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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 (ID #IRB00000096)
- IRB #2 Amarillo (ID #IRB00000097)
- IRB #3 El Paso (ID #IRB00000098)

Unless otherwise specified, IRB #1 refers to the IRB located in Lubbock that is also the IRB for the Odessa and Midland Campuses. References to the “Lubbock IRB” imply references to Odessa and Midland as well, unless those campuses are specifically excluded. Similarly, IRB #2 refers to the IRB located in Amarillo that is also the IRB for the Dallas and Abilene Campuses. References to the “Amarillo IRB” imply references to Dallas and Abilene as well, unless these campuses are specifically excluded. Each may also be referred to as “local IRB” in the context just enumerated.

The IRB Policy and Procedures Manual will be revised and updated as new guidances, clarifications, and other information become available. IRBs will work with all investigators to assist them in adhering to current policies and procedures. Applications approved under any version of the Policies and Procedures may require modifications as federal, state, and local rules change.

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) staff, the Associate Vice President for Research (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 an approved, signed Federalwide Assurance (FWA00006767) with DHHS. As set forth in this FWA, 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 IRBs provide initial and continuing review of research applications and protocols involving human subjects.

Each IRB shall uphold the TTUHSC FWA as filed with OHRP.

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

The definition of research for the purposes of the IRB may be found at http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm

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

Only research using human subjects requires IRB review. Researchers who are unsure if their research falls into this category should consult the decision tree found at http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm or contact the HRPO office. Research using unidentifiable commercially available human cell lines or material from human cadavers does not require submission to the IRB for review or exemption. Previously collected data may only be used if they are completely de-identified. Any other research involving these data requires a new IRB submission prior to their use.

All human research which is exempt under section 45 CFR 46.101(b)(1-6) will be conducted in accordance with TTUHSC policies and procedures and the Belmont Report. Federal regulations do
not permit an investigator to determine whether proposed research is exempt from the Common Rule -- whether research is exempt is an HRPO decision.

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 (unless this is the only connection to 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 uses 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 and has a signed agreement with TTUHSC;
- Any employee or student of TTUHSC is engaged in research in connection with his or her responsibilities to TTUHSC.

TTUHSC retains the right to designate another entity’s IRB as the reviewer of specified TTUHSC studies. All reviews of designated research will take place following OHRP guidance and TTUHSC policies and procedures.

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 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, and subparts B, C, & D
- 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.

Any changes made to these rules will be immediately adopted by all TTUHSC IRBs, supplanting anything written in the TTUHSC Policies and Procedures.
2.5 TTUHSC Institutional Official and Reporting Procedures

The Associate Vice President for Research (AVPR) is the TTUHSC Institutional Official with overall responsibility for the TTUHSC IRBs (see TTUHSC OP 73.06, FWA00006767); the TTUHSC Research Compliance Program; and the Human Research Protection Office (HRPO) (see TTUHSC OP 10.16). The Chair or authorized designee of each TTUHSC IRB shall have signatory power for review and actions taken by each local IRB. Electronic documents found in iRIS including all finalized IRB minutes, all stamped documents, all documents referenced in electronic letters, and all official correspondence already approved by the Full Board have the full approval of the IRB chair/designee and have the authority of signed documents. IRB minutes in iRIS are not official until they have been approved by the full board of the IRB.

Human Research Protection Office (HRPO)
The HRPO answers to the AVPR and 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 Federalwide Assurance and TTUHSC policy. This report must take place within 5 working days after all circumstances have been determined. However, once a problem requiring reporting has been identified, the AVPR may notify relevant agencies of on-going investigatory activities.

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

2.6 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). In order to achieve quorum, at least one member present must be a non-scientist.
In addition, each TTUHSC IRB is encouraged to 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 may not vote nor be considered in determining quorum. TTUHSC attorneys may participate in all discussions and remain in the meeting while protocols are being voted upon, however must leave the meeting if a conflict of interest arises.

Consideration must be given to the inclusion of members with diverse backgrounds including experience in areas involving vulnerable subject populations. A TTUHSC IRB that serves as the IRB of record for non-TTUHSC entities may appoint a representative from each affiliate, but is not required to do so. If a representative is appointed from an affiliate, the representative will be a full IRB member who may vote and be counted toward the quorum. If an IRB is reviewing a protocol that is outside the level of expertise of IRB members, an expert consultant may be requested to assess the protocol and present findings, written and/or orally to the IRB. The consultant is not counted toward quorum and must leave the meeting during the final discussion and vote on the protocol.

**Alternates**
Formally appointed alternates should have backgrounds and/or knowledge similar to those whom they are replacing. 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.

2.7 Selection of IRB Members

All IRB members, including each Chair, shall be appointed by, serve at the discretion of, and report to the AVPR. Recommendations for appointees may be made to the AVPR by the IRB chairs, by current IRB members or administrators, or through self-referral. In general, the AVPR appoints all members effective September 1 of each year. Appointments during other times of the year are made as necessary to replace members leaving the Board or to add additional board members and/or alternates. Unless otherwise specified, terms expire on August 31 of the specified year. Each IRB member will be designated as fulfilling one or more of the following roles:

1. Scientist
2. Non-scientist
3. Unaffiliated
4. Prison Representative
5. Other
2.8 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.

2.9 IRB Member Training Requirements

**Necessary Documentation:** All new IRB members must provide their local IRB office with the following:

- A current *curriculum vita* or equivalent
- Evidence of completion of required training
- A signed copy of the *IRB Member Agreement*
- A completed *Financial Disclosure Form* (TTUHSC OP 73.09)

**New Member Orientation:** 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 designee. 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;
- Local IRB Member Roster and IRB Office Roster;
- Investigator’s Handbook; and

All new IRB members are all required to successfully complete TTUHSC IRB mandatory training.

**Continuing Education:**

IRB members are encouraged to participate in at least six (6) hours of continuing education annually on the protection of human research subjects. The AVPR will be kept aware of the continuing education opportunities made available to IRB members. Engaging in any of the
following is considered evidence of continuing education.

- All IRB members are required to receive continuing education on the protection of human research subjects every three years. The current approved course for continuing education is the “Collaborative IRB Training Initiative (CITI) Protection of Human Research Subjects” administered by the University of Miami.
- Educational presentations as part of regularly scheduled IRB meetings, including changes in Federal Regulations, IRB processes, or forms;
- Relevant books, periodicals, or handouts furnished to IRB members;
- TTUHSC training seminars focusing on relevant topics;
- Regional or national seminars or conferences.

2.10 IRB Meetings

Quorum

A quorum is present when a majority of the appointed voting members (or their alternates) of the IRB are present and the requirements of the Common Rule are met. The quorum must include at least one member whose primary concerns are in a non-scientific area.

The IRB may only review proposed research at convened meetings at which a quorum is present. A quorum is not present when a sitting member must recuse him/herself for any reason and that person was necessary for quorum. No official action may be taken at a meeting where a quorum is not present. Despite the presence of a quorum, no action should be taken at an IRB where the assembled members do not have the expertise to review the proposed research.

Conflict of Interest

All TTUHSC IRBs are bound to the policies set forth in TTUHSC OP 10.08, Ethics Policy and TTUHSC OP 73.09, Conflict of Interest in Research. Unaffiliated members of the IRB, while not specifically mentioned in these policies, are also bound by them and are requested to fill out the form reporting annual disclosures. Failure of any IRB participants to comply with these policies may result in suspension of submission privileges or membership by the AVPR. An IRB member may not participate in the initial or continuing review of a project in which the member has a conflicting interest except to provide information requested by the IRB.

IRB members shall recuse themselves from the meeting during the final discussion and vote on research in which any conflict exists, and such shall be noted in the IRB meeting minutes. 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.
- Involvement in the research as PI, sub-investigator, consultant, etc.
- 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.
Meeting Attendance

Guests or consultants to the IRB may attend the meeting only with advance notice and approval by the Chair and after signing a Confidentiality Agreement prior to the start of the meeting.

