



Institutional Review Board (IRB) External Researcher Guidelines

Applicability

These External Researcher Guidelines apply to all individuals not currently affiliated with the St. Mary's University (StMU) who are interested in conducting research involving StMU, its students, faculty, staff, or alumni.

Purpose

The purpose of these guidelines is to establish a standard method of reviewing and approving any research conducted that involves StMU faculty, staff, students, or alumni as research participants and to balance a cooperative, collaborative research effort with existing research and data collection by researchers affiliated with StMU. Any and all external researchers (anyone currently unaffiliated with the University) are required to follow these guidelines.

Background

The StMU Institutional Review Board (IRB) was established for the review of any research involving humans as subjects and is in compliance with Federal Regulations concerning experimentation involving human subjects (45 C.F.R. Part 46, Protection of Human Subjects). The purpose of this Board is to provide review of all research conducted by faculty, staff, and students to insure protection of human subjects and compliance with the federal regulations. All research conducted on the StMU campus involving StMU students, faculty, staff, alumni, or StMU resources is subject to compliance with all federal regulations regarding human subject research.

Education

All individuals engaged in research involving human subjects must complete an educational program related to the responsible conduct of research prior to initiation of a research project. StMU requires its faculty take the NIH Protecting Human Research Participants Training and provide proof of completion (<http://phrp.nihtraining.com/users/login.php>). Others who wish to conduct research at StMU will be required to provide proof of this training or a similar training such as Collaborative Training Initiative (CITI). CITI is an on-line educational training course that provides relevant, up-to-date information on the protection of human research subjects in the format of instructional modules.

Guiding Principle

It is the guiding principle of the Office of Academic Research and Sponsored Projects at StMU that all research, whether conducted by an internal or an external researcher, involving human subjects must be approved by the StMU IRB before any human subjects are recruited for the study. For all research activities, an external researcher must identify a StMU employee (regular, full-time) willing to serve as the local sponsor for the duration of the research project. The local sponsor should be able to answer questions about the project, serve as the campus contact for questions or concerns about the research, and has completed the required CITI or NIH educational program.

Procedure

Researchers who are unaffiliated with StMU but wish to recruit participants on the StMU campus, must request permission from the IRB before recruiting alumni, students, or employees at StMU (via poster, flyer, email announcement, newspaper ad, or any other method of recruitment). Unaffiliated researchers must submit one copy of the full packet of materials submitted to the IRB at their own institution, including the letter of IRB approval for the project, to the StMU IRB Office. Researchers who do not have an IRB at their home institution should submit all required documents, using StMU application materials found at <https://www.stmarytx.edu/academics/research-programs/institutional-review-board-irb/>, to the StMU IRB. The packet should include, but may not be limited to, the IRB protocol application, consent form or information sheet, recruitment flyer or ad, instruments or measures to be used, and any supporting documentation.

For research activities that qualify as exempt from IRB review, evidence must be provided from the home institution that exempt status has been granted. The IRB Chair or his/her designee will review the request and issue a letter of permission to recruit on campus. The IRB reserves the right to have requests for permission to recruit on campus go to the full board for review and approval, should the Chair decide that the nature of the study requires the independent scrutiny of the IRB to protect its students and employees.

The StMU IRB only considers the protection of human subjects; it does not grant authority for the Researcher to conduct the research at StMU. Therefore, the authority to conduct research on the StMU campus must also be obtained from the appropriate university official relative to the research to be conducted. For assistance in obtaining this approval, contact the STMU Research Compliance Officer, Dr. Mark Roltsch (mroltsch@stmarytx.edu) in the Office of Academic Research and Sponsored Projects.