reports are confidential and privileged Medical Committee documents.

6.3 Research Without IRB Approval

If research is or has been conducted by TTUHSC faculty, staff, or students without IRB approval, any person with knowledge about this shall immediately report it to the AVPR and/or the IRB. Results from such studies shall not be published.

6.4 External Audits

Federal Regulatory Agency

PI shall notify HRPO Research Compliance Officer immediately upon receipt of impending notice of audit or investigation.

Sponsor Monitoring Reports

PI shall send a copy of external sponsor monitoring reports to HRPO Research Compliance Officer within 10 days of receipt.

7.0 INFORMED CONSENT

7.1 Documentation of Informed Consent

The IRB may approve procedures for documentation of the informed consent process that involve either a written consent form signed and dated by the subject; or in limited circumstances, the IRB may waive the requirement for the PI to obtain a signed and dated consent form (see below). The informed consent form must be typed and presented in a manner that is easily understood by a subject.

The consent form shall be written in non-scientific language at or below the 7th Grade Level. TTUHSC research studies shall utilize the TTUHSC Informed Consent template found on the iRIS system. It includes the required basic elements of consent (45 CFR 46.116) and optional elements summarized below:

- a statement that the study involves research and a statement of why the research is being done;
- a statement regarding the subject's selection for participation in the study;
- a clear statement of what is involved in the research and identification of any procedures which are experimental;
- the expected duration of the subject's participation;
- a description of any reasonably foreseeable risks or discomforts to the subject;
- a description of additional potential risks if the subject is a female;
- a description of any benefits to the subject or to others which may reasonably be expected from the research;
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- the name of the sponsor of the study;
- any costs to the subject for participating in the study;
- an explanation as to whether any compensation is provided to the subject;
- an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- a statement of the subject's rights as a voluntary participant; and
- an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

Informed Consent Documents from Unaffiliated PIs

PI's who are self employed or employed by another entity without a TTUHSC faculty appointment cannot use TTUHSC consent forms. Consent form must be approved by the TTUHSC IRB prior to use.

Written Consent Form Signed by Subject or Authorized Representative

In most circumstances, the IRB will require that the informed consent process is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's authorized representative. This form may be read to the subject or the subject's authorized representative during a face-to-face presentation. However, the PI shall allow the subject or

the authorized representative adequate opportunity to read, review and consider the consent document before it is signed. A signed and dated copy of the document shall be given to the person signing the form. The requirement that the copy be signed may be waived by the IRB on a case-by-case basis following a written request by the investigator.

No Stamped Signatures

The PI (or authorized designee listed in the Application) also signs the consent document contemporaneously with the subject or Authorized representative. Stamped signatures for the PI are not acceptable.

Subjects who do not speak English

These subjects will be presented with an informed consent document written in a language understandable to them. The PI shall submit the foreign language consent form for review after full Board approval of the English consent form. A TTUHSC Spanish language consent template shall be available as a template in iRIS.

Oral Presentation

In cases **where the subject is unable to read** the required consent form, the approved consent form shall be read to the subject in its entirety in a language understood by the subject or the subject's authorized representative. A third party witness unaffiliated with the research study will be present during the reading and will be required to sign and date the consent form as a witness to the consent procedure. (See also Section 17 HIPAA requirements).

Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the PI to obtain a signed consent form for some or all subjects if the IRB finds:

- that the only record linking the subject and the research is the consent document; and
 - the principal risk is the potential harm resulting from a breach of confidentiality;
- OR
- that the research presents no more than minimal risk of harm to subjects; and
 - does not involve procedures for which written consent is normally required outside of the research context

In cases in which the documentation of consent requirement is waived, the IRB may require the PI to provide subjects with a written statement regarding the research.

7.2 Waiver of Informed Consent Process

Waiver for Minimal Risk Studies

The IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent or waive the requirement to obtain informed consent entirely provided the IRB finds and documents in the meeting minutes that:

- the research involves no more than minimal risk to the subjects; and
- the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- the research could not practicably be carried out without the waiver or alteration; and

- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

A waiver of informed consent shall not be granted to research involving fetuses, pregnant women, human in vitro fertilization, prisoners, or cognitively impaired/disabled subjects.

This policy is not intended to limit the authority of a physician to provide emergency medical care, to the extent that the physician is permitted to do so under applicable Federal and State law.

7.3 Assent (See also Section 9.1 regarding research with children and minors)

If a subject is not legally capable of giving informed consent, including assent by minors over 7 years of age, or if the subject is cognitively impaired, the IRB must find that adequate provisions are made for soliciting the assent of the subject when in the judgment of the IRB, the subject is capable of providing assent. Failure to object to participation in a research study is not assent.

In determining whether subjects are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the subject involved. This judgment may be required for each subject individually or for all subjects in a particular research study as the IRB deems appropriate. If the IRB determines that the capability of some or all of the subjects is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the subject and is available only in the context of the research, the assent of the subject is not a necessary condition for proceeding with the research.

7.4 Approval and Expiration Dates on Informed Consent Documents

IRB approved informed consent documents will have the IRB approval and expiration dates stamped on the consent documents. Investigators shall only use copies of the consent document with the current approval date and stamp affixed in obtaining consent.

Approval Date

The date of approval of the informed consent document will be determined based on the type of submission to the IRB. The approval date will be the date of final approval by the IRB for new studies, the date of continuing review approval for ongoing studies, or the date of approval of a modification to the informed consent document.

Expiration Date

The expiration date shall be the date of the expiration of the current IRB approval period. In the case of expedited reviews, the expiration date will be calculated based on the approval period recommended by the IRB Chair (or designee) using the date the initial IRB application or continuing review application was approved.