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

PI Presence During Meeting
The PI is encouraged to attend the IRB during the general discussion of his/her submission. The IRB may specifically request that the PI be present during discussion at a meeting to address the IRB and/or provide answers to IRB inquiries. The PI will be dismissed during the final discussion and vote. Reviewers are encouraged to contact PI’s prior to the meeting to get questions answered and allow time for changes to the submission to be made.

IRB and TTUHSC Administrative Staff Members
IRB or TTUHSC administrative staff members who are not appointed to the IRB but attend IRB meetings by virtue of their position may not be counted toward quorum and do not have voting privileges.

Meeting Schedule
Meeting times and locations are located on the relevant IRB website where all changes will also be posted. IRB members may request that the regularly scheduled meeting date be changed due to conflicts with holidays, faculty meetings, conferences, etc.

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 each of these actions including (a) members present for the vote (located in the IRB Voting section in iRIS for each submission); (b) the number of members voting for, against, and abstaining;
- The basis for requiring changes in or disapproving initial and continuing research; and
- Thorough discussion of research issues and their 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 recused from a discussion/vote due to a conflict of interest and a
description of the conflict of interest.

2.11 Research conducted at more than one TTUHSC campus or alternate site by a single PI

Research that is being conducted at more than one TTUHSC campus may be reviewed at the IRB of
the campus of the PI only. However, IRB administrators or members at other campuses involved in
the research may submit comments to the IRB at the campus of the PI prior to the IRB meeting at
which the review is scheduled. 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 4.0, Local Research Context).

Occasionally, a researcher will wish to open a research protocol on another campus/site that is
already being conducted on the researcher’s home campus. If the research will continue to be
conducted under the supervision of the original PI, but on another campus or site, an amendment
must be submitted adding the second campus or other site as an additional site.

Alternate sites for research, e.g. doctor’s offices, clinics, etc. may be considered for research when
the PI is from TTUHSC or an affiliate and TTUHSC serves as the IRB. Please consult the local IRB
administrator if alternate sites might be used.

2.12 Similar research conducted at more than one TTUHSC campus by different PIs

If either the sponsor or the researcher wishes to open a second, independent protocol of a study that
is already open on a campus of TTUHSC with a different PI and a different research team than the
original study, the second protocol must be submitted to the local IRB as a new, independent
application. OHRP rules do not allow for research protocols, even if they are identical, that are being
run by independent research teams to be considered as the same proposal. Each of these open
studies must have all amendments, continuing reviews, and other documents submitted separately.
Note that the IRB administrators will not routinely communicate with one another regarding these
studies.

2.13 Designating TTUHSC as an IRB

Agencies that are unaffiliated with TTUHSC and wish to affiliate with any one of the TTUHSC IRBs
must contact the director of the HRPO. They must:
- Have an existing Federalwide Assurance (FWA) (see:
  http://www.hhs.gov/ohrp/assurances/index.html);
- Have an agreement/memorandum of understanding with TTUHSC;
- Have designated the TTUHSC IRB(s) on its FWA.

2.14 Records and Confidentiality

The IRB is a committee of the TTUHSC established for the purpose of carrying out requirements
governing research involving human subjects under federal law and TTUHSC policies and
procedures. The IRB 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.”

2.15 IRB Office Records

**File Composition**
The IRB Office files shall be maintained, either electronically or on paper, 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 IRB paper files for three (3) years after the final expiration date of the research study.

2.16 PI Research Records

Every PI, whether with TTUHSC or with an affiliated entity, 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, unless otherwise specified. 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. All TTUHSC research records (including data) are the property of TTUHSC and shall not be transferred to another entity without prior approval of the AVPR. All researchers must comply with the records retention rules of every granting or regulatory agency involved in their research.

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.

2.17 Submission to External IRB

Any designation of an external IRB (another entity's or independent IRB as the IRB of record for a TTUHSC research project) must be documented by a written agreement between TTUHSC and the external 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.
3.0 INVESTIGATOR REQUIREMENTS

3.1 Faculty Status

Principal Investigator Eligibility

Principal Investigators from TTUHSC
TTUHSC PIs ("PI") must have a TTUHSC faculty appointment (full or part time) or have a clinical appointment and be doing research as part of their employment at TTUHSC. TTUHSC employees who do not have faculty status (including residents, students, assistants, fellows, or other individuals receiving training at TTUHSC) cannot 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, in most cases, must use the TTUHSC approved informed consent template.

For clinical trials which are currently active, the PI's faculty status will be verified at the time of continuing review

Principal Investigators from Affiliated Entities
Employees of entities affiliated with TTUHSC may be named as PI in a research study if, at a minimum, all of the following conditions are met:

- Affiliated entity has a Federalwide Assurance (FWA) approved by DHHS;
- Affiliated entity has designated at least one of the TTUHSC IRBs on its FWA;
- Affiliated entity has a current IRB Agreement/Memorandum of Understanding with TTUHSC;
- PI submits application and protocol in accordance with federal regulations and TTUHSC policy with signature of authorized official from the affiliated entity. The signature of the authorized authority from the affiliate entity signifies that the affiliated entity (1) approves of the research; (2) has sufficient resources to conduct the research; and (3) agrees that the PI has the appropriate education and experience to conduct the research.
- The PI agrees to comply with the compliance requirements of TTUHSC.

The PI may be asked to submit professional qualifications for review and approval to the TTUHSC AVPR or designee prior to submitting a proposal to an IRB. Researchers should be aware that they should have malpractice insurance that covers them while they are doing research.

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 Federalwide Assurance (FWA) approved by DHHS;
- PI has a current, signed 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;
- PI possesses a terminal degree, with professional qualifications appropriate for the conduct of the proposed research;
- PI has resources available to conduct proposed research; and
The PI may be requested to submit professional qualifications for review and approval to the TTUHSC AVPR or designee prior to submitting a proposal 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.

3.2 TTUHSC Employment Status and IRB Use

TTUHSC faculty employees (where research is considered part of the faculty member’s job duties):

- Must use the TTUHSC IRB unless an agreement designating an alternate IRB is in place.
- 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 IF the study is funded by an industry sponsor.
- School of Medicine faculty physicians are covered under the TTUHSC Professional Liability Self-Insurance Plan; other HSC schools should 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.

Note: An Individual Investigator Agreement may be used by a TTUHSC investigator to extend – for one or more research protocols – the applicability of the TTUHSC FWA to cover either collaborating independent investigators or collaborating institutional investigators. Information regarding this agreement and its use may be found at http://www.hhs.gov/ohrp/humansubjects/assurance/guidanceonalternativetofwa.htm. Any Individual Investigator Agreements will originate from the HRPO office and be filed there. Contact your local IRB administrator prior to submitting any research that might require this agreement.

Faculty member with a TTUHSC faculty appointment (usually clinical), who is conducting research that is not connected to the TTUHSC appointment. This person is generally self-employed or employed by another entity and 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:

A. Can use the TTUHSC IRB only if individual or employing entity:
• Has a Federal-wide Assurance approved by DHHS.
• Has designated a TTUHSC IRB by executing an IRB Agreement with TTUHSC as applicable.
• Has agreed that the TTUHSC Research Compliance Office shall have access upon request to research project records for audit and compliance purposes.

B. Must pay IRB review fees and iRIS use fee upon receipt of invoice IF the study is funded by an industry sponsor.

C. Cannot use TTUHSC on the heading of the consent form or suggest that the research is being conducted, approved, or sponsored in any way by TTUHSC. Any consent form must be approved by the TTUHSC IRB;

D. Cannot use TTUHSC facilities for conduct of the research;

E. 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 http://www.fda.gov/cder/guidance/959fnl.pdf, in designing and conducting clinical trials.

3.4 Notice of Absence

A PI is required to notify the IRB in writing as soon as possible prior to any employment change, extended absence, or faculty development leave during which the PI will be engaged in research. (See TTUHSC 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

All TTUHSC PIs are bound to the policies set forth in TTUHSC OP 10.08, Ethics Policy, and TTUHSC OP 73.09, Conflict of Interest in Research. Unaffiliated PIs, while not specifically bound by these policies, are also responsible to monitor themselves and are bound by their research ethics to report any potential conflicts of interest to the IRB. Failure of any PIs and their research personnel to comply with these policies may result in suspension of submission privileges.

