Human Subjects Review Board Manual

St. Louis Community College

Introduction

Pursuant to the National Research Act (P.L. 93-348 § 212a) and CFR 45.690 and other related federal regulations, an Institutional Review Board (IRB) is a board established by institutions to review projects or proposals involving research with human participants. The Institutional Review Board at the College is known as the Human Subjects Review Board (HSRB).

This document establishes policy for human subjects research at St. Louis Community College (STLCC). STLCC's HRSB shall follow the U.S. Department of Health & Human Services policy and recommendations regarding human subjects protection set forth by the Office for Human Research Protection (OHRP). To the extent possible, this document will reference appropriate laws, policy, and guidelines published by OHRP. Only policy 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 purpose of STLCC's HSRB is only 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 on the principal investigator(s).

The federal regulations governing the use of human participants in research are located on the internet: Federal Regulations

To meet the HSRB's responsibility to protect human subjects, the HSRB uses the following procedures to oversee all human subjects research projects at STLCC:

(a) Review applications for approval or denial of a research project
(b) Conduct regular reviews of the ongoing research projects that have been approved
(c) Review requests for approval to changes in a previously approved research project
(d) Resolve any appeals from decisions
(e) Suspend or terminate previously approved projects

Additionally, 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.

Administration of the HSRB

The Vice Chancellor for Academic Affairs (VCAA) oversees the administrative functions and activities of the HSRB. The VCAA has the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research. Institutional level communications and notices shall be made by the HSRB through the VCAA. The VCAA appoints all of the members of the HSRB.

HSRB Point of Contact and Records Maintenance

The co-chair based in the Institutional Research Department (IR) will act as the administrator for the HSRB and will serve as the primary point of contact for HSRB activity. The IR-based co-chair will maintain an electronic file storage site dedicated to HSRB. This site will contain copies of all HSRB materials. This will be a secure site with access limited to HSRB members.

The co-chair based in the Institutional Research Department will maintain any hard copy material related to HRSB in a secure location at the STLCC administrative headquarters so that it is accessible to HSRB members and others with access privileges.

The HSRB shall prepare and maintain adequate documentation of its activities, including, among other things, those items specifically set forth in 45 CRF 46.115, 45 CFR 46.116(d), and 45 CFR 46.117.

STLCC policy is that HSRB members will have access at any time during working hours to HSRB materials

HSRB Membership

STLCC shall follow the requirements for membership set forth in 45 CFR 46.107.

OHRP guidance regarding HSRB membership can be found at: OHRP Guidance

The STLCC HSRB consists of 9 voting members and 2 ex-officio members.

Voting members:

(a) One member of the Institutional Research Department serving as co-chair. This co-chair will be responsible for maintaining records and documentation for the HSRB.
(b) One co-chair appointed by the Vice Chancellor for Academic Affairs
(c) One physical/biological scientist
(d) One social scientist
(e) Two non-scientists
(f) One person not affiliated with STLCC and is not part of the immediate family of a person who is affiliated with STLCC
(g) Two at-large members chosen

The composition of the HSRB shall be chosen such that, using every non-discriminatory effort, there is diversity of membership regarding race, ethnicity, gender, and cultural background. Notwithstanding the above, no selection of membership shall be made on the basis of gender, nor shall the HSRB consist entirely of members of one profession.

Ex-officio (non-voting) members:

(a) The Vice Chancellor for Academic Affairs (VCAA)
(b) The Associate Vice Chancellor of Institutional Research and Academic Process (AVC)

If deemed necessary by the HSRB, experts in areas beyond the expertise of the HSRB members may be called upon to assist with reviewing a proposal. However, these experts will not have voting privileges.

Membership is voluntary and terms will last two years. Members may serve additional terms if asked by the Vice Chancellor for Academic Affairs. Members may be dismissed or replaced at any time by the VCAA. Any changes in HSRB membership will be reported to the Office for Human Research Protections at HHS.

HSRB Member Training

OHRP does not specify what training is required for HSRB members.

STLCC will make efforts to see that training opportunities are provided to HSRB members.

HSRB Meetings

HSRB meetings, including required meeting minutes, shall be held in compliance with the requirements of 45 CFR 46.108(b), 45 CFR 46.107(e) and 45 CFR 46.115(a)(2).

