I. Introduction

In accordance with TCU's concern for human dignity, as well as individual freedom and integrity, TCU has adopted this policy for the protection of the rights and welfare of Human Subjects involved in TCU Research.

This policy generally describes TCU's program for the protection of Human Subjects, which is managed by the TCU Institutional Review Board, with assistance from the Office of Research and oversight from the Associate Provost for Research. The combination of this policy and supporting procedures, along with related policies and procedures, is designed to conform to the federal regulation promulgated by the U.S. Department of Health and Human Services ("HHS") to implement the Federal Policy for the Protection of Research Human Subjects, 45 CFR 46 Subparts A ("Common Rule"), as revised from time to time.

II. Applicability

This policy and supporting procedures apply to all Research involving Human Subjects in which TCU is engaged, regardless of the source of funding or location for the activities. When a Research sponsoring agency has more restrictive requirements for the protection of Human Subjects, such requirements will control to the specific Research activities that the agency sponsored and to the extent that such requirements are inconsistent with TCU's requirements.

III. Definitions

The definitions used in this policy, but not otherwise defined, have the same meaning given to them in the Common Rule.

Clinical Trial. Research in which one or more Human Subjects are prospectively assigned to one or more interventions, which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

De-identification. The process used to prevent the identity of the human subjects being readily ascertained, directly or through identifiers linked to the subjects.

Department Review Board ("DRB"). An internal, advisory committee to the TCU IRB that is established by a Department Chair or college Dean in a department or college that permits students to participate in Human Subjects Research in which TCU is or will be engaged and is led by a faculty member. Each DRB reviews the protocols proposed within the DRB's department or college using the same standards as the TCU IRB and makes recommendations of action to the IRB.

Engagement. A term used to determine if an institution that is involved in some aspect of Human Subjects Research is "engaged" in that Research. In general, TCU is considered engaged in a particular Human Subjects Research project when its employees or agents for the purposes of that project obtain: (1) data about the Human Subjects of the Research through intervention or interaction with them; (2) identifiable private information about the subjects of the Research; or (3) the informed consent of Human Subjects for the Research.

The term TCU "employees or agents" refers to individuals who (1) act on behalf of TCU; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. Employees or agents can include staff and students among others, regardless of whether the individual is receiving compensation.

Exempt Research. Research activities in which the only involvement of Human Subjects appears on the list of categories of research established by HHS that is deemed exempt from the Common Rule. Exempt determinations shall only be made by a member of the TCU IRB, or the Director, Research Compliance.

Expedited Research. Human Subjects Research that the IRB Chairperson or designated IRB member has determined to be no more than minimal risk and that appears on the list of categories of research established by HHS that may be reviewed through an expedited process; or minor changes in previously approved research during the period for which approval is authorized (one year or less).

Federalwide Assurance ("FWA"). A document filed with the Office for Human Research Protections ("OHRP") of HHS expressing an institution's commitment to comply with the HHS' regulations for the protection of Human Subjects.

Human Subjects. A living individual about whom an investigator (whether professional or student) conducting Research obtains: (i) information or biospecimens through *intervention* or *interaction* with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

- *Interaction* includes communication or interpersonal contact between investigator and subject.

- *Private Information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and can reasonably be expected not to be made public (e.g., medical record). Private information must be individually identifiable.

- *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

- *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Institutional Review Board ("IRB"). A committee established by an institution in accordance with the Common Rule that has been formally designated to approve, monitor and review Human Subjects Research to protect the rights and welfare of the Human Subjects involved in the Research.

IRB approval. The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Legally authorized representative. An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the Research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

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 daily life or during the performance of routine physical or psychological examinations or tests.

Public health authority. An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Principal Investigator ("PI"). The lead investigator on a research project with the ultimate responsibility for all aspects of the projects, including preparation, conduct, and administration of a research grant (if any), compliance with applicable laws and regulations and TCU policies and procedures. A Principal Investigator must be a TCU faculty or staff member.

Research. Any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research regardless of the term used to refer to the activity.

For purposes of this policy, the following activities are deemed not to be Research:

- Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Sponsor-Investigator. An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug, biologic, or device is administered or dispensed. The term, as defined in FDA regulations, does not include any entity other than an individual.