If the IRB determines that a TTUHSC PI conflict of interest exists, the issue must be referred to the Conflict of Interest Committee (COIC) established by TTUHSC OP 73.09. The IRB may not review a submission until the COIC has met and made its recommendations. Affiliated entities should submit documentation to the IRB specifying the identified conflict of interest and how it will be managed.

3.6 Responsibility for Research Activities

The PI retains ultimate responsibility for the conduct of all research activities including payment to subjects 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

Initial TTUHSC Training Program

All principal investigators, co-investigators, all research staff, and IRB members from TTUHSC and its affiliates 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 Protection of Human Subjects administered by the University of Miami through the Collaborative IRB Training Initiative (CITI). All TTUHSC and affiliate PIs, co-Investigators, all research staff, and IRB members are also required to receive training in the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to research. This training is attached to the end of the CITI course. PIs are responsible to ensure that all personnel associated with human subject research complete the initial training program prior to beginning work on any study. The HRPO may also offer additional training on a scheduled basis or as requested by researchers, administrators, or departments.

If applications submitted to the TTUHSC IRBs have co-investigators or research staff from schools or hospitals that are not formally affiliated with TTUHSC, the TTUHSC IRBs retain the right, at their discretion, to request documentation of training regarding the rights and protection of human subjects in research, or, in its absence, require the unaffiliated co-investigators or research staff to take TTUHSC required training prior to final IRB approval. Other forms of human research training may be approved at the recommendation of the HRPO and at the final discretion of the Educational Coordinator. 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. Any Biomedical CITI training that is current within 3 years is acceptable upon receipt of the completion certificate by the Educational Coordinator. In this case additional HIPAA training may be required.

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) 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. This also fulfills the requirements for continuing education in HIPAA. Questions about continuing education requirements shall be directed to the Educational 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, relevant conferences, and the Internet Research Information System (iRIS). Books, periodicals and other relevant educational materials are available at all of the IRB offices.
4.0 LOCAL RESEARCH CONTEXT

TTUHSC’s responsibilities under its Assurance apply 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:

- Document in writing that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants.
- Necessary information under DHHS regulations includes all of the following:
  - the anticipated scope of the entity's research activities;
  - the types of subject populations likely to be involved;
  - the size and complexity of the entity;
  - institutional commitments and regulations;
  - applicable law;
  - standards of professional conduct and practice;
  - method for equitable selection of subjects;
  - method for protection of privacy of subjects;
  - method for maintenance of confidentiality of data;
  - language(s) understood by prospective subjects;
  - method for minimizing the possibility of coercion or undue influence in seeking consent; and
  - safeguards to protect the rights and welfare of vulnerable subjects.
- 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.

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, 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:

- 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;
- Periodic discussion with appropriate consultants knowledgeable about the local research context;
- Regular interaction with one or more of the entity’s designated liaisons; and
- 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.
5.0 IRB SUBMISSION MECHANISM, SCREENING, DEFINITIONS, FEES, AND RELATIONSHIPS TO OTHER COMMITTEES

5.1 Submission Mechanism

All submissions including initial applications, continuing reviews and amendment requests must be submitted using Internet Medical Research Information System (iRIS) Software. This is also the mechanism through which information is communicated between investigators and the IRB. All correspondence generated by iRIS and sent to research personnel are considered official (See section 2.5).

5.2 Submission Screening

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. If a PI wishes a more extensive screening by the IRB Administrator; efforts should be made to submit the application as much in advance of the deadline as possible. When the submission is adequately prepared for review, it will be placed on an agenda for IRB review.

5.3 Definition of Human Research

In order to require IRB review, studies must involve research that uses human subjects. Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. For instance, a single case study is not considered research because it is neither a systematic investigation nor is its results generalizable. However, if a researcher wishes to combine more than one case study to find a common thread, or conduct a retrospective chart review, these activities would involve a systematic investigation looking for generalizable knowledge, and would be considered research.

In order to be considered human research, the study must involve living individuals. Research using commercially sponsored de-identified cell lines or cadavers, for example, is not human research and does not have to be submitted to the IRB for either exemption or review. Note that HIPAA requirements differ somewhat in this area. Before submitting an IRB application, Investigators should review HIPAA requirements on research with cadavers.

Contact the appropriate IRB Administrator if there is any question as to whether or not you are conducting human research.

5.4 Types of Research Review

Three categories of review are recognized by federal regulations. Rules for submission in each of these categories may be found elsewhere in this manual.

- **Exempt**: Research that may be exempted from federal regulation requirements regarding human research by the IRB Chair or designee.
- **Expedited**: Research that federal regulations allow the IRB Chair or designee to perform the initial review.
- **Full Board**: Research must be reviewed at a convened meeting of the IRB.
5.5  IRB Fee Policy for Industry-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 the HRPO and established during contract negotiations with sponsors and in IRB Agreements with affiliated entities [see: TTUHSC Operating Policy (OP 73.08)].

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 or affiliated entity. 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 are 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.

5.6  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

The IRB may request that approval from any of these committees be obtained prior to TTUHSC IRB approval.
6.0 EXEMPT STUDIES

The determination of whether a TTUHSC study qualifies for exempt status must be made by the person(s) designated by the chair of the IRB; TTUHSC researchers may not make these judgments themselves. The designation must be granted prior to the research commencing. IRB approval may never be granted for research already in progress or completed.

If a PI, after reviewing the decision charts found at the OHRP website (http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm) considers a study to be exempt, only the following documents need be submitted:

- Exempt IRB Application found in iRIS;
- The full research protocol;
- A HIPAA Waiver for studies using PHI; and
- Any other available documentation to help support the application, including any data collection forms, surveys, etc.

If the designated reviewer determines that a non-exempt application is required, the PI will be notified of this decision in writing. Questions about exempt status should be directed to the IRB Administrator located on the appropriate campus.

Federal regulations 45 CFR 46.101(b) provide for six specific categories of activities that may qualify as exempt. Exempt status will never apply to research involving prisoners. While exempt status may be determined in studies involving children, extra care must be given to ensure that their rights are protected. The exemption 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. An example of a study that might be exempt is one conducting a survey on all graduate students by stopping them in the hallway but not asking for their names or any other identifying information.

- 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. An example of this category is a retrospective chart review where no identifiers are taken. Remember that
this is research and that the exemption must be granted by the IRB office prior to the research taking place.

- 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). The IRB chair/designee retains the right to refer any application for expedited or full board review, even if it appears to meet the qualifications for exemption.
7.0 EXPEDITED REVIEW

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. Federal regulations allow the IRB to review certain applications on an expedited basis if they meet specified criteria.

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. Expedited review is appropriate for research activities that

- present no more than minimal risk to human subjects, and
- involve only procedures that are listed in one or more of the research categories that may be found at this website:  [http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)

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.

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 should cite the specific permissible category or categories justifying the expedited review.
8.0 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 (minimal, greater than minimal) to human subjects as determined by the Chair. Any proposed studies using investigational drugs or devices; approved drugs or devices in unapproved categories; or vulnerable populations, e.g. prisoners, pregnant women will always require full board review. The PI is encouraged to attend the IRB meeting at which his/her protocol is being presented in order to answer any questions the members may have.

The full Board review process includes the following components:

- IRB Chair or designee shall assign each protocol for review to at least two IRB members, one of whom will be designated the primary reviewer, one the secondary reviewer, for review. All study materials, with the possible exception of a lengthy sponsor’s protocol, are available to all IRB members through the iRIS system. A copy of the sponsor’s protocol will be made available to all IRB members. The primary and secondary reviewers conduct an in-depth review of all materials and enter their comments into iRIS; all IRB members are asked to review all submissions and make comments. Reviewers are encouraged to contact PIs prior to the IRB meeting with any questions they have so that these issues may be addressed in advance of the full Board meeting. A summary of the study and recommendations regarding the disposition of the study shall be presented to the full Board and is available to all IRB members through iRIS. Clarification and discussion by the full Board then takes place.