Tissue Bank Consent Documents

Tissue Bank Informed consent documents must contain IRB approved financial benefit language as well as the current approval and expiration dates stamped on the consent documents. (See also Section 10.0).

8.0 RECRUITMENT AND ADVERTISING

8.1 IRB Approval of Recruitment/Advertising

All Recruiting and Advertising Materials Must be Approved by the IRB

When advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication to determine that the procedure for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

Any advertisement to recruit participants shall be limited to the information the prospective participants need to determine their eligibility and interest.

Advertising materials shall not include the following:

- claims, either explicit or implicit, that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
- claims, either explicit or implicit, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention;
- terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational, meaning non FDA-approved;
- promise of "free medical treatment," when the intent is only to say that participants will not be charged for taking part in the investigation;
- an emphasis on the payment or the amount to be paid, by such means as larger or bold type. The IRB has the authority to approve whether compensation information shall be included in the advertisement.

Employees as Participants

No researcher may give an indication that an employee is required or shall consent to participate as a research subject. No coercion or inference that employment status could be affected with respect to participation in research activities is allowed.

Students as Participants

Prior to enrollment in a course where students may be requested to participate as research subjects, students shall be informed of the possibility. The course syllabus shall clearly describe proposed participation in research activities for course credit and include an alternative means of earning the course credit. The IRB shall review:

- that consent for participation is sought only under circumstances which minimize the possibility of coercion or undue influence,
- that methods used to maintain confidentiality are clearly identified, and
- that genuinely equivalent alternatives to participation are available.

Any IRB concerns regarding the use of students will promptly be forwarded to the AVPR.

8.2 Payments to Subjects

The IRB must determine that the risks to subjects are reasonable in relation to anticipated benefits and that the consent document contains an adequate description of the study

procedures as well as the risks and benefits. Payment to research subjects for participation in studies is not considered a benefit. Rather, it shall be considered compensation for time and inconvenience. The amount and schedule of all payments shall be presented to the IRB at the time of initial review. The IRB shall review both the amount of payment and the proposed method and timing of disbursement to determine that neither are coercive nor present undue influence.

Timing of Payments

Payment(s) shall be made to the subject as the study progresses and shall not be contingent upon the subject completing the entire study.

Disclosure of Payments

All information concerning payment, including the amount and schedule of payment(s) shall be set forth in the informed consent document.

Alterations in Payments

Any alterations in human research subject payment or revising of the payment schedule must be reported to the IRB prior to implementation as an amendment.

Finder's Fees

The IRB does not allow the use of any form of compensation to individuals (including faculty, staff, students, family members, etc.) who identify and/or recruit subjects for participation in a research study.

Documentation of Payments

The PI must keep documentation of payment(s) made to each subject in study files. All records shall be made accessible for inspection and copying by authorized TTUHSC representatives, including TTUHSC Compliance personnel, IRB Office, TTUHSC HRPO, the AVPR, as well as federal regulatory officials.

9.0 SPECIAL CATEGORIES OF RESEARCH

9.1 Children and Minors

When children or minors are research subjects, researchers must obtain both the consent of the parent or authorized representative and the assent of the child if he/she is 7 years or older. Mere failure to object is not assent. The IRB has the authority to waive the assent requirement. Special regulations applying to children may be found in 45 CFR 46.402(D).

9.2 Pregnant women and fetuses

Special DHHS regulations applying to pregnant women and fetuses may be found in 45 CFR 46 Subpart B. These studies are not eligible for exempt status. No research may be conducted with pregnant women or fetuses unless the conditions specified in 45 CFR 46.402 are met.

9.3 Prisoners

Special DHHS regulations applying to prisoners may be found in 45 CFR 46 Subpart C. This includes situations in which the subject becomes a prisoner after the research has commenced. No research may be conducted with prisoners unless the conditions set forth in 45 CFR 46.305 and 46.306 have been met and are reflected in the IRB minutes. (See also Section 2.8).

10.0 GENETIC RESEARCH

Genetic information must be carefully maintained in order to protect against stigmatization, discrimination, or significant psychological harm to the subject.

IRB review considers the following issues in both the application and the informed consent document, as applicable:

- Information that can be obtained from DNA samples in general, and the specific questions to be addressed in this study.
- The extent of subject and sample confidentiality if the sample and subsequent information will be part of a registry or database.
- The rights and limitations of subjects to request destruction or removal of their sample and/or associated data at a future date. The rights and limitations of subjects to request that their sample and or associated data be stripped of any identifying information.
- Identifying information available to other researchers if their sample and/or associated data are part of a registry or database.
- Mechanisms for maintaining confidentiality in long-term studies, registries, or databases.
- Potential for commercial profit by the entity, PI or sponsor from information gathered in this study.
- A clear statement of financial benefit to subject in tissue bank consent documents using IRB approved financial benefit language.
- The availability or access to genetic counseling in cases where a study may reveal genetically important information (i.e., possessing genetic defects which could be passed on).
- A clear statement that the sample/data, any cell lines, profits from data etc., are the property of TTUHSC or the entity sponsoring the research.
- If genetic information will be disclosed to the subject or another party, the PI disclosing the information must be named and the specific genetic information being disclosed must be stated.
- Information disclosed must be in a manner consistent with the recipient's level of knowledge, e.g., information would be phrased differently when disclosed to a lay person versus a physician.
- Subjects must have the right to decline receiving genetic information.
- In the absence of a specific authorization to maintain a DNA sample, DNA samples collected and stored or analyzed in connection with a research project shall be destroyed upon completion of the project or withdrawal of the individual from the project. This information must be clearly stated in the informed consent document.