TCU Institutional Official ("IO"). The individual authorized to act for TCU and, on its behalf, obligates TCU to the terms of its FWA.

Vulnerable Population. Those Human Subjects who have limited or compromised autonomy, which may make them vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons.

Written, or in writing. For purposes of this part, refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format.

IV. Policy Statements

A. TCU IRB

1. Designation. TCU designates its Institutional Review Board as the TCU IRB. The TCU IRB may consist of one or more committees as is necessary to properly review and approve Human Subjects Research for TCU.

2. Authority. The TCU IRB is granted authority to approve, make modifications in, or disapprove Human Subjects Research in which TCU is engaged, in accordance with applicable law. TCU may not approve Research lacking approval by the TCU IRB. Implementation of TCU IRB-approved Research protocols may be prevented or terminated by decision of the Associate Provost for Research or the Provost, although the TCU IRB approval will not be voided by such action.

The TCU IRB shall review all Research covered under this policy in accordance with applicable law, as well as this policy and supporting procedures. Notwithstanding the foregoing, the TCU IRB may utilize additional external IRBs to act in the capacity of the TCU IRB as circumstances require; provided proper documentation is in place and the external IRB is expressly designated in writing and subject to TCU FWA prior to any utilization.

The TCU IRB shall consider all of the following items when reviewing Research protocols:

- All applicable TCU policies and procedures;
- Standards of professional conduct and practice applicable to the Research subject to the review; and
- All applicable federal, state and local laws and guidance, including but not limited to, those related to the Protection of Human Subjects, privacy laws, and state laws regarding legal authorization to consent.

The IRB should not issue approval of any Human Subjects Research protocols until all other applicable TCU approvals, if any, are attained.

3. Resource Allocation for Human Research Protection Program. TCU, through the Institutional Official, will provide for meeting space and sufficient staff to support the TCU IRB's review and recordkeeping duties.

4. Composition. The composition of the TCU IRB shall meet all of the following requirements:

- Have a minimum of five members with varying backgrounds to ensure complete and adequate review of TCU Research activities commonly conducted;
- Be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds, including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of Human Subjects;
- Include both men and women members from more than one TCU department and college;
- Include at least one member whose primary concerns are in scientific areas (scientist) and one member whose primary concerns are nonscientific (nonscientist);
- Include an alternate member who is qualified as a prisoner representative and who will serve as a regular member for review of any research involving prisoners; and
- Include at least one member who is not otherwise affiliated with TCU and who is not part of the immediate family of a person who is affiliated with TCU.

The TCU IRB may have ex-officio members as deemed necessary by the Associate Provost for Research to carry out its duties.

5. Membership.

a. Members. Member appointments to the TCU IRB are made by the Chancellor of TCU, as recommended by the Institutional Official. Each member's term, excluding officers, will be three years, unless otherwise terminated earlier, with or without cause, by the member or TCU. A member may be reappointed after an initial term for up to two additional three-year terms. All appointments are confirmed with a written approval letter.

b. Officers.

i. The TCU IRB shall have at least two officers: an IRB Chairperson and Vice-Chairperson, appointed by the Chancellor. Additional officers may be appointed at the discretion of the Chancellor, as recommended by the Institutional Official. All officers must be an active member of the TCU community who is well-informed in regulations relevant to the use of human participants in research.

ii. Officer Terms. All officers must have served as a member on the TCU IRB for at least one year prior to any officer appointment. Officers that have not served the immediately prior year as an officer may be appointed to the position of Vice-Chairperson.

Regardless of the status of their current membership term prior to officer status, the Vice-Chairperson will be appointed with a new term of two years. Upon the expiration of the Vice-Chairperson's term, the Vice-Chairperson will be appointed as Chairperson, for a two year term. Upon the expiration of the Chairperson's term, the Chairperson, will be appointed as "Past Chairperson" for one year, which is a voting member, non-officer appointment.

c. Liaisons. Institutional Official may designate liaisons to attend IRB meetings and assist with administrative and compliance matters. Such persons are not members of the IRB.