- Existence of quorum.

- A majority vote of the voting members to formalize IRB decisions.

IRB review will result in one of the following actions:

**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 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 IRB and the required frequency of continuing review will be provided in writing to the PI.
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.

**Request Additional Information or Modifications from PI**

The IRB may request clarifications, protocol modifications, revisions to the informed consent document, or other supporting documentation. In iRIS, these requests are generally found in the section entitled “Stipulations”. A stipulation is a request made by a reviewer that must be addressed before an IRB submission can be approved. For each stipulation, the investigator is asked, “Do you accept this stipulation?” The investigator replies “yes” or “no” and provides an explanation of the response. The responses are subsequently reviewed through administrative review if the stipulations involve minor modifications and/or the proposal is eligible for expedited review; or by the full board of the IRB if the proposal initially required full board approval and the modifications are greater than minor. The IRB determines at the original Board meeting whether the modifications are minor. 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. Full Board review of the minor requested changes is not necessary.

The PI is requested to address stipulations and/or for additional information in writing 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 may be administratively closed by the IRB and further review of the study will require a new application to be submitted to the IRB.

**Study Tabled**

A study may be tabled under the following circumstances:

- Numerous greater than minor changes required orIncomplete application.
  - The IRB has reviewed the study and determined that extensive substantive 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.

- 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, unavailability of required member for a thorough review, or the need for outside consultation to assist the IRB. The study will be rescheduled with no action required by the PI.

- Necessary documentation from other pertinent TTUHSC committees, e.g. Conflict of Interest Committee, has not been provided. The study will not be rescheduled until all necessary documentation is provided.

**NOTE:** All studies that are tabled at a full Board meeting will require subsequent full Board
review unless substantial changes place them in a different category.

**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. 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.
9.0 INITIAL REVIEW OF APPLICATIONS

TTUHSC PIs shall submit research studies for review to the TTUHSC IRB at the campus of their appointment: Lubbock, 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). Section 5.0 contains specific requirements for submitting an initial application.

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 covered by a TTUHSC IRB who are conducting research at a site 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. PIs wishing an Unaffiliated Investigator Agreement should contact their local IRB administrator.

In conducting the initial review of proposed research, the IRB must obtain information in sufficient detail to make the determinations required under federal regulations. If the designated IRB does not have the expertise necessary to review any study, including those involving a vulnerable population, the IRB Chair may request a review from a consultant or request referral of the study to another TTUHSC IRB for appropriate review, as long as the receiving IRB has an appropriate Institutional Agreement. 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 4.0 Local Research Context).

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

- Completed TTUHSC IRB (exempt or non-exempt) application form;
- Full protocol;
- Any applications for funding;
- Investigational New Drug (IND) or Investigational Device Exemption (IDE) number (see Section 18.0);
- Investigator’s Brochure (if required);
- Proposed informed consent document using TTUHSC IRB-approved format;
- All proposed data collection forms;
- Authorization to Use and Disclose PHI for Research (HIPAA authorization) or Request to Use and Disclose PHI Without Authorization for Research (see Section 11.0);
- Department Chair approval (or signature of authorized official designated in entity’s IRB Agreement);
- Copies of letters of assurance or cooperation with research sites;
- Recruitment materials;
- Relevant grant applications, including umbrella grants;
- Surveys, questionnaires, or videotapes;
- Documentation of review by required TTUHSC institutional committees;
- CV of PI and/or others as requested;
- Other materials as requested.

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.
10.0 INFORMED CONSENT

10.1 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 alter or waive the requirement for the PI to obtain a signed and dated consent form (see below). The informed consent form must be written and presented to the subject in a manner that is not threatening or coercive. If PIs are uncertain as to how to obtain informed consent, training will be provided by the HRPO office.

The consent form must be written in non-scientific language that is easily understood by all subjects. The non-scientific members of the IRB should be asked to review consents to ensure that they are clear and understandable. All TTUHSC research studies shall utilize the TTUHSC Informed Consent template found on the iRIS system. It includes, but is not limited to, all of the required basic elements of consent (45 CFR 46.116). HIPAA language in the consent form is unnecessary and will not replace the requirement for a HIPAA form. A copy of the consent shall be given to the person signing the form.

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.

Written Consent Form Signed by Subject or Representative

The PI or designee must provide the opportunity to discuss the informed consent with the subject, reviewing all of the elements, preferably during a face-to-face presentation to the subject or the subject’s representative. The PI shall allow the subject or the 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. If the subject is an adult but for medical reasons is unable to sign the informed consent, the subject will be asked to sign the informed consent once s/he is physically able. If the subject does not wish to sign the consent, the research will be halted appropriately and, if the subject wishes and it is possible and the consent permits it, the subject’s data will be removed from the research data base. The requirement that the consent be signed may be waived by the IRB on a case-by-case basis following a written request and justification by the investigator.

No Stamped Signatures

The PI (or authorized designee approved by the IRB to obtain informed consent) also signs the consent document at the same time as the subject or representative signs. 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 foreign language version should be submitted after the IRB has approved the English version. A TTUHSC Spanish language consent template is available in iRIS.
Oral Presentation
In cases where the subject is unable to read the required consent form, the approved consent form may be read to the subject in its entirety in a language understood by the subject or the subject’s 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 11.0 HIPAA requirements).

A short form written consent document stating the elements of informed consent required by 45 CFR 46.116 may be presented orally to the subject or subject’s representative. When this method is used there shall be a third party witness and the IRB must approve a written summary of what is to be said to the subject or subject’s representative. The subject or subject’s representative shall sign the short form but the witness shall sign the copy of the summary and the short form. The person obtaining the consent shall sign the summary. A copy of the summary and short form shall be provided to the subject or subject’s representative [45 CFR 46.117(b)(2)].

Waiver of Documentation of Informed Consent
Waiver of the documentation of informed consent may take one of two forms:

(a) some portions of the documentation of informed consent may be waived, or
(b) the IRB may waive the requirement for the PI to obtain a signed consent form for some or all subjects if it 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.

10.2 Waiver of Informed Consent Process

The IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent or may waive the requirement to obtain informed consent entirely provided:

- 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. The waiver may be granted by expedited review by the IRB chair or designee.
10.3 Assent (See also Section 19.3 regarding research with children and minors):

If a subject is not legally capable of giving informed consent 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, cognitive, 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.

10.4 Approval and Expiration Dates on Informed Consent Documents

Only the most-recently IRB approved Informed Consent may be used by the researcher to obtain consent for a study. IRB-approved Informed Consents will have the TTUHSC seal and approval and expiration dates affixed to the document.

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.

10.5 Special Considerations for Tissue Bank Consent Documents
Tissue Bank Informed consent documents must contain language indicating whether or not the subject/donor will financially benefit from any product developed from their tissue. They must also have the current approval and expiration dates stamped on the consent documents. A sample consent may be found in iRIS.
11.0 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

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, unless there are changes required on the HIPAA form.

Further information regarding HIPAA compliance, including approved forms, can be found at [www.ttuhsc.edu/hipaa](http://www.ttuhsc.edu/hipaa).

11.1 HIPAA Authorization

Each TTUHSC 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 there is no expiration date or that the authorization continues in effect until the end of the research study. If there is any question as to whether PHI is being collected, contact your IRB administrator. Requests to alter HIPAA documents shall be submitted to the TTUHSC Privacy Officer.

Principal Investigators who are members of unaffiliated organizations that have designated TTUHSC as their Privacy Board may use the TTUHSC HIPAA authorization form that is found in iRIS. All references to TTUHSC should be deleted except as it pertains to the IRB stamp. This policy does not prohibit organizations from using their own HIPAA Authorization Form in addition to the TTUHSC HIPAA Authorization Form, should they so wish.

11.2 Screening for Recruitment:

All researchers should check with their respective IRB administrator prior to screening any subject population for possible inclusion in research. The researcher should check with the administrator, even if screening is used simply to determine if an adequate number of eligible subjects exists, because HIPAA Waivers may be needed.