HSRB meetings will be held regularly for the purpose of initial review of new proposals, review of any existing research that requires monitoring, review of any protocol changes, and review of reports of unanticipated problems or of serious or continuing noncompliance. Meetings can be held in-person or via electronic methods that meet the needs of the committee. Additional meetings may be called by the chairperson(s) as necessary.

A minimum of five (5) of the voting members that include at least one (1) non-scientist is required for voting on full reviews. A member who recuses him or herself due to a potential conflict of interest will not count toward the five (5) members need for a quorum. However, an HSRB member who abstains from voting will counts towards the quorum. Should the quorum fail during a meeting (e.g. recusals due to conflict of interest, etc.), the HSRB may not take further actions or votes unless the quorum can be restored.

Documents to be reviewed at HSRB meetings shall be submitted to the HSRB no later than fifteen (15) days prior to the HSRB meeting.

No HSRB member may participate in any initial or continuing review of a project in which the member has a conflict of interest, except to provide information requested by the HSRB. In situations where HSRB members have a conflict of interest, said HSRB members shall absent themselves from the HSRB meeting room during the review (unless requested by the HSRB to be present to provide information) and such should be noted in the HSRB meeting minutes.

Meeting minutes shall, at a minimum, include sufficient detail to show:

(a) attendance at meetings,
(b) actions taken by the HSRB,
(c) the vote on these actions, including the number of members voting for, against, and abstaining,
(d) the basis for requiring changes in or disapproving research, and
(e) a written summary of the discussion of any controverted issues and their resolution.

HSRB Review Process

Standards of Review for Applications for Approval

In conducting the review of research, the HSRB shall follow the regulations stated in 45 CFR 46.109, and meet the criteria as set out in 45 CFR 46.111. Any HSRB approval will be contingent upon assurance that the risks are kept to an absolute minimum and that any risks are clearly outweighed by the potential benefits and that respondents are fully informed about the risks before they consent to participate. To ensure that these standards are met, the HSRB will evaluate the applications for maintaining confidentiality of the information, assessment of the risks and the benefits of the research, precautions to be used when the project involves

deception, assurance that the informed consent will be received by the subject(s), local context issues and ethical considerations.

Levels of Review

This section describes three levels of HSRB review for studies that involve Human Research Subjects: exemption from review, expedited review and full review. The process is covered in the HSRB Review Process section.

Exemption Certification Review

Research activities in which the human subjects involvement constitute no more than minimal risk and falls within one or more of the exemption categories that are described below and/or in 45 CFR 46.104(d) may be eligible for an Exemption Certificate. An Application for Exemption will be reviewed by the Chairperson(s) or their designee(s). If it is determined that the project qualifies to be exempt from review, an Exemption Certificate shall be issued to the PI. Upon receipt of the Exemption Certificate, the PI may initiate the project and no longer be subject to review. Even though the project may be exempt from review, if the PI desires to make any modifications to the project, the PI must seek approval for any proposed modifications prior to implementation of such modifications.

Expedited Review

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the categories published by the DHHS (as referenced in 45 CFR 46.110) (carried out through standard methods) may be reviewed by the HSRB Chairperson(s) or their designee(s).

Full Review

Research activities in which the involvement of human subjects involves more than minimal risk and does not fall within the exemption or expedited categories discussed above or involves certain vulnerable populations shall be subject to a full review of the application for approval of the project.

All “full review” proposals will be forwarded to the HSRB for review under the full review process. Upon completion of the review, the HSRB may take one of the following actions:

- Approve the research proposal and determine the length of time the research is approved.
- Require additional information or modifications to the project.

- Disapprove the research proposal.

The Review Process

Initial Review of Research

The application, including all necessary documentation, shall be filed with the Institutional Research (IR) representative co-chair.

The IR representative co-chair, based on the application form, shall assign the application to the appropriate entity for review, as follows:

Application for Exemption

The HSRB Chairperson(s) or their designee(s) shall review the application against the requirements for projects that are exempt from review pursuant to 45 CFR 46.101.

If a project is determined to be exempt, an Exemption Certificate is issued, and then the PI may initiate the research, and no further action is necessary with the HSRB unless the PI determines that the project should be modified. In such a circumstance, the modification needs to be brought before the HSRB for approval before the modification may be implemented.