Minors

For genetic research involving minors, the informed consent document must give parents/guardians the option of whether or not they want the results (if available) of the genetic analysis disclosed to them. Whenever appropriate, the minor's assent shall be solicited. If minors reach maturity, they shall be re-consented if identifiers are taken.

Genetic Relationships

In some cases it may be possible to determine that some members of the family are not genetic relatives. Issues of genetic relationships (paternity or maternity, as could be hidden by adoption or donor fertilization) and other incidental information shall not be revealed to the subject.

11.0 UNANTICIPATED PROBLEMS AND/OR ADVERSE EVENTS

The IRB is charged with the responsibility of reviewing reported unanticipated problems involving risks to subjects and adverse events in accordance with this policy. The IRB and/or AVPR has the authority to suspend/ terminate approval of research that has been associated with unexpected serious harm to participants or others or for failure to conduct research in accordance with IRB approved protocol.

PI Responsibility Regarding Reporting

Unanticipated adverse events:

PI shall submit a written report to the IRB in writing via iRIS (or to IRB office in Amarillo):

- all unanticipated adverse events or problems (both serious and non-serious) involving risks to subjects that occur at TTUHSC or an affiliated entity
- **known to be** related or **may possibly be related** to the research activities
- two (2) business **days** after the PI becomes aware of the event
- PI is responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to subjects.
- Reports of all adverse events or unanticipated problems must be retained in both the PI files and the IRB office files for reference if needed.

The IRB may conduct an expedited review of the event if there is no change in the risk/benefit ratio, the research proposal, or the consent form; otherwise, full Board review is required. The Chair or designee, at the time of expedited review, may refer any adverse event to the full Board for review.

Serious Adverse Event (SAE):

PI shall submit a written report to the IRB via iRIS (or in writing to IRB office in Amarillo):

- SAE includes death; a life threatening experience; hospitalization (for a person not already hospitalized); prolongation of hospitalization (for a patient already hospitalized); persistent or significant disability or incapacity; congenital anomaly and/or birth defects; or an event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.
- **as soon as possible**, but in any event, no later than **two (2) business days** after the PI becomes aware of the event.

IND/IDE Event Reports: PI shall submit IND/IDE reports to the IRB within IRB within five (5) business days from the date the information is received by the PI.

Data Safety Monitoring Board Reports: PI shall submit any independent data safety monitoring board reports to the IRB within five (5) business days from the date the information is received by the PI.

12.0 RECORDS AND CONFIDENTIALITY

Every PI is required by TTUHSC and federal regulations to maintain records of all correspondence relating to the use of human subjects in research. Correspondence with the IRB, notices of approval, and original signed Informed Consent Documents must be maintained in the PI's records. All records of human subject research are subject to inspection by federal authorities, TTUHSC officials, including but not limited to HRPO and Compliance Officers, AVPR and the IRB. Research records (including data) are the property of TTUHSC and shall not be transferred to another entity without prior approval of the AVPR. All research records must be kept for a minimum of five years after the close of the study at the local research site. Studies that involve drugs or devices seeking FDA approval must be kept for two years after the FDA has taken final action on the marketing application.

The conditions for maintaining confidentiality of the subjects and the research records are required for the life of the data. These rules apply equally to any and all research conducted or assisted by students, staff, and faculty. Studies conducted with FDA regulated articles must be kept in accordance with current FDA regulations or life of the data, whichever is longer.

13.0 INVESTIGATIONAL DRUGS/DEVICES

13.1 IND/IDE Application

The use of an unapproved investigational drug, device or biologic requires an FDA investigational new drug application (IND) as detailed in 21 CFR 312 or a FDA investigational device exemption (IDE), detailed in 21 CFR 812.

Before submitting an application to the IRB that involves an investigational new drug, device, or biologic, the PI must secure an IND or IDE number from the FDA or correspondence from the FDA waiving this requirement. This FDA number or letter waiving the requirement for an FDA number shall be included in the submission to the IRB.

13.2 Emergency Use

If an emergency situation arises in which it is not possible for the PI to submit a study to the Board for approval prior to administration, the drug/device may be used provided that such emergency use is reported in writing to the IRB within five (5) business days. The PI must have the IND/IDE number at the time of use. The IRB may request that the PI complete the required forms for submission to the IRB at that time. Any subsequent use of the test article at TTUHSC or affiliated entity is subject to IRB review prior to use (21 CFR 56.104).

13.3 Storage, Handling, and Dispensing of Investigational Agents

All inpatient and outpatient research studies involving either FDA approved or investigational agents (including radioactive agents used therapeutically or diagnostically) will receive automatic review by an IRB member who is a pharmacist or if not available, the IRB may request review by a pharmacist who is not an IRB member. Such review will include an assessment of source, purity, quality, and method of preparation and delivery.

Investigational agents to be given to inpatients shall be dispensed through affiliated entities' pharmacy whenever possible. The PI is required to send the following materials to the pharmacy prior to initiation of the study:

- IRB approval letter
- Full protocol
- Investigator's Brochure (if available)
- IND/IDE documentation.

Investigational agents dispensed on an outpatient basis shall follow the above procedures when possible. If affiliated entities' pharmacies are not used, the PI shall be responsible for proper storage and documentation pursuant to State and Federal regulations and Institutional policies.

Affiliated entities external to TTUHSC are responsible for proper storage, handling, and dispensing of investigational agents used in research at those facilities.

14.0 CERTIFICATE OF CONFIDENTIALITY

Data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) requires the protection of confidentiality beyond preventing accidental disclosures. Under federal law, an advance grant of confidentiality, known as a Certificate of Confidentiality is available.