11.3 HIPAA Waiver Request to Privacy Board

All PIs may request to use and disclose specified PHI without an individual’s authorization and/or without the necessity for an opportunity for the individual 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 IRBs 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 are in place prior to a Privacy Board Review. IRB administrators are members of the Privacy Board and may grant HIPAA Waivers. The IRB as Privacy Board shall review the PIs Request and provide a written response in iRIS.
12.0 RECRUITMENT AND ADVERTISING

12.1 IRB Approval of Recruitment/Advertising

Screening for Recruitment:
All researchers should check with their respective IRB administrator prior to screening any subject population for possible inclusion in research. The researcher should check with the administrator, even if screening is used, simply to determine if an adequate number of eligible subjects exists. HIPAA Waivers may be needed.

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. An expedited review may be used for approval, but all advertising may be referred for full board review at the reviewer’s discretion.

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.

Solicitations from the PI or any member of the research team to physicians, agencies, or others in order to recruit subjects must also be approved by the IRB prior to implementation.

Employees as Participants
No researcher may give an indication that an employee is required 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
Students must always be informed if participation in research is a course requirement and they must be offered an alternative activity if they choose not to participate. The syllabus shall clearly describe proposed participation in research activities for course credit and the alternative means of earning the course credit, which must require an equivalent amount of time and effort. 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.

12.2 Payments to Subjects

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 in proportion to the portion of the study completed and shall not be contingent upon the subject completing the entire study. A schedule for the amount to be paid for each activity will not suffice; a timetable for the payments themselves must be submitted, approved, and presented to every subject as part of the Informed Consent process.

Method of Payments
The Informed Consent must clearly establish how the subject is to be paid, i.e. cash, check, etc. A subject must sign a receipt for any cash payment, and this procedure must also be described as part of the Informed Consent process. The description must also inform the subject if any money received will be reported to the Internal Revenue Service (receipt of $600 or more per year must be reported to the IRS). If subjects are receiving cash and are not being paid by check, a rationale must be presented to the IRB.

Alterations in Payments
Any alterations in human research subject payment or revising of the payment schedule must be submitted to the IRB as an amendment prior to implementation. A document to be sent to the subjects informing them of payment changes must be part of this submission.

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.

12.3 Finder’s Fees

The TTUHSC 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.
13.0 AMENDMENTS TO PREVIOUSLY APPROVED STUDIES

For previously approved projects (including exempt studies that, with the proposed change, may no longer qualify for this status), 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.

Modifications

1. **Minor modifications** proposed for previously approved studies may be reviewed (during the period for which approval was authorized) 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. Examples of minor modifications include but are not limited to: changes in reagents; changes in a mailing address; editorial corrections; changes in non-treatment equipment that will not affect the study outcome. The IRB chair or designee will determine if the proposed change is eligible for expedited review. Modifications to the protocol require submission of an updated copy of the protocol with changes clearly identified.

2. **Greater-than-minor modifications** proposed for previously approved studies must be reviewed (during the period for which approval was authorized) by the full board of the IRB 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. Examples of greater-than-minor changes include but are not limited to: omitted or changed items (e.g., funding) that may affect the level of risk; an increase in the number of study subjects; a change in procedure that requires a change in the consent; changes in the inclusion/exclusion criteria that result from changes in side effects; changes that may affect the level of risk. Modifications to the protocol require submission of an updated copy of the protocol and consent, if necessary.

3. **Change of Research Personnel** proposed for previously approved studies (during the period for which approval was authorized) may be handled administratively, but the full board of the IRB must be informed via the agenda for the next meeting. PI shall notify IRB of any changes in research personnel by amendment 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 will be promptly conveyed to PIs in writing by the IRB Office. Written notification from the IRB Office of any decision to disapprove an amendment to a study will be accompanied by the reasons for the disapproval and an opportunity for the PI to reply, using iRIS. Replies are due within 30 calendar days of the date of written notice to the PI unless otherwise specified.
Continuing review of all research approved by the IRB, whether funded externally or not, will take place within a year of the initial review. 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.

Information required for continuing review includes:

- 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 benefits or risks/benefits to the subjects;
- A summary of any unreported incidents of the following: adverse events, 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);
- Unreported amendments or modifications to the research since the last review;
- An updated complete protocol (if changes have been made);
- Any relevant multi-center trial or Data Safety Monitoring Board (DSMB) reports, unless already submitted;
- Any other information which may be relevant to making a determination regarding the potential risks, benefits, or scientific merit of the study.
- Updated Financial Disclosure (HSC OP 73.09a) statements may also be submitted at the time of annual review

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**

Studies that were originally approved by the Full Board and that are actively enrolling subjects or are continuing to provide study treatment to subjects require a Continuing Review by the Full Board. Documentation received prior to the submission deadline (see website for appropriate IRB) 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:

- Studies that received expedited initial review;
- Studies in which enrollment has not yet taken place and no additional risks have been identified;
- Studies closed to accrual of new subjects **and** where subjects are no longer contacted.
- Studies in which subjects continue to be enrolled but are no longer receiving study treatment. These studies must be reviewed at least annually until such time that there is no need to re-contact enrolled subjects.
- Studies in which only data analysis continues to take place.

**Failure to Provide Continuing Review Information.**

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 effective the date of expiration.** 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 thirty days after the expiration date, the study will be closed administratively by the IRB. Studies that are administratively closed by the IRB are no longer approved for any research activity. An investigator who wishes to reinitiate a research protocol that has been cancelled must submit the project as an initial application (see section 8.0).
Exempt Studies
Exempt studies are not approved by the IRB and do not require continuing review. However, on an annual basis investigators may receive a notice asking them to inform the IRB if any of the following has occurred:

- Any changes in the study procedures that may remove the study from the Exempt category or affect the risk level of the study, or
- Whether the study remains open.

There is no penalty for failure to reply.
15.0 PROTOCOL DEVIATIONS

Protocol deviations are unplanned or unforeseen changes in the implementation of an IRB-approved protocol. They generally refer to a modification of procedures that has already occurred for a single subject; they are not intended to modify the protocol. Such deviations may be minor or major.

15.1 Minor Protocol Deviations

Minor protocol deviations do not need to be reported to the IRB at the time of discovery. Nothing in this policy will restrict minor modifications from being reported to the IRB or corrective actions being required. Minor protocol deviations include:

- Deviations that do not increase the risk to the subjects;
- Deviations that do not affect the scientific validity of the study;
- Deviations that do not result from deliberate misconduct of the investigator;
- Deviations that do not necessitate any change to the approved protocol.

Examples of minor deviations include delayed follow-up visits (if no medication, treatment, or supervision is missed) or short delays in the delivery of medication to a subject.

15.2 Major Protocol Deviations

Major protocol deviations are reportable to the IRB. These deviations must be reported to the IRB by the PI within 10 working days from when the PI becomes aware of them, and more quickly if serious harm results. Major protocol deviations include, but are not limited to:

- Deviations that increase the risk, including any deviation that results in a change in a subject’s medical status;
- Deviations that cause physical, mental, or psychological harm to a subject or otherwise impede a subject’s rights;
- Deviations that damage the scientific integrity of the study;
- Deviations as a result of deliberate misconduct on the part of the investigator;
- Deviations that cause the study to be seriously or continuously out of compliance with federal, state, or TTUHSC regulations;
- Multiple minor deviations have occurred on the same study or on other studies from the same investigator(s);
- Failure to follow a corrective action plan.

