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 a program 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 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 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.

IV. Definitions

Department Review Board ("DRB"). An internal, advisory committee to the TCU IRB that is established by a department Chairperson or college dean in a department or college that permits students to conduct Human Subjects Research in which TCU is or will be engaged. Each DRB reviews student research 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 regulatory 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.

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 conducting Research obtains data through *intervention* or *interaction* with the individual or identifiable *private information*.

- *Intervention* includes both physical procedures by which data are gathered and manipulations of 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. Private information must be individually identifiable.

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.

Protocol Deviation. Any change, divergence, or departure from the study design or procedures of a Research protocol that is under the investigator's control and that has not been approved by an IRB.

Research. Any systematic investigation 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.

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

V. 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 institutional 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

- 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. Member appointments to the TCU IRB are made by the Chancellor of TCU, as recommended by the Associate Provost for Research. The TCU IRB Chairperson and Co or Vice Chairperson, if any, are named by the Associate Provost for Research. Each member's term will be three years, unless otherwise terminated earlier, with or without cause, by the member or TCU.

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. Event Reporting. All protocol deviations must be promptly reported to the TCU IRB. Any change, divergence, or departure from the study design or procedures of a research protocol that affects a Human Subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data constitutes a **protocol violation**. Changes or alterations in the conduct of the protocol that do not have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data are considered minor protocol deviations.

8. 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. 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 for review prior to any initiation of Research activities. 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. Every department or college that permits students to conduct Human Subjects Research in which TCU will be deemed engaged should have at least one DRB responsible for reviewing student Human Subjects Research protocols that are proposed to be conducted within that department or college and submitting recommendations to the TCU IRB.

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

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

3. When the activity is not represented to Human Subjects as 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 Not Being Conducted by a TCU Principal Investigator. All investigators that are not acting under the aegis or on behalf of TCU, who desire to conduct any Human Subjects Research that access any TCU facilities, staff, or students must either identify a TCU faculty member to serve as a TCU Principal Investigator for the project or submit the project to the TCU IRB for preliminary review. This review will determine the following:

- Whether the study must have a TCU faculty member serve as a Principal Investigator, or
- Whether the study can be certified as exempt, and/or
- Whether the study will require TCU IRB or other review and approval.

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

- Designating the Chairperson, Vice-Chairperson and Chair Elect

- Recommend to the Chancellor individuals to appoint as members 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

- That, when the Human Subjects participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included 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 policies and 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. Investigators. 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. Investigators should be knowledgeable about federal and state laws pertaining to Human Subjects and TCU policies. Responsibilities of Principal Investigators include the following:

- Ensuring no Research activity is initiated and no written information 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;

- 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;

- 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;

- Upon discovery, reporting to the TCU IRB all unanticipated and reportable events, protocol deviations, and all allegations or findings of non-compliance (event reporting);

- Properly maintaining necessary documentation related to the Research; and

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

4. Department Review Boards (DRB). Department Review Boards must be composed of not less than two members with at least one member being a faculty member of the department or college in which the Research will be conducted. All DRB members must be appointed by the department Chairperson or the college dean of the responsible department or college.

Each DRB is responsible for reviewing all student Research activities within their department or college, prior to submission of a student's Research protocol to the TCU IRB, following the same procedures and criteria for protocol as used by the TCU IRB. The DRB does not approve or reject protocols, but rather reviews and recommends. Additionally, each review must determine that:

- The student and any faculty member who is assisting the student are qualified to conduct the Research;

- The hypothesis and procedures of any Research study are consistent with generally accepted scientific principles in the discipline; and

- Appropriate resources including facilities are available to conduct the Research.

5. 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.

VI. Enforcement

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

VII. 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.

VIII. Policy Sponsor

Bonnie Melhart, Associate Provost for Research

IX. Related Research Policies and Procedures

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

X. 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”)