A Certificate of Confidentiality provides protection for the researcher and the subjects against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research (Public Health Service Act 301(d), 42 U.S.C. 241(d)). Under this Act, the Secretary of HHS may authorize persons engaged in research to protect the privacy of subjects by withholding the names or other identifying characteristics of the subjects from all persons not connected with the conduct of the research. This means that researchers may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify their subjects.

The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects but only protects subjects from compelled disclosure of identifying characteristics by the researcher. Researchers, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatened violence to self or others. If an investigator intends to make such voluntary disclosures, however, the consent form shall clearly indicate this possibility to subjects.

In order to seek a Certificate of Confidentiality, a PI shall identify the potential for compelled disclosure in the application. The consent document shall also include and describe possible disclosure situations. The IRB shall determine whether the risks to subjects are minimized, informed consent is appropriate, and privacy and confidentiality protections are adequate. Once approved by the IRB or Institutional Privacy Board, an application for a Certificate of Confidentiality will be sent to the appropriate NIH Institute or Center by the AVPR.

15.0 LOCAL RESEARCH CONTEXT

TTUHSC's responsibilities under its Assurance applies whenever TTUHSC or its employees are engaged in human subjects research, which is not otherwise exempt from applicable federal regulations regardless of the geographic location of the research. This is particularly critical when the research involves greater than minimal risk to subjects or vulnerable categories of subjects (OPRR Guidance: IRB Knowledge of Local Research Context 8/27/98).

When the IRB is geographically removed from the local research context, the IRB must demonstrate that it has obtained necessary information about the local research context through compliance with one of the standards below. These standards reflect minimum levels of adequacy. More stringent standards may be required, depending upon the nature of the proposed research or the relevant research context.

- a. Where the research involves minimal risk to subjects, the IRB shall document in writing that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants.
- b. Where the research involves greater than minimal risk to subjects but the local research context involves no intervention or interaction with subjects and the principal risk associated with the local research context is limited to the potential harm resulting from a breach of confidentiality, the IRB shall:
 - (i) Document in writing that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants.
 - (ii) Necessary information under DHHS regulations includes all of the following:
 - A. the anticipated scope of the entity's research activities;
 - B. the types of subject populations likely to be involved;
 - C. the size and complexity of the entity;
 - D. institutional commitments and regulations;
 - E. applicable law;
 - F. standards of professional conduct and practice;
 - G. method for equitable selection of subjects;
 - H. method for protection of privacy of subjects;
 - I. method for maintenance of confidentiality of data;
 - J. language(s) understood by prospective subjects;
 - K. method for minimizing the possibility of coercion or undue influence in seeking consent; and
 - L. safeguards to protect the rights and welfare of vulnerable subjects.
 - (iii) Determine and specifically document that provisions to protect the privacy of subjects and maintain the confidentiality of data are adequate.
- c. Where the research involves greater than minimal risk to subjects and paragraph (b) above does not apply, the IRB shall document in writing that it has obtained necessary information about the local research context through one or more of the following mechanisms, or through other mechanisms deemed appropriate by OHRP for the proposed research and the local research context.

- (i) Personal knowledge of the local research context on the part of one or more IRB members, such knowledge having been obtained through extended, direct experience with the research entity, its subject populations, and its surrounding community.
- (ii) Participation (either physically or through audiovisual conference) by one or more appropriate consultants in convened meetings of the IRB.
 - A. Such consultant(s) shall have personal knowledge of the local research context, such knowledge having been obtained through extended, direct experience with the research entity, its subject populations, and its surrounding community.
- (iii) Prior written review of the proposed research by one or more appropriate consultants (see (b) above), in conjunction with participation (either physically or through audiovisual conference) by the consultant(s) in convened meetings of the IRB, when such participation is deemed warranted either by the consultant(s) or by any member of the IRB.
- (iv) Systematic, reciprocal, and documented interchange between the IRB and elements of the local research context. Such interchange shall include:
 - A. Periodic visits to the research site, occurring several times per year, by one or more IRB members in order to obtain and maintain knowledge of the local research context, including the research entity, its subject populations, and its surrounding community;
 - B. periodic discussion with appropriate consultants knowledgeable about the local research context;
 - C. regular interaction with one or more of the entity's designated liaisons; and
 - D. review of relevant written materials.

When relying on another IRB's review, the TTUHSC IRB has a responsibility to verify in the meeting minutes that the particular characteristics of the local research context are considered, either (i) through knowledge of the local research context by the reviewing IRB (see paragraph 2 above); or (ii) through subsequent review by appropriate designated institutional officials, such as the Chair and/or other members of its local IRB.

Submission to External IRB

Any designation of an external IRB (another entity's or independent IRB) must be documented by a written agreement between TTUHSC and the IRB organization and approved by OHRP. Approval for external IRB review shall be made by the AVPR prior to submission and subject to federal regulations and TTUHSC policy.

16.0 INTERNATIONAL RESEARCH

The IRB shall review all research involving human subjects conducted under the auspices of TTUHSC, regardless of the research location, including research conducted in foreign countries. When reviewing an international proposal, the IRB must be aware of the local research context (see Section 15.0). The IRB shall review translations of all relevant research documents (including informed consent, recruitment materials, and questionnaires, etc.) for accuracy. Protections afforded to subjects participating in research in a foreign county must approximate the protections provided to subjects in the United States. Requests to review and modify standard elements of domestic approvals may be considered by the IRB.

