Principal Investigator Manual

Introduction

This guide is intended to provide guidance for any person, whether an employee or student, wishing to conduct research involving human subjects at St. Louis Community College (STLCC). The person leading a research project is referred to in this and other Human Subject Review Board (HSRB) documents as the "Principal Investigator" (PI).

The primary purpose of STLCC's HSRB is to protect human subjects during research activities. STLCC's HRSB and PIs shall follow: (i) U.S. Department of Health & Human Services policies and recommendations regarding human subjects protection set forth by the Office for Human Research Protection (OHRP); and (ii) the requirements set forth in STLCC's HSRB Manual. To the extent possible, this document will reference appropriate laws, policy, and guidelines published by OHRP. Only policies specific to St. Louis Community College will be fully documented here.

The HSRB is required to review all research involving human subjects prior to the conducting of any research. The primary purpose of STLCC's HSRB is to determine if proposed research at STLCC meets appropriate human subjects protection. The HSRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. The HSRB cannot provide or guarantee any support or permission from STLCC administration, departments, or individuals regarding proposals reviewed. The burden for acquiring any permission or resources related to completing an HSRB approved proposal is solely the responsibility of the PI.

The federal regulations governing the use of human participants in research are located on the internet at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111.

If a question arises as to whether the project is defined as research or some other assessment tool, the HSRB is the body to make that determination. The HSRB may also offer advice on safeguarding the rights and welfare of human subjects as part of its approval.

Human Subjects Protection Training for PIs

PIs are required to review the *St. Louis Community College Human Subjects Review Board Manual* (the "HSRB Manual") in order to understand and follow the applicable procedures set forth therein. In particular, PIs must pay special attention to those sections of the manual addressing changes in a project and reporting requirements.

PIs and staff interacting with research subjects (or information that could identify research subjects) should complete a human subjects research protection training course. Any appropriate training course is acceptable. STLCC's HSRB does not require any particular training, however, training may be taken into consideration when reviewing a project for approval.

Primary Obligations of the Principal Investigator

Human Subjects Protection Obligations

It is the responsibility of the PI to be aware of and follow rules, regulations, and policy regarding human subjects protection. In addition to standard HSRB guidance, some research projects may require additional or different protections. It is the responsibility of the PI to be aware of these and to bring them to the attention of the HSRB.

A fundamental tenet of human subjects protection is *informed consent*. Informed consent is the disclosure of the subjects rights, risks, rewards, and obtaining the research subjects statement that they freely engage in the research study. The general requirements for informed consent can be found at: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116

Proposed informed consent form(s) should be turned in to the HSRB along with other application materials for review. The proposed informed consent form(s) must be approved by the HSRB. Informed consent documentation should be obtained in writing and kept in a secure location. If requested by proper authorities, the PI must be able to produce evidence of informed consent.

There are limited conditions under which obtaining written consent may be waived or altered. These can be found at: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117

Decision charts to help determine if informed consent can be waived or altered can be found at:
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c10 and
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c11.

Administrative Obligations

Progress Reporting

Generally, research projects and research sponsorship are awarded approval in one-year increments unless permission is requested and granted. Extensions may be granted by asking the HSRB and the research sponsor for an extension.

Exempt and Expedited research projects do not require reporting/monitoring unless the conditions below apply. Changes in research conditions or activities may result in a new review.

Additional Reporting Requirements
The PI must immediately report to the HSRB any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with HSRB.

Changes in Research Activity
Changes in research activity during the period in which HSRB has already been given may not be initiated without HSRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. If changes are desired, please review the HSRB manual for the procedures to be followed.

Proposal Review Process

The HSRB Manual sets forth in detail the proposal review process. The general process is that a proposal will be reviewed and the PI will receive HSRB approval or rejection. If approved, the proposed project may move forward and the PI will report on progress as required in the notice of approval letter issued by the HSRB. If a proposal is rejected an appeal may be filed with the HSRB. Please consult the HSRB Manual for more detail on the appeals process.

Not all research proposals require a full review of the HSRB. Most proposals fall within either an Exempt or Expedited Review category. To determine the proper category, the PI should review the HSRB document *Application Selection Decision Charts.*
This form may also be found online at:
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html.

Exempt Category
Research projects falling into the Exempt category do not require a review – only a determination that the project is exempt. To qualify for exemption, the PI must submit an *Exemption Review Application* to the HSRB. Only the HSRB can make the determination that a project is exempt. Exempt research does not require a waiver of informed consent or documentation of informed consent from the IRB.

Expedited Review Category
Research falling into the Expedited Review category may be reviewed by an HSRB chairperson or a designated HSRB member. Expedited review will follow an accelerated time-table, and a decision will usually be issued within 30 days. To qualify for expedited review, the PI must submit an *Expedited Review Application* to the HSRB.

Full Review Category
Proposals that are not within the Exempt or Expedited categories, will require a full review. For this type of proposal, the PI should submit a *Full Review Application* to the HSRB. A full review requires that the HSRB convene with enough member to make a quorum.

Proposal Submission Dates
STLCC's HSRB meets quarterly to review proposals requiring a full review and to review annual progress reports, end-of-project reports, and appeals. All material for full reviews should be turned in to the HSRB administrative contact at least 15 working days prior (but not more than 30 days prior) to the HSRB quarterly meeting. Failure to meet this deadline may result in the proposal not being reviewed that quarter. Exempt and Expedited proposals may be submitted at any time and are reviewed on an ongoing basis.

HSRB Contact Information

The co-chair based in the Institutional Research Department (IRP) is the administrator for the HSRB and is the primary point of contact for HSRB matters.

More information about the HSRB and members can be found at https://www.stlcc.edu/about/institutional-research/human-subjects-review-board.aspx.