Examples of major (hence reportable) deviations include:

- Enrolling subjects who do not fulfill inclusion/exclusion criteria;
- Subjects receiving any research-related activity prior to approved informed consent being obtained;
- Not reporting serious, unexpected adverse events;
- Variations in use of study device or in dispensing, dosing, or storing of research medications;
- Loss or corruption of study data;
- Incorrectly performing or missing tests or procedures required by the protocol;
- Premature “unblinding” of a subject;
- Anything identified by a monitor that may affect the safety of a subject or integrity of data.
Any protocol deviation may be reported to the IRB. Researchers should err on the side of caution when deciding whether or not a deviation must be reported. Questions may be directed to the respective IRB Administrator or Chair. All protocol deviations, whether or not they have been reported to the IRB, are kept on file by the PI and are reported and explained at the time of the annual review. All deviations must also be available for inspection at the time of audit.
16.0 UNANTICIPATED PROBLEMS AND/OR ADVERSE EVENTS

The IRB is charged with the responsibility of reviewing reported unanticipated problems and adverse events involving risks to subjects 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. In the case of a study’s suspension or a serious unforeseen risk, all appropriate reporting will take place. A more complete discussion of this section may be found in the OHRP Guidance dated 01/15/07 found at http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm.

The PI and all study personnel are responsible for knowing the correct definitions for all terms used in this section. These definitions may be found in Appendix A – Glossary. Every time a defined term is used within this section, it will be italicized. If there is any question, HRPO personnel and the appropriate IRB chair, in conjunction with the AVPR, will make the final determination as to the category of the event and any external reporting needs.

16.1 Unanticipated Problems

Please see the definition in: Appendix A – Glossary. Note that an unanticipated problem may or may not be an adverse event. Examples of unanticipated problems that are not adverse events are as follows. Each meets all 3 of the criteria for an unanticipated problem: (a) unexpected; (b) related to research participation; and (c) placed the subject or others at greater risk than previously identified.

- Stolen or lost sensitive, identifiable data.
- Gross pharmaceutical dosing error that resulted in no known harm to the subject.
- Donor sera were not appropriately screened.

Note that none of these examples represented any detectable harm or adverse effect to the subject, but each requires substantive changes in the protocol and/or informed consent or other corrective actions to protect the safety, welfare, and rights of the subject.

If an unanticipated problem is identified, it must be reported to the IRB within 7 days of the PI becoming aware of it. The IRB will notify the Institutional Official who will notify appropriate agency heads and OHRP. The IRB will work with the PI in determining what other actions must be taken.

Any report of an unanticipated problem that is submitted to the IRB must contain the following information:

1. appropriate identifying information for the research proposal, such as the title, investigator’s name, and IRB number;
2. a detailed description of what happened;
3. an explanation of the basis for determining that the incident represents an unanticipated problem;
4. a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.
16.2 EXTERNAL ADVERSE EVENTS (ALSO KNOWN AS IND SAFETY REPORTS)

If an External Adverse Event is identified as:
- Unexpected;
- Related or possibly related;
  AND
- Serious Adverse Event

it must be submitted to the IRB. If an External Adverse Event does not meet all of the above criteria, it does not need to be submitted to the IRB. If a sponsor requires IRB submission, the PI may submit them via iRIS and the submission will be acknowledged by the IRB. The External Adverse Event will not be deliberated by the IRB. If the External Adverse Event changes the risk status or any other element of the consent, an amendment must be filed with the IRB (see: Amendments Section 13.0) within 7 days of the investigator receiving the information and must include the sponsor’s rationale for the change(s).

16.3 INTERNAL ADVERSE EVENTS

PIs shall submit a written report to the IRB in writing via iRIS all unanticipated (i.e. not consistent with the current investigator’s brochure or with other current risk information) adverse events or problems (both serious and non-serious):
- that involve research at TTUHSC or an affiliated entity
- known to be related or may possibly be related to the research activities
- within two (2) business days after the PI becomes aware of the event.
- The PI is responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and other unanticipated problems.
- Reports of all unanticipated adverse events 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.

16.4 SERIOUS ADVERSE EVENTS (SAE)

By definition, SAEs are internal events. All PIs shall submit a written report to the IRB via iRIS:

(i) Of any SAE that includes death; a life threatening experience; hospitalization (for a person not already hospitalized); prolongation of hospitalization (for a subject 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,
(ii) as soon as possible, but in any event, no later than two (2) business days after the PI becomes aware of the event.

The AVPR, in conjunction with HRPO personnel, and the appropriate IRB chair will make the final determination of the category of the event and any external reporting needs.
17.0 STUDY CLOSURE/TERMINATION/SUSPENSION

17.1 Study Closures

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 through iRIS and include a summary of findings to date.

Completed Studies

Studies that have been completed, including final data analysis, and are closed at the local research
site, will be designated as “Completed” in iRIS. The PI shall submit the “Study Closure Report” to the
IRB, which will include the total number of subjects, any major problems, and a summary of the
findings. A manuscript may be substituted for the summary of the findings. Once a study is
designated “Completed”, any links (codes, etc.) between the data and identifiers must be destroyed
and as any videos, tapes, etc. that were targeted for destruction at the completion of the study.
Study materials must be stored for a minimum of 3 years, and must be stored as long as additional
applicable federal or contractual regulations stipulate.

Once the IRB has sent a written acknowledgment that the study is designated “Completed”, no
further actions are necessary by the PI.

Cancelled Studies

If, after IRB approval, a study is permanently closed by the researcher or sponsor for any reason
prior to its completion, it will be designated as “Cancelled” in iRIS. The PI shall submit the “Study
Closure Report” to the IRB, which will include the total number of subjects, any major problems, and
a summary of the findings. Once a study is designated "Cancelled", any links (codes, etc.) between
the data and identifiers must be destroyed and as any videos, tapes, etc. that were targeted for
destruction at the completion of the study. Once the IRB has sent a written acknowledgment that the
study is designated “Cancelled”, no further actions are necessary by the PI.

Temporarily Closed Studies

Studies that are temporarily closed to accrual by the PI, Sponsor, or IRB will remain in “Open” status
in iRIS. No new subject enrollment may take place while studies have this designation. Continuing
reviews of the research by the IRB are required.

The IRB sends written acknowledgement of the temporary closure status, and it is lifted only by
written notice from the IRB. If the sponsor has temporarily closed the study, the PI must notify the
IRB upon its closure and when the sponsor re-opens it. Study activity may not resume until the PI
receives written approval from the IRB.

Administratively Closed Studies

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

- non-responsiveness to requests for information from the investigator, or
- no enrollment of subjects in the study for a period of three or more years.

No further research activity is permitted for studies which are administratively closed. Any further
activity on such studies will require the submission of a new application to the IRB.
17.2 Suspension/Termination of Approval for Cause

The IRB and/or the AVPR have authority to suspend/terminate research for cause. The term “Suspension/Termination” applies when the IRB withdraws its approval from a study for any of the following causes:

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

Notification of suspension/termination requires immediate cessation of all research activities, including data analysis, 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.

Studies that have been terminated/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.

17.3 Appeal of 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 notification of suspension/termination.

Review by Subcommittee and Recommendation to Board

Within 14 days of the appeal of suspension, the PI’s request for reconsideration shall be reviewed by a subcommittee consisting of the IRB Chair and two IRB members jointly selected by the IRB Chair and Senior Director of HRPO. The subcommittee may also invite individuals with expertise in that area of research to assist the subcommittee in its review of the issues (See 21 CFR 56). Individuals assisting the subcommittee 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 recommendation to the full Board at its next regularly scheduled meeting, if possible. At the discretion and invitation of the subcommittee, the PI may address the 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.
18.0 INVESTIGATIONAL DRUGS/DEVICES

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.

18.1 IND Application

Before submitting an application to the IRB that involves an investigational new drug or biologic, the PI must secure an IND number and approval 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.

18.2 Special Requirements for an IDE Application

The IDE regulations specify that there are two different types of device studies, “significant” risk (SR) and “nonsignificant” risk: (NSR). The determination is initially made by the device manufacturer and must be made based on the proposed use of a device in and investigation, not just on the device alone. The IRB must review the risk level.

SR Studies

- An SR device study is defined as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; or (4) otherwise presents the potential for serious risk to the health, safety, or welfare of a subject.
- Determination of SR is made by sponsor.
- Must be reviewed by the IRB.
- Governed By Investigational Device Exemption (IDE) regulations (21CFR 812)
- Both IRB and FDA must approve the investigation
- IRB should consider information including results of prior investigations using device; proposed investigational plan; subject selection criteria; and monitoring procedures
- Sponsor must furnish the IRB with a risk assessment and the rationale for making the determination [21 CFR 812.150(b)(10)].