17.0 HIPAA

HIPAA Authorization

Each PI shall present subjects with an “Authorization to Use and/or Disclose Your Protected Health Information for Research Study” before using or disclosing protected health information (PHI). Such authorization shall satisfy the requirements of 45 CFR 164.508, except that the authorization may state that it does not expire, that there is no expiration date or event or that it continues until the end of the research study.

HIPAA Waiver Request to Privacy Board

TTUHSC PIs may request to use and disclose specified PHI without an individual’s authorization and/or without the necessity for an opportunity to agree or object for research purposes **if** the PI submits a “Principal Investigator’s Request to Use and Disclose Protected Health Information Without Authorization for Research Purposes” form to TTUHSC or Institutional Privacy Board for review and decision.

For purposes of HIPAA, the TTUHSC Institutional Review Boards will act separately as Privacy Boards as defined by 45 C.F.R. Part 164.512(i). IRB Administrators shall verify Privacy Board Agreements with affiliated Entities.

The IRB as Privacy Board shall review the PIs Request and provide a written response on the form “Action by Institutional Review Board or Privacy Board on PI Request to Use and Disclose PHI Without Authorization for Research Purposes”.

The HIPAA Authorization form or the Waiver of Authorization request form shall be included in initial applications or continuing review documentation for projects reviewed after April 14, 2003. Once the HIPAA documentation has been reviewed for compliance with TTUHSC policy, it does not need to be re-submitted for the duration of the study.

Duplicative HIPAA language shall not be included in the Informed Consent document. Sponsors requests to change HIPAA documents shall be submitted through the TTUHSC HIPAA Privacy Officer, but in general, shall not be considered.

Further information regarding HIPAA compliance, including approved forms, can be found at www.ttuhscc.edu/hipaa.

18.0 HIV REPORTING REQUIREMENTS

HIV Testing

PIs at TTUHSC and all its affiliates must comply fully with all applicable Federal and State laws, including those concerning notification of HIV serostatus. Individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling.

APPENDIX A – Glossary of Terms

ADMINISTRATIVELY CLOSED Administrative decision of the IRB based on PI non-responsiveness to IRB requests. This can occur prior to initial IRB approval or any time following IRB approval.

ADVERSE EFFECT An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g. headache following spinal tap or intestinal bleeding associated with aspirin therapy).

ADVERSE EVENT (AE) Any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research, or any risk associated with the research or the research intervention, or the assessment.

APPROVED The IRB has reviewed the study and made a determination that the study has met all requirements. Subjects may be enrolled in the study.

ASSENT Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. Mere failure to object to the research may not be construed as assent.

ASSURANCE A formal written, binding commitment that is submitted to a federal agency in which an entity promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

- **FEDERAL-WIDE ASSURANCE (FWA)** An agreement between a federally funded entity and OHRP that stipulates methods by which the entity will protect research participants (66 Fed Reg 19139, 19141(April 13, 2001))
- **MULTIPLE PROJECT ASSURANCE (MPA)** An agreement between an entity and OPRR that stipulates the methods by which the entity will protect the rights and welfare of research participants. Under OHRP, MPAs will be replaced by FWAs.

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 human subjects in biomedical and behavioral research.

AUTHORIZED REPRESENTATIVE A person authorized to make decisions on behalf of another person. In human 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.

AUTONOMY Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

BELMONT REPORT A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

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.

BENEFICENCE An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

CANCELLED 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.

CHILDREN Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)].

CLINICAL TRIAL A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

CLOSURE *See Study Closure*

COGNITIVELY IMPAIRED Having either a psychiatric disorder (*e.g.*, psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (*e.g.*, mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

COMPETENCE Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (*See also: Incompetence, Incapacity.*)

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

CONFIDENTIALITY Pertains to 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.

CONFLICT OF INTEREST COMMITTEE See *TTUHSC OP 10.8*

CONSENT See: *Informed Consent*.

CONTINUING REVIEW Periodic review of a research study by an IRB to evaluate whether risks to participants are reasonable in relation to potential benefits and to verify that the study continues to meet regulatory and institutional requirements. Continuing review shall be conducted at intervals appropriate to the degree of risk but not less than once per year. (*45CFR 46.109(e); 21 CFR 56.109(f)*)

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.

DATA AND 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.

DEVICE (MEDICAL) See: *Medical Device*.

DHHS A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

DISAPPROVED The IRB has reviewed the study and determined that it is not approved and may not receive further review. See also *Request for Reconsideration*

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.

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

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

EXEMPT RESEARCH Exempt research is research determined by the Institutional Review Board (IRB) to involve human subjects only in one or more of certain minimal risk categories [38 CFR 16.101(b)].

EQUITABLE Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

EXPEDITED REVIEW Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. 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.

FDA Food and Drug Administration; an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

FETUS The product of conception from implantation until delivery [45 CFR 46.202].

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

FEDERAL-WIDE ASSURANCE (FWA) (*See Assurance*)

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.

GUARDIAN An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)].

HIPAA Health Insurance Portability and Accountability Act of 1996

HUMAN IN VITRO FERTILIZATION Any fertilization involving human sperm and ova that occurs outside the human body.

HUMAN RESEARCH PROTECTION OFFICE (HRPO) Office responsible for the oversight and direction of the human research protection program at TTUHSC, which includes administrative oversight of the IRB, the TTUHSC Research Compliance Program and TTUHSC Educational requirements for human research.

HUMAN SUBJECTS Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

IDE See: *Investigational Device Exemptions*.

INCAPACITY Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. (See also: *Incompetence*.)

INCOMPETENCE Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: *Incapacity*.)

IND See: *Investigational New Drug*.

INFORMED CONSENT A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the entity or agents thereof from liability for negligence.

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.

INSTITUTIONALIZED Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).

INVESTIGATIONAL DEVICE EXEMPTIONS (IDE) Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations.