If the HSRB Chairperson(s) or their designee(s) determines that the project is not eligible for exemption certification, the PI shall be informed in writing of this determination, and the PI may either revise the application and re-apply for review or exemption or appeal the determination pursuant to the appeal procedure as set forth in this manual

Application for Expedited Review

Expedited reviews shall comply with the procedures set forth in 45 CFR 46.110.

If an Application for Expedited Review is submitted, the HSRB Chairperson(s) shall review the application against the appropriate standards to determine if expedited review is appropriate. If the HSRB Chairperson(s) determines that the project does not qualify for expedited review, then the application shall be forwarded to the HSRB for full review.

If the project qualifies for expedited review, then the HSRB Chairperson(s) or their designees shall review the project to determine that the project meets the guidelines for appropriate human subjects research. If it is determined that the project meets HSRB guidelines, then the PI shall receive written notification of the decision and may then begin initiating the project. If

the HSRB Chairperson(s) determines that the project does not meet the guidelines for Human Subjects Research, then the application shall be forwarded to the HSRB for full review.

All expedited review decisions, whether granted or denied, shall be communicated in writing by the HSRB Chairperson(s) to the HSRB at the HSRB quarterly meetings.

Application for Full Review

The HSRB shall review the application against the guidelines for appropriate Human Subjects Research as set forth in 46 CFR 46.111.

If the HSRB determines that the proposal needs to be modified before it can be approved, the HSRB shall give written notice to the PI, who can choose to make the requested modifications and re-submit the application for full review or appeal the determination that modifications are necessary to the proposal.

If the HSRB determines that no modifications are necessary, then the HSRB is determine if the proposal can be approved. If the project is approved, written notification of the approval is given to the PI, and they may initiate the project.

If the HSRB determines that the project is to be denied, written notification of the denial including reasons why the project was denied will be provided to the PI within 10 working days. The PI may then choose to either submit a new application or appeal the determination as described in the appeals process section of this manual.

Continuing Review of HSRB Approved Projects

Exempt and expedited research projects do not require any additional regularly scheduled reporting per OHRP guidelines. However, research projects are subject to further review should the HSRB or one of the HSRB co-chair request additional information regarding a project.

Those projects approved under a Full Review by the HSRB shall be subject to continuing review during the duration of the project. Such review shall occur at least annually but may occur on a more frequent basis as determined by the HSRB. The PI will be informed of the frequency of review in the HSRB approval letter. Failure of the PI to submit a required progress report can result in the suspension of a project.

When determining the frequency of continuing review, the HSRB shall make the determination on a project by project basis, and the interval of review shall be established at the time of initial approval. In addition, the frequency itself shall be part of the continuing review.

When determining the frequency, the HSRB shall consider the following factors:

- The nature of any risks posed by the research project
- The degree of uncertainty regarding the risks involved
- The vulnerability of the subject population
- The experience of the investigators in conducting research
- The HSRB's previous experience with the PI's involved (e.g., compliance history, previous problems with the PI obtaining informed consent, or prior complaints from subjects about the PI)
- The projected rate of enrollment
- Whether the research project involves novel interventions

Continuing review of research will be substantive and meaningful, and the HSRB shall ensure that the requirements of 45 CFR 46.111 continue to be satisfied.

In addition, the HSRB shall consider whether projects under continuing review need verification from sources other than the PI that no material changes have occurred since previous HSRB review. In making this determination, the HSRB shall review such criteria as:

(a) review of randomly selected projects involving the PI
(b) complex projects involving unusual levels or types of risk to subjects
(c) projects conducted by investigators who previously have failed to comply with regulatory requirements or determinations of the HSRB
(d) projects where concern about possible material changes occurring without HSRB approval have been raised based upon information provided in continuing review reports or from other sources

Projects Approved for One Year

Most projects will be approved for one year. Additional time for a project may be requested in writing to the HSRB. Projects exceeding one year are also subject to obtaining additional permission from the research sponsor.

