HUMAN SUBJECTS RESEARCH **Policy Number: G.07.02**

Scope: All members of the University of St. Thomas community (administrators, faculty, staff, and students) conducting or supervising research with human subjects.

Purpose: To define human subjects research; describe the role, membership, and responsibilities of the Institutional Review Board; and describe the responsibilities of researchers conducting research with human subjects.

POLICY

Definitions

A human subject is defined by Title 45 of the Code of Federal Regulations §46.102(e)(1) as "a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains 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."

Research is defined by Title 45 of the Code of Federal Regulations §46.102(l) as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." Note that 45 CFR §46.102 excludes the following scholarly and journalistic research activities from its definition of research: oral history, journalism, biography, literary criticism, legal research, and historical scholarship.

Principles

The University of St. Thomas affirms that the principles of *respect for persons, beneficence, and justice* should be interpreted in the light of *Ex Corde Ecclesiae* and in the context provided by the following documents and regulations:

- The code of medical and general ethics promulgated by the World Medical Association in the *Declaration of Helsinki*
- The *Belmont Report* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- The *Federal Policy for the Protection of Human Subjects* ("Common Rule," 2018 update)

Respect for Persons: Research participants must be treated as autonomous individuals who enter into research voluntarily and with adequate information. Researchers extend additional protections to participants with diminished autonomy.

Beneficence: Researchers have an obligation to avoid harming research participants and to maximize benefits to participants while minimizing possible risks.

Justice: Selection and treatment of research participants must be fair.

Because the participation of human beings in research and training projects may raise fundamental ethical and civil rights questions, no distinctions in monitoring projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, projects carried out on-campus or off-campus, or between projects carried out by members of the University of St. Thomas community and by persons outside this community.

The Institutional Review Board

Role: The role of the University's Institutional Review Board (IRB) is to review proposals for human subjects research sponsored by any member of the University community in light of the protection of human subjects.

Membership: The President of the University will appoint five voting members to the IRB. Voting members will include four UST faculty members, including at least one scientist and at least one non-scientist, appointed for three-year overlapping, renewable terms. The fifth voting member will be a member of the community not affiliated with UST, appointed for a one-year, renewable term. The President may name alternate voting members to substitute when members are unavailable for an extended period. In addition, ad-hoc, non-voting consultants with expertise in a specific area (e.g., research with prisoners) may be added to the IRB review process when needed, based on the specifics of the study protocol and expertise of current IRB members. The need for an ad-hoc consultant will be determined by the IRB chair or the chair's representative. The Chair will be elected from the IRB members for a one-year, renewable term. A quorum consists of one more than half of the voting members.

Responsibilities: In addition to upholding the principles of the policy, all IRB members have the following responsibilities:

- Complete training in human subjects research at the time of joining the IRB and regularly thereafter as indicated in the IRB Procedures.
- Participate in the review of applications when requested by the chair.
- Attend convened meetings.
- Request recusal from reviews in which the IRB member has a conflict of interest.
- Treat IRB-related correspondence and documents as confidential.

Researcher Responsibilities

Researchers considering conducting human subjects research should consult the IRB Procedures and/or IRB chair prior to seeking IRB approval and when questions arise following IRB approval. The Procedures are updated regularly and include guidance on the following topics:

- Whether one's work constitutes human subjects research
- Whether approval is needed for work involving various types of archival data
- What constitutes private, identifiable data

- What category of review one's research falls into (exempt, expedited, or full review)
- Methods of protecting vulnerable participants
- Elements of informed consent
- How to respond to unanticipated problems in human subjects research

Researchers acting in their capacity as employees or students of UST must obtain approval from the UST IRB prior to conducting any human subjects research, whether on- or off-campus.

All activities involving human subjects research must provide for the safety, health, and welfare of participants. Faculty, staff, students, and administrators who conduct human subjects research have the following responsibilities:

- Obtain appropriate training in human subjects research at intervals outlined in the IRB Procedures.
- Obtain IRB approval from UST and any other participating institution(s) prior to conducting the research.
- Document faculty sponsorship of the research, if the primary researcher is a student.
- Use research procedures consistent with sound research design, with the reasonable expectation that the design will permit the research question(s) to be answered.
- Protect participants against unnecessary risk.
- Address existing risks relative to expected benefits of research.
- Use an equitable participant selection process.
- Obtain participants' informed consent unless a waiver has been granted.
- Protect participants' privacy and confidentiality.
- Appropriately store data for a period of time consistent with disciplinary standards, but no less than three years from the time the IRB protocol expires or is closed.
- Report any conflict of interest, including significant financial interest held by or for the benefit of the researcher, his or her spouse, or any dependent children, that may reasonably appear to be affected by the proposed research. A "significant financial interest" is anything of monetary value, other than salary or other remuneration received from the University of St. Thomas, or income from services provided to public or nonprofit entities.

External Applications

Researchers external to the University who wish to petition review from the IRB must follow IRB Procedures for submitting an application. External applications must have approval from the external applicant's sponsoring institution, be sponsored by a University faculty member, and demonstrate potential benefit to the University community.

APPROVED: Dr. Richard Ludwick

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