INVESTIGATIONAL NEW DRUG OR DEVICE A drug or device permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

INVESTIGATIONAL PRODUCT A device or pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

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

IN VITRO Literally, "in glass" or "test tube;" used to refer to processes that are carried out outside the living body, usually in the laboratory, as distinguished from *in vivo*.

IN VIVO Literally, "in the living body;" processes, such as the absorption of a drug by the human body, carried out in the living body rather than in a laboratory (*in vitro*).

IRB See: *Institutional Review Board*.

IRB RECORDS IRB records include but are not limited to: all minutes of IRB 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 IRB membership with a resume for each member.

iRIS Internet Medical Research Information System—the software through which all IRB applications, reviews and approvals are submitted and through which information is communicated between investigators and the IRB.

JUSTICE An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

LEGALLY AUTHORIZED REPRESENTATIVE An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

MEDICAL DEVICE 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 include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

MINIMAL RISK Minimal risk means that 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 [45 CFR 46.102(i); 21 CFR 50.3(k)]. In research involving prisoners, minimal risk is also defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. [45 CFR 46.303(d)].

MONITORING The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

MULTIPLE PROJECT ASSURANCE (MPA) (*See: Assurance*)

NONAFFILIATED MEMBER Member of an Institutional Review Board 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).

OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP) The office within the U.S. Department of Health and Human Services, responsible for implementing DHHS regulations [45 CFR Part 46] governing research involving human subjects.

PERMISSION Parent(s) or guardian's written agreement to the participation of their child or ward in research.

PI *See: Principal Investigator.*

PREGNANCY The period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery [45 CFR 46.202].

PRINCIPAL INVESTIGATOR (PI) The scientist or scholar with ultimate responsibility for the design and conduct of a research project.

PRISONER Any individual involuntarily confined or detained in a penal entity. The term is intended to encompass individuals sentenced to such an entity under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal entity, and individuals detained pending arraignment, trial, or sentencing.

PRIVACY BOARD IRB or another review body which reviews requests to use or disclose Private Health Information (PHI) for research purposes without authorization under HIPAA.

PROSPECTIVE STUDIES Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

PROTOCOL The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

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

REQUEST FOR ADDITIONAL INFORMATION The IRB has reviewed the study and has requested changes or clarifications.

RESEARCH Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 102(d)].

RESPECT FOR PERSONS An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

RETROSPECTIVE STUDIES Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

REVIEW (OF RESEARCH) The concurrent oversight of research on a periodic basis by an IRB. 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.

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 ADVERSE EVENT (SAE) A SAE is defined as death; a life threatening experience; hospitalization (for a person not already hospitalized); prolongation of hospitalization (for a patient already hospitalized); persistent or significant disability or incapacity; congenital anomaly

and/or birth defects; or an event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.

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.

STUDY All components of a research project.

STUDY CLOSURE Study approved by the IRB can be closed by the investigator, the sponsor, the IRB, TTUHSC, or by an affiliated entity. (*See: Section 5.5*) *See: Administratively Closed*

STUDY COMPLETED Study completed as approved by IRB, including data analysis, and finalized.

SUSPENSION/TERMINATION IRB approval is suspended/terminated and all research activity halted as the result of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with 45 CFR Part 46; or the requirements or determinations of the IRB (See Sections 5.6, 5.7). Requires prompt reporting to federal regulatory authorities and TTUHSC pursuant to federal Assurance and 45 CFR Part 46.

SURVEY Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

TABLED The IRB has reviewed the study and determined that extensive changes are necessary. The study will be re-reviewed by once changes have been made.

UNEXPECTED ADVERSE EVENT (UAE) An UAE is any adverse event and/or reaction, the specificity or severity of which is not consistent with the informed consent, current investigator brochure or product labeling. Further, it is not consistent with the risk information described in the general investigational plan or proposal.

VOLUNTARY Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

APPENDIX B – TTUHSC Affiliated Entities

Entities that are legally separate entities from TTUHSC which possess OHRP-approved Assurances and IRB Agreements with TTUHSC:

IRB00000096 – TTUHSC IRB #1 (Lubbock / Odessa)

Amarillo Heart Clinical Research Institute (AHCRI) (FWA00005010)
Amarillo Heart Group (AHG) (FWA00003899)
Baptist St. Anthony's Health System (BSA) (FWA00005990)
Coffee Memorial Blood Center (CMBC) (FWA00003800)
Ector County Hospital District (d/b/a Medical Center Hospital)(FWA00006363)
PharmaTex Research (FWA00004320)
University Medical Center Health System(UMC) FWA00005898

IRB00000097 – TTUHSC IRB #2 (Amarillo)

Amarillo Heart Clinical Research Institute (AHCRI) (FWA00005010)
Amarillo Heart Group (AHG) (FWA00003899)
Amarillo Veterans Affairs Health Care System (AVAHCS) (FWA00000732)
Baptist St. Anthony's Health System (BSA) (FWA00005990)
Coffee Memorial Blood Center (CMBC) (FWA00003800)
Don and Sybil Harrington Cancer Center, Inc. (HCC) (FWA0000058)
Ector County Hospital District (d/b/a Medical Center Hospital)(FWA00006363)
Northwest Texas Healthcare System (NTCS) (FWA00003086)
PharmaTex Research (FWA00004320)
University Medical Center Health System UMC) FWA00005898