6. Voting; Quorum. Each TCU IRB member shall be entitled to one vote. A quorum shall consist of more than half of the regular voting members of the TCU IRB. A quorum and the presence of a nonscientist member are necessary for any Board meeting that will grant or deny approval for a Research protocol. For the Research to be approved, it must receive the approval of a majority of those members present at the meeting. If Research involving prisoners is being reviewed, the alternate prisoner representative must also be present as a voting member.

7. Miscellaneous. When necessary or desired, the TCU IRB Chairperson may appoint one or more ad hoc consultant members with competence in special areas to assist in the review of complex issues which require expertise beyond, or in addition to, that available on the campus. These individuals shall not have the right to vote with the TCU IRB.

B. TCU Human Subjects Research

1. All individuals conducting Human Subjects Research in which TCU is or will be engaged must follow all applicable TCU policies and procedures, all determinations of the IRB of record, terms and conditions of applicable awards/contracts, policies of sponsor, terms of the approved protocol, and all applicable federal, state and local laws.

2. Prospective IRB Approval. All Research projects that include Human Subjects and in which TCU will be deemed engaged must be submitted to and approved by the TCU IRB prior to any initiation of Research activities, including screening, recruitment, or enrollment; provided however, that the TCU IRB may choose to rely on another IRB as further described in paragraph 3 of this section and evidenced by written agreement.

If there is a question regarding whether a project includes Human Subjects or TCU is engaged, the TCU IRB, in consultation with the IO, is the final arbiter. Examples of such Research include the following:

a. All faculty and staff paid by TCU who are conducting Human Subjects Research within the course and scope of their duties, regardless of the source or amount of funding.

b. All TCU students, including post-graduate trainees, conducting Human Subjects Research as part of their educational training at TCU.

c. All Human Subjects Research conducted by TCU faculty or staff that access any TCU personnel, students, or facilities owned and operated by TCU.

d. All Human Subjects Research that is supported by intramural or extramural funds granted to or applied for through TCU.

e. All Human Subjects Research conducted with TCU funding at non-TCU sites.

f. All Human Subjects Research for which TCU has a written agreement to provide IRB review for such Research.

Human Subjects Research activities may be conducted only after the TCU IRB (or IRB of record) approves the associated protocol. If IRB approval is not granted, the Human Subjects Research must not take place.

3. In the event that TCU engages in cooperative Human Subjects Research, TCU will seek to rely on a single IRB for that portion of the research that takes place within the United States, with certain exceptions and provided that the IRB of record is the only IRB directly responsible for compliance with the Common Rule. TCU may not defer to another IRB if (a) cooperative research for which more than single IRB review is required by law (e.g., FDA-regulated devices); or (b) research for which the federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular study.

C. No TCU IRB Approval Required. TCU IRB approval is not required for Human Subjects Research in any of the following scenarios:

1. Human Subjects Research determined to be exempt by the TCU IRB or its delegate**.**

2. When faculty are not acting as staff members, employees, or agents of TCU.

3. When no TCU personnel, students or facilities owned and operated by TCU are involved.

4. When the activity is not being conducted under the aegis of TCU.

No approval is required because, generally, any individual associated with TCU (e.g. faculty, staff, student, etc.) that is involved in Research not at, on behalf of, or sponsored by TCU is not deemed a TCU employee or agent in association with that specific Research, unless their involvement with the Research will be used to address or fulfill requirements associated with their role at TCU. In such cases, however, investigators holding TCU appointments must nevertheless obtain approval for the use of Human Subjects from a duly constituted IRB, not necessarily at TCU.

D. Research Conducted at TCU by Investigators Affiliated with Other Institutions. TCU officials and faculty may be approached by investigators at other institutions for cooperation in their research. In addition, investigators at other institutions may propose a study to be conducted, all or in part, at TCU. For example, the Provost Office, Department Chairs or Deans may be asked to assist in the distribution of surveys to faculty or students. Other requests may simply involve approval to post recruitment flyers on the TCU campus.