NSR Studies

- An NSR study investigation is one that does not meet the definition of a serious risk study.
- Both SR and NSR studies require initial and continuing IRB approval and informed consent.
- Determination of NSR is made by the sponsor.
- IRB acts as FDA surrogate because sponsors are not required to report NSR device study approvals to the FDA.
IRB Risk Determination

The IRB may agree or disagree with sponsor’s NSR designation.

- If IRB agrees and approves study, it may begin without submission of an IDE application to the FDA.
- If IRB disagrees, the IRB will notify the sponsor who must notify the FDA that an SR determination has been made and apply for approval of an IDE application.

The IRB minutes must document the rationale for SR/NSR and subsequent approval or disapproval decisions for clinical investigations.

18.3 Emergency Use of Drug/Device

Definition of Emergency
An emergency exists when
(a) a patient/subject meets the requirements for emergency use established by the FDA (21 CFR 812); and
(b) an IND/IDE exists for an investigational drug/device, but there is no IRB approved study at TTUHSC.

After Emergency Use of Investigational Drug/Device Procedures
- Use of drug/device must be reported to the IRB within 5 business days of its use. This report must contain a description of the investigational drug/device and include rationale for its use.
- The likelihood of similar need for the investigational drug/device must be evaluated and an IRB application initiated immediately if subsequent use appears likely.

18.4 Unanticipated Adverse Device Effects

This is a category of adverse events. When there is an unexpected adverse event involving a device, there are different reporting requirements. In this case, sponsors must report the unexpected adverse event directly to the IRB, not to the investigator. This report must be made within 10 days of the sponsor’s receipt of the information. The full board of the IRB must then determine if the level of risk has changed. The PI will be notified in iRIS of the IRB’s decision.
19.0 SPECIAL CATEGORIES OF RESEARCH

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. If research with children and minors and/or pregnant women and fetuses is being reviewed, strong consideration should be given to using consultants if qualified members are not on the IRB board.

19.1 Pregnant women and fetuses

Special DHHS regulations applying to pregnant women and fetuses may be found in 45 CFR 46 Subpart B. No research may be conducted with pregnant women or fetuses unless the conditions specified in 45 CFR 46 Subpart B are met.

When the IRB considers research with pregnant women, the following conditions must be met.

- If scientifically appropriate, animal studies and studies on non-pregnant women should have already been completed.
- If the risk to the fetus is greater than minimal, the experimental procedures must hold out the prospect of direct benefit for the woman or fetus, and must not be obtainable using any other means.
- There must be the least possible risk possible to achieve the objective.
- Legal consent must be obtained, unless the study is exempt and consent is waived.
- Both the mother and the father must sign the consent regarding risk to the fetus unless the father is unavailable, incompetent, temporarily incapacitated, or the pregnancy is the result of rape or incest.
- Each person giving consent is fully aware of the impact of the research on the fetus or neonate.
- If the pregnant woman is a child, provisions at 45 CFR 46, Subpart D must be followed.
- No inducement may be offered to terminate a pregnancy.
- Individuals involved in the research may have no involvement in any decisions regarding termination of the pregnancy.
- Individuals involved in the research will have no part in determining the viability of the neonate.

Research Involving Neonates

Regardless of neonate viability, all research involving neonates must meet the following conditions:

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- Each individual identified above is informed regarding the reasonably foreseeable impact of the research on the neonate.
- Individuals involved in the research will have no part in determining the viability of the neonate.
Neonates of Uncertain Viability

No research may take place until the following conditions have been met:

1. The IRB finds that:
   - The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; or
   - The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

2. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s designated representative is obtained as stated in the section above. The consent of the father or his representative does not need to be obtained if the pregnancy resulted from rape or incest.

Nonviable Neonates

After delivery, nonviable neonates may not be involved in research covered by this policy unless all of the following conditions are met:

- Vital functions are not artificially maintained;
- The research will not terminate the heartbeat or respiration of the neonate.
- There will be no added risk to the neonate resulting from the research;
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- The legally effective informed consent of both parents of the neonate is obtained, except under the circumstances listed above; a representative’s signature is not allowed. The consent does not have to specify risks to the neonate.

Viable Neonates

Research may be done after delivery of a viable neonate if all rules following informed consent (Section 10) and research with children (Section 19.3) are followed.

Research Involving After Delivery, the Placenta, the Dead Fetus or Fetal material.

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

If information associated with material described in previous paragraph of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.
Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Fetuses, or Neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of other regulations in this section only if:

- The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

- The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:

  1. That the research in fact satisfies the conditions of regulations, as applicable; or

  2. The following:

     (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

     (ii) The research will be conducted in accord with sound ethical principles; and

     (iii) Informed consent will be obtained in accord with the informed consent provisions.

19.2 Prisoners

Special DHHS regulations applying to prisoners may be found in 45 CFR 46, Subpart C. 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). Research involving prisoners may not be exempted nor may initial reviews involving prisoners be expedited; there must be full board review.

Definition of Prisoners

Prisoners are any individuals involuntarily confined or detained in a penal institution. It includes persons who are detained pending arraignment, trial, or sentencing, and persons who become prisoners after research has begun.

Types of Research Permitted

The following categories are listed in 45 CFR 46, Subpart C [section 306(a)(2)].

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior; or

2. Study of prisons as institutional structures or of prisoners as incarcerated persons.
Because categories 1 and 2 likely do not directly benefit the subject, studies in these categories can carry no more than minimal risk.

3. Research on conditions particularly affecting prisoners as a class (e.g. vaccines on illnesses that are more prevalent in prisons than elsewhere; research on psychological/social problems); or

4. Research on practices, accepted or innovative, that may have the intent and expectation of improving the health or well-being of the subject and require control groups who will not benefit from the research.

Categories 3 and 4 require a letter sent to the Secretary of DHHS or designee who will consult with appropriate experts and publish notice in the Federal Register the intent to approve such research.

5. Research with prisoners that is part of any federal grant.

This research cannot proceed until it is certified by the Secretary of DHHS or a designee.

For categories 3, 4, and 5, the IRB administrator/Coordinator will write the requisite letter to the Secretary of DHHS or a designee and follow the Informal Subpart C Document: Prisoner Research Certification Letters to OHRP, updated August 3, 2003, or a later version if such is issued.

Approval Criteria for Prisoner Research

Before research with prisoners can be approved by the IRB, subpart C specifies that the following additional requirements must be met. Each specific requirement must be addressed by the IRB with discussion, if any, reflected under the specific condition in the IRB minutes. Each condition must be voted on separately, and each vote must be recorded under the appropriate condition in the IRB minutes.

- The research being reviewed falls into either category 1, 2, 3, or 4 listed above.
- Any possible advantages to prisoners participating in the proposed research do not outweigh the risks associated with the research. Discussion of this point should take into account the limited choices available in a prison environment.
- The risks to the prisoners are no greater than they would be to non-prisoners involved in the same research.
- All prisoners who meet study eligibility criteria must be considered for participation without arbitrary intervention by authorities or other prisoners. Unless the IRB members are provided written justification for other procedures, all subjects in control groups must be chosen randomly from the pool of eligible subjects.
- Information about the study must be presented to the subjects clearly and in a form that is understandable.
- Adequate assurance is given to the prisoner that participation or lack of participation in the study will not affect chances of parole. Additionally, there must be adequate assurance that parole boards will not consider the individuals participation or lack of participation in the study when making a decision.
- The IRB members must consider if there may be a need for follow-up care of participants after their part in the study has concluded and whether provision for this follow-up has been made, taking into account the varying length of the participant’s sentences and whether the participant has been informed of this fact.
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. Research within the TTUHSC system may be reviewed by any IRB with a prisoner advocate.

19.3 Children and Minors
The TTUHSC IRBs have adopted 45 CFR 46 subpart D, which provides special safeguards for children and minors when they are subjects in research studies. In addition, the TTUHSC IRBs adopt all Food and Drug Administration regulations found in 21 CFR 56.