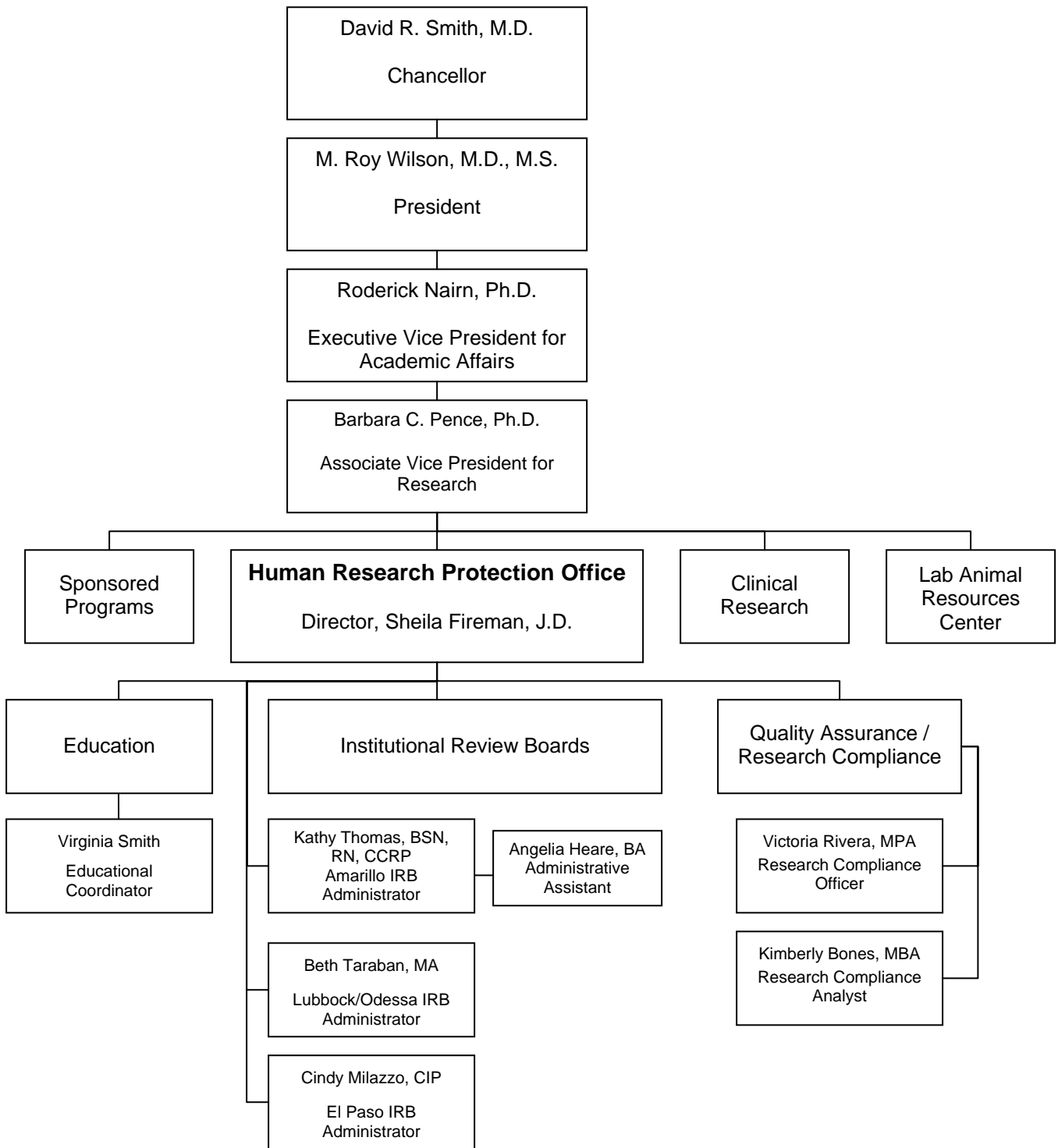
IRB00000098 – TTUHSC IRB #3 (El Paso)

Amarillo Heart Clinical Research Institute (AHCRI) (FWA00005010)
Amarillo Heart Group (AHG) (FWA00003899)
Baptist St. Anthony's Health System (BSA) (FWA00005990)
Coffee Memorial Blood Center (CMBC) (FWA00003800)
Ector County Hospital District (d/b/a Medical Center Hospital)(FWA00006363)
El Paso County Hospital District
d/b/a R.E. Thomason General Hospital (Thomason) (FWA00006280)
PharmaTex Research (FWA00004320)
University Medical Center Health System(UMC) FWA00005898

TTUHSC ACTING AS PRIVACY BOARD (BY WRITTEN AGREEMENT):

Amarillo Veterans Affairs Health Care System (AVAHCS) (FWA00000732)
Baptist St. Anthony's Health System (BSA) (FWA00005990)
Coffee Memorial Blood Center (CMBC) (FWA00003800)
Don and Sybil Harrington Cancer Center, Inc. (HCC) (FWA0000058)
Northwest Texas Healthcare System (NTCS) (FWA00003086)