The need for review by the TCU IRB will depend upon the nature of the involvement of the individual who is affiliated with TCU, the proposed use of TCU facilities, resources, and/or non-public data in the latter circumstance. Therefore, the research protocol including copies of any surveys/questionnaires and recruitment flyers, and a copy of IRB approval (if the researcher obtained approval from another IRB) should be submitted to Research Compliance for administrative review and a determination as to whether TCU IRB review is also needed (if the researcher does not want to seek this determination via a formal submission to the IRB).

Administrative review, rather than formal review by the TCU IRB, is generally required if, in the case of proposed collaboration, the individual who is affiliated with TCU is not engaged in human subjects research, i.e., the individual will not: a) intervene or interact with living individuals for research purposes; b) obtain individually identifiable private information for research purposes; or c) receive a direct federal award. In these situations administrative IRB approval, as defined below, is required for university offices or officials to inform members of the university about research or provide them with information about contacting investigators if they wish to participate.

E. TCU Engagement of Research. The TCU IRB reviews Human Subjects Research when TCU is or will be Engaged in the Research. Determinations of whether TCU is or will be Engaged in Research for any study will be made by the IRB Chairperson in consultation with the IO, and legal counsel, when appropriate, using OHRP

regulations and guidance for Engagement in Research as the standard for decision. In debatable situations referral for determination will be made to the appropriate federal agency, when applicable, in accordance with federal regulations.

F. Responsibilities. The responsibility for the protection of Human Subjects at TCU is a shared responsibility between the TCU Institutional Official, the TCU IRB, TCU academic departments, and the investigators, including members of their Research teams.

1. TCU Institutional Official. The TCU Institutional Official is responsible for all of the following:

- Oversight of TCU's Human Subjects Protection Program, including development and implementation of necessary policies and procedures
- Oversight of TCU IRB activities, including communication, education, record keeping, reporting, monitoring, and development of procedures to determine when Research is exempt or otherwise does not fall under TCU's FWA or other regulations
- Act as the TCU Institutional Official under its FWA
- Allocate resources to the Human Subjects Protection Program
- Recommend to the Chancellor individuals to appoint as members and officers of the TCU IRB

The Institutional Official may delegate the responsibilities set forth in the first two bullet points of this Section F(1), as appropriate.

2. TCU IRB. The TCU IRB is obligated and/or authorized to:

- Knowledgeably review Human Subjects Research in which TCU is engaged, in accordance with applicable federal, state, and local law, and TCU policies and procedures.
- Approve, disapprove, or require modifications for approval for all Human Subjects Research.
- Determine:
    - that risks to Human Subjects participants are minimized by using procedures consistent with sound Research design and not unnecessary;
    - that risks to Human Subjects participants are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may be expected to result;
    - that selection of Human Subjects is equitable; and

- That informed consent will be sought and documented from each subject unless waiver of informed consent process or its documentation is proper under federal regulations.

- When appropriate, determine:
  - That the Research plan makes adequate provisions for monitoring the data collected to ensure the safety of Human Subjects;
  - That there are adequate provisions to protect the privacy of Human Subjects and the confidentiality of the data;
  - Whether Research includes Human Subjects or whether TCU is engaged; and
  - When Human Subjects participants are likely to be considered a part of a Vulnerable Populations, and impose additional safeguards in the Research to protect the rights and welfare of these subjects.

- Perform, or have another party perform, compliance monitoring, assessments, routine and for-cause audits of any or all protocols.

- Observe, or have a third party observe, the consent process and/or the Research. This includes review of Research records as well as Research activity.

- Suspend or terminate approval of ongoing Research that violates the TCU IRB's requirements or that has been associated with unexpected serious harm to Human Subjects.

- Notify parties in writing of its decisions to approve, disapprove, or require modifications to approve Research.

- Have written procedures to help ensure prompt reporting to regulatory agencies, and the TCU Institutional Official of unanticipated problems involving risks to Human Subjects or others, and serious or continuing noncompliance with this policy, federal regulations, or TCU IRB requirements or determinations.