For those projects being reviewed on an annual basis (those requiring a full review), the PI will be required to prepare an annual progress report that is to be filed at least 15 days but not more than 30 days before the review date. If the HSRB is satisfied that the guidelines and principles of the HSRB are being and will be met, then the HSRB may grant approval for the project to continue. The HSRB, based on the circumstances leading to the hearing, and the

information gathered at the hearing, may choose to approve continuing the project for one year, set a continuing review date for the project less than one year from the annual review date, or suspend or terminate the project.

If the chairperson(s), upon review of the annual progress report declines to grant approval, the PI will be directed to appear before the HSRB prior to the annual review date for a more comprehensive review, and the HSRB will determine whether the project shall be allowed to continue.

Appeals Process

PI may appeal a decision of the HSRB by filing a written request for an appeal of the decision to the IRP representative HSRB co-chair within 15 working days of the date of the decision. The written request for appeal shall include any additional appropriate documentation and materials in support of their appeal. The PI may also request in writing an appearance before the HSRB to speak in support of their appeal.

The HSRB shall meet and issue its decision on the appeal within 15 working days of the receipt of the notice to appeal. If a decision will require more than 15 working days, the HSRB will notify the PI of the additional anticipated time required to issue the decision.

While STLCC may override and disapprove any project that is approved by the HSRB, STLCC may not approve any project that has not been approved by the HSRB.

Changes in Project

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. Training programs and materials for PI's shall address this requirement and, where deemed necessary by the HSRB, random audits of research records shall also be undertaken.

The following procedures must be followed when proposed changes are desired:

(1) The PI must submit a complete description of the proposed changes to the HSRB
(2) The proposed changes must be promptly submitted to the HSRB such that the HSRB has adequate time to consider the request
(3) The level of detail provided in the proposed changes must be sufficient for the HSRB to undertake an adequate review of the factors set forth in 46 CFR 46.111 and, when applicable, any additional regulatory provisions applicable to the proposed changes

Reporting Requirements

The co-chair based in Institutional Research (IR) shall promptly report to the HSRB any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with this policy or the requirements or determinations of the HSRB.

The HSRB shall determine whether such problems or non-compliance shall require additional reporting to the appropriate department or agency head, and/or other action. Such action may range from simple discussion and clarification of the issues, or steps needed to correct the issues, or could result in suspension of HSRB approval as set forth below, depending on the nature of the issue.

Reports required by this section shall be made timely enough to minimize risks to subjects. In no event shall reports required under this section be submitted later than twenty (20) days after discovering the matter to be reported.

Suspension of HSRB Approval of Project

The HSRB chairperson(s) shall have the authority to suspend approval of a project at any point after approval of the project has been granted. The suspension shall be based on information received about harm to any subject of research or that the research is not being conducted according the policies and direction of the HSRB.

When a chairperson decides to suspend any project, they shall immediately notify the PI involved with the project, the HSRB, and the VCAA in writing stating the reason(s) for the suspension. The VCAA shall notify the appropriate department head or funding agency head.

The HSRB shall meet within 10 working days of the notice of suspension to consider further action on the project. The HSRB shall determine whether to:

- Make the suspension a full termination of the project,
- Continue the suspension until the PI can make modifications to the research sufficient to satisfy the HSRB that continuing the project would be within the guidelines and principles of the HSRB, or
- Remove the suspension if the PI can present information and/or implementation of modifications approved by the HSRB indicating that continuing the project would be within the guidelines and principles of the HSRB.

Access to Confidentiality and Informed Consent Records

OHRP guidance regarding informed consent can be found in 45 CFR 46.116 and 46 CFR 45.117.

STLCC has the right of access to the supporting records for all research at the college or supported by the college-sponsored funds, provided such access to the records shall be reasonable cause, at reasonable times, and after reasonable notice. The college's right of access to the data shall continue regardless of the location of the principal investigator. Information or data that would violate the confidentially of sources or subjects involved in the research should not be disclosed. External participants providing support for research at STLCC may also have the right to review the data and records resulting from that their support. Co-investigators and trainees who are an integral part of a research project have the right to review all records and data which are part of that project.

Revisions of Policies and Procedures

From time to time revisions to the policies and/or procedures of the HSRB will need to take place. Recommendations for changes in policies or procedure will be directed to the HSRB chairperson(s) for consideration. Changes in policy and procedures will be discussed by HSRB and, if approved by a majority of members, shall be documented and sent to the VCAA for review and final approval.