Greater Than Minimal Risk Research (Full Board Review) Procedures

I. Introduction

These procedures supplement the Protections of Human Subjects in Research Policy (the "Policy").

II. Definitions

All terms used in these procedures have the same meaning set forth in the Policy, unless otherwise defined in these procedures.

III. Greater Than Minimal Risk Research

A. **Full Board Review.** All initial and continuing review of studies that are greater than minimal risk or do not qualify for one of the expedited review categories, and any other study that would benefit from additional expertise provided by the convened IRB, will be reviewed at a fully-convened IRB meeting. A majority of IRB members must be present to conduct the meeting and satisfy voting requirements. At least one member whose primary concern is in nonscientific areas must be present. The convened IRB will also review certain modifications/amendments to research and Unanticipated Problems Involving Risks to Subjects or Others (UPs) in accordance with the IRB Review of Modifications and UP SOPs, respectively.

1. The IRB Chairperson will call the meeting to order once enough members are present to meet quorum requirements.

    a. Quorum must be maintained throughout the meeting.

    b. Should the quorum fail during the meeting or if a non-scientific member is not present, the IRB may not take further action or vote for approval of the review, unless quorum can be restored.

2. IRB meetings are convened with all members physically present. However, due to extenuating circumstances where one or more members are not able to attend the meeting in person, their participation may be included via teleconference as long as the member has received all materials required by these policies in advance of the meeting.

    a. When an extra convened board meeting is scheduled to review any type of business and time, weather, or other extenuating circumstances do not allow for a convened board meeting, the entire meeting may be held by teleconference when all other TCU IRB policy and procedure requirements are upheld.

    b. The Chairperson will announce at the beginning of the IRB meeting that anyone present with a conflict of interest must be excused from the meeting and leave

the room for the portion of the meeting that reviews the study with which they have a conflict.

c. At the discretion of the IRB Chairperson, IRB Staff and/or primary reviewer, investigator(s) may be invited to attend the IRB meeting to answer questions, clarification of specific points, or discussion. Invited investigator(s) are required to leave the meeting for subsequent discussion and voting on their protocol.

d. The official meeting minutes document the number of votes for, against, or abstaining. A simple majority vote of the members present at the meeting is required for approval.

e. The meeting minutes must be in sufficient detail to show the actions taken by the IRB, the vote on the actions, a summary of the discussion of controversial issues and their resolution, and include all items required by TCU policies and procedures.

f. Investigators are notified in writing of the decision of the IRB and suggested modifications that might be required for approval.

g. A copy of the minutes will be made available to the Institutional Official.

B. **Operational Details.**

1. The TCU IRB meets once a month and the schedule is published on the IRB webpage. IRB meeting documents will be distributed through email to each board member no less than five calendar days prior to the meeting and will include the following items, as applicable:

- Copy of the IRB meeting minutes from the previous IRB meeting;
- Meeting agenda;
- A copy of all proposed projects to be reviewed, including (if applicable):
    - Proposed Informed Consent Document(s) (i.e., informed consent form, verbal consent script) or justification for waiver of consent);
    - Protocol;
    - Clinical Investigator Brochure;
    - Drug package insert (if the research involves an FDA-approved drug);
    - Device manual (if the research involves an investigational device);
    - Conflict of Interest (COI) assessment;
    - CVs/resumes of Principal Investigators;
    - Summary of education and training for the research team; and
    - Any recruitment materials, including flyers, advertisements, and recruitment letters intended to be seen or heard by potential subjects.

2. The full board review uses a primary reviewer system of review.
   - The primary reviewer documents compliance with regulatory requirements utilizing the *Protocol Checklist*;
   - A copy of the form(s) is provided to each member and available on the IRB webpage;
   - The contents of the form will be discussed at the convened meeting;
   - The form will be signed and dated by the reviewer; and
   - The form(s) will be placed in the IRB study file.

IV. Related Research Policies and Procedures

Research Integrity Policy
Research Integrity Procedures
Protection of Human Subjects in Research Policy
Human Subjects Research Procedures
Human Subjects Research Oversight and Monitoring Policy
Human Subjects Research Oversight and Monitoring Procedures
Review of Human Subjects Procedures

V. Effective Date

Effective Date: January 21, 2019