3. IRB Chair. The IRB Chair responsibilities include:

- Determining the type of review appropriate for new protocols (expedited, full board);
- Serving as primary reviewer of protocols, when appropriate, or delegating this responsibility to another IRB member;
- Conducting the business of full board meetings following basic parliamentary rules;

- Reviewing on behalf of the IRB, revisions to protocols/consent documents required as a condition of approval;
- Reviewing reports of unanticipated problems involving risks;
- Reviewing reports of serious non-compliance in coordination with the Research Integrity Officer and the IO;
- Assessing and recommending appropriate IRB training for the IRB, investigators, and support staff;
- Ensuring that submitted protocols receive an efficient review; and
- Serving as a resource for investigators and IRB members.

4. IRB Vice Chair. The Vice Chair assumes the responsibilities of the IRB Chair whenever the IRB Chair is not available to conduct IRB business. When substituting for the IRB Chair, the Vice Chair shall fulfill all the roles and responsibilities of the IRB Chair described above.

5. IRB Members. Responsibilities of members include:

- Attending IRB meetings;
- Reviewing protocols, consent document(s), participant and recruitment material(s) to be discussed at IRB meetings, including new submissions, modifications/amendments, continuing review, unanticipated problems involving risks, and noncompliance cases;
- Being prepared to discuss issues related to human participants protections at IRB meetings;
- Serving as primary reviewer at IRB meetings or on expedited protocols when requested by the IRB Chair;
- Being informed about the specific requirements regulating the participation of human subjects in research; and
- Maintaining the confidentiality of IRB meeting discussions.

6. IRB Administrator. The IRB Administrator is responsible for the management and administration of the IRB Office and the IRB Committee.

7. Principal Investigators. Principal Investigators have the primary responsibility for protecting the rights and welfare of Human Subjects and complying with all applicable provisions of TCU's FWA, and laws and regulations governing their

Research activities. PIs should be knowledgeable about federal and state laws pertaining to Human Subjects and TCU policies.

a. Responsibilities of Principal Investigators include the following:

- Ensuring the protection of human subjects and the ethical conduct of Research;
- Ensuring that the Research is conducted in compliance with TCU policies and procedures and all state and federal regulatory requirements;
- Ensuring that all investigators (PI and co-investigators) disclose financial conflicts of interest according to the TCU policy and comply with any imposed conflict of interest management plan;
- Ensuring no Research activity is initiated and no written information about the study is provided to participants prior to receipt of formal written approval or formal exempt determination from the TCU IRB for the protocol;
- Ensuring Research staff are properly trained and knowledgeable about and follow all legal and regulatory requirements, as well as applicable TCU policies and procedures;
- Obtaining and documenting the informed consent of each participant or the participant's legally authorized representative, unless the IRB has waived these requirements;
- Giving a copy of the informed consent document to each participant or the participant's legally authorized representative;
- Appropriate delegation of responsibilities of the study to co-investigators and research staff and for ensuring that responsibilities are delegated to individuals who are qualified and appropriately trained to conduct those responsibilities;
- Performing Research in accordance with generally accepted scientific principles, TCU ethical principles, and with sufficient Resources to protect Human Subjects;
- Conducting Research in accordance with the IRB–approved protocol and all IRB determinations;
- Upon discovery, promptly reporting to the TCU IRB all unanticipated and reportable events and all allegations or findings of non-compliance (event reporting);
- Properly maintaining necessary documentation related to the Research;
- Ensuring prompt reporting to the IRB of proposed changes in a Research

activity, and for ensuring that such changes in approved Research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject;

- Ensuring safety monitoring of human subjects to ensure that potential risks to subjects are eliminated or minimized to the extent possible;

- When conducting a clinical trial or therapeutic intervention, providing reasonable care to ameliorate medical or health problems that arise during or at the end of a study that appear to be potentially related to the Research, or referring to another provider when a consult is appropriate (the compensation of such care will be provided in accordance with the plan in the contract, IRB-approved protocol, or informed consent form);

    - When conducting a clinical trial sponsored/supported by the National Institutes of Health, the PI must complete a Good Clinical Practice course that includes ICH-E6 (R2) GCP guidelines;
    - When conducting a clinical trial, the investigator must comply with the investigator agreement and any Clinical Trial Agreement (CTA) between TCU and the sponsor;
    - Must maintain an Investigator Site File (commonly called a Regulatory Binder) that includes all regulatory documentation for the study.