When children or minors are research subjects, researchers must obtain both the consent of the parent or 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.

Additional Required Determinations
The IRB can approve research involving children only if it falls into one of the following categories. The chosen category (45 CFR 46.404-407) will be documented in the IRB meeting minutes.

1. Research presenting no greater than minimal risk to children.
2. Research involving greater than minimal risk of children that offers the prospect of direct benefit or may contribute to the well-being of the individual child.
3. Research involving only a minor increase over minimal risk, yet does not offer any, prospect of direct benefit or contribute to the well-being of the child.

Research that does not fit into one of these categories must either be disapproved or referred to the Secretary of the Department of Health and Human Services (DHHS). Minimal risk is defined as follows: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical and or psychological examinations or tests. This standard is indexed to the lives of healthy children.

Child or Minor Representative on IRB
An IRB considering a study involving children as subjects shall:

1. 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
2. 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.
Assent of Child or Minor

Assent is a child’s/minor’s affirmative agreement to participate in research (See Section 8.3). If a child/minor merely does not refuse to participate in research, assent has not been obtained. While the IRB may use its discretion as to whether assent of a child/minor is required, and how this shall be obtained (i.e., orally, in writing, etc.), in general, children age 7 and over should be allowed the opportunity to assent. Opportunities for assent should be made in language and under circumstances that insure that the child/minor understands and does not feel pressured by parents or professionals. Assent may be waived under normal circumstances where consent would be waived (See Section 8.2), or if the research offers a promise of direct benefit not available outside of the research and the parent consents.

Parents or guardians of the child/minor must give consent for the child/minor to participate in research (as an amendment See Section 8.3) unless the IRB determines that, for the protection of the child/minor (e.g. research on neglected or abused children), consent of the parent/guardian is not required. In such a case, the IRB must go to extraordinary lengths to insure that the rights of the child/minor are protected.

Placebo Controls

Placebo groups are not specifically prohibited in children’s research, but they may be used only in studies where there is no proven prophylactic, diagnostic, or therapeutic treatment in existence. The IRB must consider the risks and benefits to the child of the study without concern for the success or failure of the study.

Wards

Children who are wards of the State or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

- related to their status as wards; or
- conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.
Data Safety Monitoring Boards (DSMB)/Data Monitoring Committees (DMC) are boards established by commercial or governmental sponsors of multi-site research. These boards review the adverse event reports from all participating sites and make reports on the safety of the project to all participating institutions.

PI shall submit any independent DSMB/DMC reports to the IRB within five (5) business days from the date the information is received by the PI. The IRB Administrator may simply acknowledge receipt of these documents if there are no changes in the conduct of the study. If problems are indicated, the administrator will promptly forward the report to the IRB chair/designee for appropriate action.

Any documents resulting from DSMB/DMC reports, e.g. amendments, revised consents, must be submitted prior to the next meeting of the IRB.
21.0 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. When 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.
22.0 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. General information may be found at http://grants.nih.gov/grants/policy/coc/.

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. Detailed instructions for obtaining the Certificate of Confidentiality can be found at http://grants.nih.gov/grants/policy/coc/appl_intramural.htm
23.0 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 4.0). 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. The TTUHSC IRB should make every attempt to have documents reviewed by a consultant from the targeted country for accuracy of translation and to assure that no local norms in the foreign country are being violated.
24.0 HUMAN IMMUNODEFICIENCY VIRUS (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. This information may also be reported to government entities as required by law. Potential subjects must be made aware of this notification. Persons obtaining consent should inform the subjects and this information must be included in the informed consent form.
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 (FWA 00006767) 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.

25.1 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. The IRB takes such actions that are in its judgment necessary to enforce compliance with applicable federal and state law, regulations, or guidelines, including action to suspend/terminate approval of research that is not being conducted in accordance with 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.

25.2 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 support 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 Research conducted by PIs
• 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 research compliance personnel 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. The IRB may report findings of non-compliance or IRB decisions to the PIs direct supervisor or others as it deems necessary.

The IRB Chair will determine the need for full IRB review of audit reports. 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.

Compliance reports summarizing all IRB compliance activities including audits shall be submitted to each IRB and AVPR by the HRPO on a pre-determined schedule. Compliance reports are confidential and privileged Medical Committee documents.

25.3 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. Corrective steps will be taken to ensure that the researcher is aware of all federal, state, and local policies and procedures. Researchers will be asked to immediately stop all research and inform any journals, meetings, etc. where research was presented or where presentation is pending that the research was conducted without IRB approval.

25.4 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 5 days of receipt.
APPENDIX A – GLOSSARY OF TERMS

ADMINISTRATIVELY CLOSED  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 EVENT (AE)  Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Also see: Internal Adverse Event; External adverse event; Unanticipated Adverse Event; Unanticipated Problem; Serious Adverse Event.

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.

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.

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.

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  Legally competent persons who may be compromised in any way in their ability to make decisions in their best interests.

COMPETENCE  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  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.


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, is legally separate from TTUHSC, and possess OHRP-approved Assurances and IRB Agreements with TTUHSC.

EXEMPT RESEARCH Research determined by person(s) designated by the Human Research Protection Office to involve human subjects in one or more of certain minimal risk categories [38 CFR 16.101(b)].

EXTERNAL ADVERSE EVENT (ALSO CALLED IND SAFETY REPORT) Adverse events experienced by subjects enrolled by investigators at other sites participating in the same clinical trial as investigators at TTUHSC/Affiliates.

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.

FEDERALWIDE 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)

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.

**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 another 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** A person’s mental status leads to the 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.

**IND SAFETY REPORT** See: External Adverse Event.

**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. At TTUHSC, the IRB is deemed to be a medical committee.

**INSTITUTIONALIZED** Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).
INTERNAL ADVERSE EVENT Any adverse events experienced by a single subject enrolled in TTUHSC or TTUHSC IRB affiliate research project. (reverse words)

INVESTIGATIONAL DEVICE EXEMPTION (IDE) An unapproved medical device that is used to save the life of a patient or to help a patient suffering from a serious disease or condition for which there no other alternative therapy exists. Patients/physicians faced with these circumstances may have access to investigational devices under one of four main mechanisms by which FDA may make an unapproved device available: Emergency Use, Compassionate Use (or Single Patient/Small Group Access), Treatment Use, or Continued Access.

INVESTIGATIONAL NEW DRUG OR DEVICE (IND) 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.

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** 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.

**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).


**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** Prisoners are any individuals involuntarily confined or detained in a penal institution. It includes persons who are detained pending arraignment, trial, or sentencing, and persons who become prisoners after research has begun.

**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.
PROTOCOL DEVIATION

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

REPRESENTATIVE A person who makes 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.

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

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.

REVIEW (OF RESEARCH) The oversight of research on a periodic basis by the 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) Any adverse event temporally associated with the subject’s participation in research that meets any of the following criteria:

(1) results in death;
(2) is life threatening (Places the subject at immediate risk of death from the event as it occurred);
(3) requires inpatient hospitalization (for a person not already hospitalized) or prolongation of hospitalization (for a subject already hospitalized);
(4) results in persistent or significant disability or incapacity;
(5) results in congenital anomaly and/or birth defects;
(6) an event that jeopardizes the subject's health 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 that may 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.

UNANTICIPATED ADVERSE DEVICE EFFECTS  Adverse effects that occur with unlicensed devices approved by the FDA for research.  These are reported directly to the IRB.

UNANTICIPATED PROBLEM  Any incident, experience, or outcome that meets all of the following criteria:

(1) events are not expected given (a) the nature of the research procedures and (b) the characteristics of the subject population being studied;
(2) related or possibly related to a subject’s participation in the research; and
(3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

UNEXPECTED ADVERSE EVENT  Any adverse event occurring in one or more subjects in a research protocol, the nature, frequency, or severity of which is not consistent with either:

(1) the known of foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
(2) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject’s predisposing risk factor profile for the adverse event.

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.