Human Subjects Research Submissions Procedures

I. Introduction

These procedures supplement the Policy for the Protection of Human Subjects in Research ("Policy"). All terms used in these procedures have the same meaning set forth in the Policy, unless otherwise defined in these procedures.

II. Categories of Review

Review will be conducted by the TCU IRB to help ensure that all Human Subjects Research at TCU conforms to applicable law and TCU policies. Categories of review include *Exempt, Expedited, and Full-Board*.

The type of review a project receives depends upon the risks to potential subjects posed by the Research. The probability and severity of possible harm (physical, psychological, social or economic) may vary from minimal to significant. Minimal Risk serves as a benchmark by which the IRB Chairperson determines whether proposed Research is eligible for an abbreviated review or require the review of the full Board.

Category	Reviewed by	What to Submit
Exempt	IRB Chairperson	Letter with specific information
Expedited	IRB Chairperson or Chairperson's Delegates	Request to Review Proposed Protocol
Full-Board Review	IRB	Request to Review Proposed Protocol

III. Review Process

A. Preparing for Submission. Before submitting a new application, the investigator should:

- Identify the Principal Investigator. This person takes full responsibility for the conduct of the project.
- Identify the research team. The team consists of all individuals who have a significant role in the research design, conduct or reporting. Assess whether any team member has an apparent or actual conflict of interest
- Complete all necessary training. All research team members must have completed human subjects protection training within the past three years of the protocol.
- Develop the protocol. The protocol should include objectives, procedures, risks, benefits, recruitment, consent processes, and procedures to maintain confidentiality.
- Gather all necessary documentation. The necessary documentation will depend on your project. You may need to include information regarding funding, drugs, devices, consent documents, recruitment materials, approval/authorization letters, certificates, data security monitoring protocols, executed agreements, etc.

B. Criteria for IRB Approval. The IRB will review each protocol in accordance with applicable law and TCU policies and decide to approve, conditionally approve, defer for additional

information, or disapprove the protocol. All of the following requirements must be met before approval may be granted:

1. Risks to subjects are minimized by (a) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. The IRB will consider those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Consent will be sought from each prospective Human Subject, or the subject's legally authorized representative, in accordance with, and to the extent required by applicable law. The special problems of research involving vulnerable populations, such as children, prisoners, mentally disabled persons, as well as economically or educationally disadvantaged persons are adequately addressed.

4. Informed consent will be appropriately documented in accordance with applicable law and TCU policy.

5. The Research plan makes adequate provisions for monitoring the data collected to ensure the safety of Human Subjects.

6. There are adequate provisions to protect the privacy of Human Subjects and to maintain the confidentiality of data.

7. When persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged are Research subjects, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects.

C. Continuing Review of Research. A continuing review of Research begins as soon as a study is initiated. The continuing review must follow the guidelines of the initial approval, whether the approval resulted from expedited or full Board review. Most protocols undergo annual review, but in situations of increased risk, continuing review may be required more frequently. Factors considered by the IRB during a continuing review include the following:

1. All criteria for approval at initial review still apply.

2. Current status of the study

3. The number of subjects does not exceed the number that the study was approved for initially.

4. Protocol revisions not previously approved.

5. Is study is progressing as planned.

6. Any unexpected events or complications.

7. Does any new information indicates a need for modification.

8. Have subjects have registered grievances.

9. Do consent documents contain previous revisions.

10. Current report from data-monitoring

11. Description of any eligibility or protocol deviations occurring in the renewal timeframe.

12. Description of changes in financial interests held by investigator or key personnel.

Protocols exempt from initial review do not require continuing reviews. Protocols approved by expedited review may have expedited continuing review. The TCU IRB may determine that a full-Board reviewed protocol has no more than minimal risk at the time of continuing review, and therefore the expedited review process can be used for continuing review. Such determination must be documented at a convened IRB meeting. All other protocols must undergo continuing review by the full board.

IV. Student Human Subjects Research

A. No Human Subjects Research may be conducted by TCU student prior to review by and approval from the TCU IRB. A student desiring to conduct Human Subjects Research must submit a protocol for review to an appropriate DRB. The DRB assess the protocol and then will submit the protocol to the TCU IRB with the DRB's recommendations.

B. Submission Process. The student must submit a protocol on the most recent TCU IRB protocol application form and follow all applicable law, policies and procedures. Students present proposals with the assistance of a faculty member. If a student's Human Subject Research is in a department without a DRB, the DRB of a related department may agree to review the protocol. If DRB review is not possible, then the protocol may be submitted directly to the TCU IRB. For a complete list of departments with DRBs, contact the IRB co-Chairperson, Dr. Timothy Barth.

V. Questions/Reports

If you have any questions about this procedure 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.

IV. Effective Date

Effective Date: May 1, 2017