

United Theological Seminary

Standard of Procedures for Research Involving Human Subjects

Mission: The mission of United Theological Seminary's (United) Human Subjects Research Board (HSRB) is to protect the rights and well-being of participants in human subjects research. The voting committee is comprised of faculty, staff, and a member not affiliated with the seminary. The HSRB aims to provide unbiased evaluation of research involving human subjects.

Key Definitions from the Code of Federal Regulations (CFR)

- Human Subject §46.102 (e) means a living individual about whom an investigator conducts research. At United, it is primarily our doctoral students who conduct research involving human subjects.
- Research: §46.102 (l) is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Required Training for Researchers

United requires completion of Human Subjects Training through United's HSRB. The training provides the necessary information that investigators must know regarding ethical principles of research for all human subjects research. This training is mandatory for all faculty and staff who supervise, and all students who conduct, research involving human subjects.

General Policy

United follows the ethical principles regarding research involving human subjects set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The primary principles of **Justice**, **Respect for Persons**, and **Beneficence** are set forth in the Belmont Report: Ethical Principles and Guidelines for Protection of Human Subject Research. These principles (Justice, Respect for Persons, and Beneficence) are classified as regulations in Title 45 Code of Federal Regulations Part 46. See:

(<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>)

The purpose of these procedures is to:

- protect participants in research from unnecessary risk
- minimize the potentially negative effects of research study methods
- assure compliance with the highest ecclesial and academic standards in research involving human participants
- ensure that research participants are properly informed and give consent to their participation with full awareness of the purposes of the research
- assure that human-subjects research will benefit the researcher's project

Moreover, as a theological institution, we uphold basic Christian ethics which requires that all persons be treated at all times with full respect for their God-given human dignity. This entails restraint from harm, from exploitation, from deception, from unnecessary risk, and from personal violation or abuse such as disclosure of personal information or views without consent. Further, respect for human dignity requires that persons be fully informed of the risks they may incur in undertaking any activity, and that they give full, free, consent. It is particularly important that these general principles be rigorously applied in all cases of research with living participants, especially when done in the name of, or for the use of the Church. These policies apply to all research conducted at United on human subjects and the HSRB has created them to provide responsible guidelines for such projects.

Participants in human subject research are protected under these procedures without exception.

Consent

Prior to signing the form consenting to their willing participation in a research project, the participants must be fully informed about the research and invited to participate without coercion of any kind.

Research may not be carried out unless the participants have signed the consent form.

Types of Human Subjects Research at United

United presumes that human research is conducted by student investigators as part of its Doctor of Ministry (DMin) program. Examples of human subjects research that typically form part of a (DMin) final project are:

- surveys
- questionnaires
- interviews
- focus groups

Human subjects research projects are not limited to the list above and may include other forms of research that would fall under the category of human subjects research.

Potential risks that must be considered in a review include those of a physical, psychological, social, economic, spiritual, religious, or legal nature. A risk versus benefit assessment should include weighing of potential harm, use of deception (if any), and steps to be taken to minimize risk and to care for subjects.

All research with human subjects involves some degree of risk in that such research may prompt participants to self-knowledge or knowledge of others that they may find painful or otherwise harmful. Such risk cannot be eliminated, so it is incumbent upon the researcher to make sure that subjects are protected as much as possible in every other way.

Loss of confidentiality and/or anonymity is the most common type of risk encountered in DMin research. Confidentiality and anonymity are presumed, and they must be maintained in all research and reports deriving from research unless the researcher obtains the express permission of the subject to do otherwise. Breach of confidentiality and/or anonymity entails at least the risks of invasion of privacy, and may carry social, economic, and legal risks as well.

What Kinds of Research Require Review?

Human subjects research requiring HSRB review includes, but is not limited to the following:

- Research in which dual roles may be present between the researcher and the subject(s), such as using students, employees, counseling clients, or members of a congregation as research participants.
- Research in which "the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
- Social scientific research (including practical and pastoral theology, sociology, anthropology) and research investigating subjective experiences or feelings about issues normally considered private or confidential, such as sexuality, addiction, boundary violations, conflict, or violence.
- Research involving subjects who are not competent to evaluate the risks and benefits of participation themselves, including minors, people with cognitive disabilities, and persons who are institutionalized. All legal requirements for working with such persons, including directives by the Department of Corrections, must be followed.
- Unless DMin research is strictly historical or focused only on published or otherwise public materials, it is presumed to be research involving human subjects.

Some research undertaken at the master's level may require HSRB review. In that case, these procedures apply to that research as well. Instructors who assign such research must submit a proposal (with sample consent form) to the HSRB for approval before the beginning of the term in which the course is offered.

Examples of research requiring HSRB review:

- Faculty-assigned research project requiring students to have interactions (interviews, small group projects in congregations, etc.) involving participants' subjective experiences or feelings.
- DMin projects using empirical research involving direct contact with clients, patients, support groups, prisoners, or any vulnerable population.
- Any research involving direct contact with minors or persons with cognitive disabilities.
- Research employing small group discussion formats in a congregational context that entail disclosure of private information of a sensitive nature, where the subjects could easily or readily be identified.

- Research on specific issues of recent conflict in congregational or other organizational life, when the actors are readily identified or identifiable.
- Research that has the potential for causing harm or inciting further conflict in congregations or in the wider community.

Human subjects research not requiring review includes (but is not limited to) the following:

- Research solely for internal institutional use (e.g., course evaluations, institutional self-study).
- Research for a classroom project that does not involve outside participants and is not disseminated publicly or part of a permanent data base.
- Research in other settings that would not reasonably create distress or harm and involving only anonymous questionnaires or public observation.
- Research using existing data, documents, or records, as long as these resources are publicly available and the human subject cannot be identified.
- Research related to organizational effectiveness in settings for which there is no risk to participants' employability.

Examples of research not requiring HSRB approval:

- Scholarly review of literature, including other published social scientific research made available to researchers.
- Archival historical research such as church records or public archives. Research must conform to the rules of the particular archive or institutional body.
- Research that engages subjects on a general level, without identification of specific persons and without reasonable potential for harm, such as evaluation responses to a program or project through instruments that maintain anonymity (e.g., responses to a new curriculum, focus groups evaluating liturgical changes in the church).

Research not requiring an HSRB review does not require an informed consent form to be obtained from participants.

Note: If there is any question about whether an HSRB review is needed on any particular part of the research, the student should consult the Chair of Human Subject Research at the following email address: hsr@united.edu

Guidelines for Researchers

No research may be carried out prior to HSRB approval of the research proposal.

Ethical Issues and Procedural Requirements in Human Subjects Research

Requirements intended to protect the rights of human subjects in research projects include:

- Subjects must give informed consent to participate in the project.
- Subjects have the right to withdraw from participation at any time, including the final stage of the project.
- There will be no financial gain based on the use of the approved human subjects research, which will exclusively be for fulfilling an academic requirement.
- In order to allow the human subject to express self--determination, the researcher must give accurate information about the project and its results and ultimate purposes.
- Researchers must guarantee that no harm will be done by participating in the research beyond what is stipulated in the approved Informed Consent Form.
- The burdens and benefits of subjects' participation in the research shall be justly distributed.