Human Subject Research Oversight and Monitoring Policy

I. Introduction

Texas Christian University, through the Office of Research, is responsible for ensuring compliance with relevant ethical principles, federal and state law and institutional policies for the protection of human subjects participating in TCU research. The TCU Institutional Review Board is authorized by federal regulations and TCU policy to verify that no material changes have occurred in approved projects without IRB approval.

In an effort to exercise appropriate compliance oversight and to protect the rights and well-being of human subjects in TCU research, the Office of Research, in consultation with the TCU IRB, will conduct confidential routine and directed (for cause) reviews of research protocols approved by the TCU Institutional Review Board. These reviews serve:

- as a quality assurance measure internal to TCU;
- to assess adherence to the Institutional Review Board approved study protocol, best practices (as such relate to the research discipline) and state and federal applicable law;
- to determine that the rights and welfare of human research subjects are being or have been adequately protected by the investigator and his/her staff; and
- to assess the integrity of the study data.

Reviews also provide an opportunity for education and training of research staff.

II. Applicability

This policy applies to all TCU faculty and staff and others conducting research at or on behalf of TCU including, but not limited to, employees, staff, volunteers, and students.

III. Definitions

Continuing Noncompliance. A pattern of non-compliance that if allowed to continue is likely to increase risk to human subjects, adversely affect the rights, welfare and safety of human subjects, or adversely affect the scientific integrity of the study.

Directed (For Cause) Review. A Review conducted in response to allegations of non-compliance or identified concerns or complaints, or at the request of any of the following parties:

- The full IRB or any individual committee member
- The Associate Provost for Research
- Any Investigator
- Any external body (e.g. OHRP or Sponsor)
- A participant, family member or other representative
- TCU personnel
- The public, media or an anonymous source

At the discretion of the Associate Provost for Research, the Office of Research may engage a third party to assist with any Directed Review.

Human Subject. 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.

Human Subject Research. Any research that involves human subjects, regardless of whether the project is funded and regardless of funding source.

IRB. The institutional review board, whose primary responsibility is to protect the rights and welfare of Human Subjects, by exercising compliance all research activities involving Human Subjects.

Minor noncompliance. Any noncompliance that is not serious or continuing. Examples of minor noncompliance may include, but are not limited to: lapses in continuing IRB approval, failure to obtain a prospective exempt determination from the IRB, minor changes in or deviations from an approved protocol, or administrative errors.

Noncompliance. Failure to follow applicable law, TCU policies, or requirements or determinations of the IRB. This may pertain to a PI, the research staff, or any member of the assisting, participating, or otherwise engaged in research. Noncompliance may be intentional or unintentional, and may range from minor to serious or continuing.

Principal Investigator (PI). The individual responsible for the administrative and programmatic aspects of the Research. Every Research project must have a designated PI and the PI must have the technical competence and substantive capabilities (scientific, administrative, and otherwise) to carry out the project.

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.

Routine Review. A periodic compliance review conducted randomly and not for any particular cause, the objective of which is to ensure proper documentation, record keeping, data analysis, and adherence to federal regulations and IRB requirements. The review assesses the study's procedure, identifies errors and omissions, and is a means to provide the PI with recommendations for corrections and improvements.

Serious Noncompliance. Noncompliance that creates an increase in risks to Human Subjects, adversely affects their rights, welfare and safety or adversely affects the scientific integrity or validity of the study or the human subjects protection program. Examples of serious

noncompliance may include, but are not limited to: initiating or conducting nonexempt human subjects research without IRB approval; inappropriate use of the exempt or expedited review categories; failure to obtain legally effective informed consent from participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to insure the safety of human subjects and the integrity of the research/data. Willful violation of policies and/or applicable law may also constitute serious noncompliance.

Continuing noncompliance: any noncompliance that occurs repeatedly after appropriate remedial education or corrective action. Examples of continuing noncompliance may include, but are not limited to: repeated failures to provide or review progress reports resulting in lapses of IRB approval, repeated failure to obtain prospective exempt determinations, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

IV. Policy Statements

A. All individuals conducting Human Subject Research at or on behalf of TCU 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 applicable law. All Human Subject Research projects occurring at TCU must be conducted in compliance with the Office of Human Research Protection ("OHRP") regulations at 45 CFR 46.

B. To promote a culture of compliance through accountability and to promote subject safety, the Office of Research may perform Routine and Directed Reviews on Research conducted at or on behalf of TCU to evaluate compliance with applicable federal, state and local laws, and TCU policies and procedures, and to verify that Research is conducted in accordance with the IRB-approved protocols.

C. Incidents of serious or continuing non-compliance with federal regulations or determinations made by the IRB of record will promptly be reported to the Institutional Official, department chair, funding agency (if applicable), and OHRP.

V. Responsibilities

A. Principal Investigators. The PI is ultimately responsible for compliance with the determinations of the IRB of record, terms and conditions of applicable awards/contracts, policies of the sponsor (if applicable), terms of the approved protocol, and applicable government regulations.

B. Office of Research. The Office of Research oversees institutional research compliance on behalf of TCU. This oversight includes performing Human Subject Research compliance reviews. The Office of Research also serves as an institutional liaison with regulatory agencies.

C. TCU IRB. The TCU IRB is responsible for overseeing all Human Subjects Research conducted at or sponsored by TCU, unless such responsibility is deferred to another

IRB (i.e. the IRB of record). The TCU IRB will review all Review reports submitted by the Office of Research and follow up on all action items to ensure completion.

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 of this Policy, 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 Policies and Procedures

Human Subjects Research Oversight and Monitoring Procedures
Protection of Human Subjects in Research Policy and Procedures
Research Integrity Policy
TCU Code of Conduct

X. Effective Date

Effective Date: Fall Semester 2016