- Maintaining confidentiality of human subject data in accordance with the IRB-approved protocol. When the Research involves Protected Health Information (PHI) or highly sensitive data (e.g., social security numbers, illicit drug use or other criminal activity, etc.), ensuring data security of the information to prevent a breach of confidentiality;

- Cooperating with all audits, reviews, inquiries and other requests of the IRB or Research Compliance;

- Submitting continuing review reports to the IRB in a timely manner;

- Properly maintaining necessary documentation related to the Research and regulatory records for at least three years after the research has been completed unless otherwise required by federal regulations and TCU policies. If the research includes Protected Health Information (PHI) then the research records must be retained for at least six years after completion of the research to comply with HIPAA requirements;

- Maintaining the integrity of the analysis of data and the publication of results/findings; and

- Notifying the TCU IRB as soon as possible whenever the PI decides that he/she will no longer be the Principal Investigator for a research project.

b. The PI has additional responsibilities if she/he serves as a Sponsor-Investigator. In such situations, the PI must adhere to all FDA regulatory requirements (i.e., 21 CFR 50, 54, 56, 312, 600, and 812), state regulations, and TCU policies and compliance with ICH-E6 (R2) version of Good Clinical Practice (GCP) Guidelines, and must:

- Submit an Investigational New Drug (IND) application for any new investigational drug or biologic in accordance with 21 CFR 312 or 21 CFR 600, respectively; or an Investigational Drug Exemption (IDE) for investigational devices in accordance with 21 CFR 812.

- Comply with the sponsor and investigator responsibilities of 21 CFR 312 when conducting a clinical trial involving an investigational drug and 21 CFR 812 when conducting a clinical trial involving a significant risk device;

- Submit all modifications to the protocol to the FDA for review in addition to the designated IRB for approval;

- Submit an annual report to FDA in accordance with 21 CFR 312;

- Maintain appropriate drug/device/biologic accountability records to ensure accurate documentation of all dispensations and receipt of investigational product. It is recommended that all investigational drugs are managed and stored by a research pharmacy that is knowledgeable with drug accountability requirements. If kept by the investigator, the PI must ensure appropriate storage and security of the investigational product to ensure its integrity and safety.

8. Department Review Boards (DRB). Department Review Boards are optional review boards within a department or college that provide preliminary review of student protocols and guidance to student researchers prior to any submission to the IRB. DRBs are not part of the IRB and are not authorized to act on behalf of the IRB. DRBs must ensure that researchers understand that a DRB's review is not a requirement of the IRB and is not a part of the IRB process.

9. TCU.

- Pursuant to its FWA, TCU assures the federal government that it will comply with federal Research regulations and no Research involving Human Subjects will be conducted without appropriate prior review and approval.

- TCU believes that an individual acting in the capacity of a TCU IRB member is acting within the course and scope of their duties as an agent of TCU and, therefore, will be provided legal representation and indemnification for judgments rendered against any individual acting in the capacity of a TCU IRB member.

- TCU will develop additional policies and procedures and other materials, as necessary, to implement this policy and a Human Subject Protection Program generally.

V. Enforcement

Failure to comply with this Policy could result in disciplinary action, including termination of employment.

VI. Questions/Reports

If you have any questions about this Policy or would like to report a potential violation, please contact the Office of Research. Reports regarding violations of this Policy may be submitted anonymously by using the independent Ethics and Compliance Hotline at 1-877-888-0002.

VII. Policy Sponsor

Associate Provost for Research

VIII. Related Research Policies and Procedures

Research Integrity Policy
Research Integrity Procedures
Human Subjects Research Procedures
Human Subjects Research Oversight and Monitoring Policy
Human Subjects Research Oversight and Monitoring Procedures

IX. Effective Date

Effective Date: May 1, 2017
(This policy and supporting procedures supersede the policy entitled “POLICY AND PROCEDURES for the PROTECTION OF HUMAN SUBJECTS in RESEARCH ACTIVITIES”)
Revised Date: January 21, 2019