APPENDIX C – Organizational Chart



APPENDIX D – IRB # 1: Lubbock/Odessa

Member Name (LAST, First MI)	Gender M / F	Highest Degree	Primary Scientific or Nonscientific Specialty	Affiliation with Entity(s) Y / N	Comments
IRB Chair: WHELLY, Sandra M.	F	PhD	Biochemistry Endocrinology	Yes-TTUHSC	
IRB Vice-Chair: O'BANION, Scott	M	RPh	Pharmacy	No	
Voting Members:					
1. ASHCRAFT, Alyce	F	PhD	Nursing	Yes-TTUHSC	
2. BALDWIN, David	M	PhD	Clinical Research	Yes-TTUHSC	
3. BOHANNON, Todd W.	M	MD	Vascular Surgery	Yes-TTUHSC	
4. DeRIESE, Cornelia	F	MD	Obstetrics/Gynecology	Yes-TTUHSC	
5. FOWLER, Melanie	F	MSN	Nursing/Oncology	No	
6. HARDWICKE, Fred L.	M	MD	Oncology	Yes-TTUHSC	
7. HELLBAUM, Rebecca (NV)	F	JD	Law	Yes-TTUHSC	
8. LAWRENCE, Jane	F	BS	Education	No	Comm. Rep.
9. MARSHALL, Michael	M	MD	Orthopedic Surgery	Yes	
10. McGLYNN, Ann	F	PhD	Behavioral Science	No	TTU
11. McGOVERN, Thomas	M	EdD	Behavioral Science	Yes-TTUHSC	
12. OWEN, Donna	F	PhD	Nursing/Oncology	Yes-TTUHSC	
13. PECK, Kimberli	F	MD	Family Practice	Yes-TTUHSC	
14. ROBINSON, Valerie	F	MD	Neuropsychiatry	Yes-TTUHSC	
15. ROHRER, James	M	PhD	Hlth Srvcs Research	Yes-TTUHSC	
16. STANFORD, Brad	M	PharmD	Pharmacy	Yes-TTUHSC	
17. TALBERT, Anthony	M	MD	Pediatrics	Yes-TTUHSC	
18. VUGRIN, Davor	M	MD	Oncology	No	
19. ZHANG, Ming	M	PhD	Audiology	Yes-TTUHSC	
Alternate Members:					
1. COX, Craig	M	PharmD	Pharmacy	Yes-TTUHSC	Alt. for # 16
2. DOWNING, William	M	BS	Public Relations	No	Comm. Rep/ Prisoner Advocate Alt. for #8
3. HANNA, Rachel (NV)	F	BS	Materials Management & Pharmacy	No	Rep. for Midland Memorial Hospital
4. JACKSON, Dorothy G.	F	MSN	Geriatric & Family Practice	Yes-TTUHSC	Alt. for #2, and # 17
5. ROBINSON-HELFRICH, Glenda. (NV)	F	JD	Law	Yes-TTUHSC	Alt. for #6
6. YOUNG, Jeffrey (NV)	M	JD	Law	Yes-TTUHSC	Alt. for #7

APPENDIX E – IRB # 2: Amarillo

Member Name (LAST, First MI)	Gender M / F	Highest Degree	Primary Scientific or Nonscientific Specialty	Affiliation with Entity(s) Y / N	Comments
IRB Chair: 1. PRUITT, Brian	M	MD	Medical/Oncology	Yes	
2. HENKE, Lori	F	PharmD	Pharmacy	No	
3. COHEN, Bernard	M	BBA	Accounting	No	
4. JOHANNESSEN, HelenMarr	F		Comm. Rep.	No	Comm. Member
5. JOHNSTON, Kenneth	M	MD	Medical/Administration	No	
6. KELLY, Gerry	M	MDiv	Pastoral Care	No	
7. KING, Constancio Y.	M	MD	Medical	No	Comm. Member
8. PISKUN, Mary Ann	F	MD	Medical/Surgery	No	
9. RICHARDS, D. Lance	M	PharmD	Pharmacy	No	
10. BOND, C.A.	M	PharmD	Pharmacy/Research	Yes	
11. ROHLAND, Barbara	F	MD	Medical/Psychiatry	Yes	
12. ROHRER, James	M	PhD	Health Services Research & Mgmt	Yes	
13. SICOLA, Virginia	F	RN, PhD	Nursing	No	
14. TURNER, Curtis Wade	M	MD	Pediatric Medical Hematology/Oncology	Yes	
15. WEBSTER, Timothy	M	JD	Lawyer	No	Comm. Member
16. WOODRING, Jimmy	M		Administration	No	
Alternate Members:					
1. HERNANDEZ, Anne	F	MEd, LPC	Counseling	No	Alt. for #14 (pediatric rep) and #4

APPENDIX F – IRB # 3: El Paso

Member Name (LAST, First MI)	Gender M / F	Highest Degree	Primary Scientific or Nonscientific Specialty	Affiliation with Entity(s) Y / N	Comments
IRB Chair:					
1. CASNER, Paul	M	MD, PhD	Internal Medicine	Yes - TTUHSC	
IRB Vice-Chair:					
2. ZUCKERMAN, Marc	M	MD	Gastroenterology	Yes -TTUHSC	
3. AKTAR, Salim	M	MD	Psychiatry	No	Comm. Rep
4. BRIONES, David	M	MD	Psychiatry	Yes-TTUHSC	
5. DOUGHERTY, Steven	M	MD	Surgery	Yes-TTUHSC	
6. LEVIN, Garrett	M	MD	Pediatrics	Yes-TTUHSC	
7. McLEAN, Susan	F	MD	Surgery	Yes-TTUHSC	
8. NELSON, Brian	M	MD	Emergency Med.	Yes-TTUHSC	
9. REILLY, Robert	M	PharmD	Pharmacology	No	Thomason Hosp. Rep
10. SILVA, Elsa	F	BA	Non scientist	No	Comm. Rep
11. STELL, Michael	M	JD	Law	No	Legal
12. TOMAKA, Joe	M	PhD	Behavioral Scientist	No	UT El Paso
13. VARGAS, Susana	F	BA	Education	No	Comm. Rep
14. WILSON, Harry	M	MD	Pathology	No	Comm. Rep
Alternate Members:					
1. ARELLANO, Fred	M	RN	Anesthesiology	No	Alt. for #9
2. GONZALES, Frank	M	JD	Law	Yes	Alt. for #11 NV- TTUHSC Gen Counsel