South Central College (SCC)
Institutional Review Board Policy and Procedures

Purpose of IRB

The purpose of the Institutional Review Board (IRB) is to protect the rights and wellbeing of human subjects involved in research at South Central College (SCC). A Human Subject means: "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (Code of Federal Regulations, 45 CFR 46.102f). All research originating from SCC faculty members, staff or students should be reviewed for the protection of human subjects by the IRB. Research originating from outside of SCC but involving the study of SCC students or employees must also be reviewed by the IRB. All research must be approved by the IRB before starting the research project.

SCC's IRB

SCC's IRB is a six-person committee, made up of three full-time faculty members and two representatives from administration, and one external representative. The Department of Research and Institutional Effectiveness will provide staff support to the IRB.

Ethical Guidelines

The guidelines set forth in the Belmont Report[1] are to be followed by the IRB. It is the charge of the IRB to review each research project and ensure that the following elements are in place:

1. **Respect for Subjects:** Subjects enter the study on a voluntary basis and are given adequate information including research protocol and purpose, risks and anticipated benefits, alternative procedures if any, and the right to withdraw from the study at any time. In some situations, it may be necessary to mask certain aspects of a study while it is being conducted. In such a case, the rationale must be justified, fundamentally necessary to the study, pose minimum risk, and have a plan for debriefing subjects.

2. **Beneficence:** Research is conducted in a manner that brings no harm or a minimum level of harm that is justified by the goals of the research study. Determination of harm will be on a case by case basis.

3. **Justice:** Research protocol should reflect a fair and equitable procedure for selection of subjects. Care should be taken to not systematically select (intentionally or unintentionally) certain classes of subjects unless there is justification.

[1] Belmont Report (April 18, 1979): The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Types of Reviews

Exempt Review: Federal guidelines (45 CFR 46.101(b)) for research on human subjects allow a project to be exempt from full review if the research involves *no risk* to the subject and the procedures are limited to the following criteria:

1. Research conducted in established or commonly accepted educational settings, involved normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) (2) of this section, if:
   (i) the human subjects are elected or appointed public officials or candidates for public office; or
   (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
   (i) public benefit or service program;
   (ii) procedures for obtaining benefits or services under those programs;
   (iii) possible changes in or alternatives to those programs or procedures; or
   (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies,
   (i) if wholesome foods without additives are consumed or
   (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agriculture chemical or environmental contaminated at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Consent: The basic elements of informed consent must be communicated to every participant. Obtaining a signed consent is generally not required for exempt reviews. The SCC IRB retains the right to require written consent on a case by case basis.

Exempt reviews are screened by Department of Research and Institutional Effectiveness staff.

Expedited Review: To be eligible for expedited review, a research procedure must be limited to the activities that are federally approved (from 63 FR 60364-60367, November 9, 1998) for expedited review and incur no more than *minimal risk* for participants, or be a *minor* change in previously approved research that involves *no additional risk* to the research subject. The activities approved in the federal regulations for expedited review include:

1. Clinical studies of drugs and medical devices.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior.
8. Continuing review of research previously approved by the convened IRB.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater that minimal risk and no additional risks have been identified.

Expedited reviews are conducted by a member of the IRB.

Full Board Review: Research involving greater than minimal risks to participants are subject to a full review. Examples of such research could include physically invasive procedures or surveys involving vulnerable populations or sensitive information regarding sexual practices or illegal behavior.

Consent: Signed consent is required for research subject to a full review.

Full reviews are conducted by all members of the IRB.

Institutional Procedures

All research, excluding standard educational or institutional assessment, involving human subjects must be reviewed by the IRB prior to any involvement with human subjects including recruitment and consent.

Research Methods Courses/Class Research Assignments

Courses with class assignments involving research with human subjects will require IRB review prior to the start of such research activities. The use of human subjects in class research activities, even when data is not intended for generalization or publication, should model appropriate and ethical research conduct. Once approved the instructor is responsible for overseeing the research activities and ensuring protection of human subjects.

Application and Review Process

1. The Principal researcher will determine if the proposed research involves human subjects and what level of review the project will require.

2. Submit appropriate application materials to the Department of Research and Institutional Effectiveness.

   Exempt Review: Complete IRB APPLICATION (available on SCC website under office of Research and Institutional Effectiveness), along with copies of all research instruments, evidence of informed consent and recruitment information. IRB only receives electronic applications.

   Expedited Review: Complete IRB APPLICATION (available on SCC website under Office of Research and Institutional Effectiveness), along with copies of all research instruments, evidence of informed consent, and recruitment information. IRB only receives electronic applications.

   For Full Board Review: Complete IRB APPLICATION (available on SCC website under Office of Research and Institutional Effectiveness), along with copies of all research materials, evidence of informed consent, and recruitment information. . Principal researcher may be required to meet with IRB in order to provide additional information.

3. IRB will review application materials and make one of three determinations:

   1 *Approve Research Proposal:* If your study meets that standards set by the IRB, you may proceed with your study after approval. However, *any changes* to your study protocol, targeted subjects, or instruments will require submission of (Changes-Modification) form to the IRB.

   2 *Request Additional Information:* If your materials are incomplete or if the proposal is sufficiently complicated, additional information may be requested prior to making a determination.

   3 *Reject Research Proposal:* If your study does not meet the standards set by the IRB, you may not proceed with your study. The IRB must provide a written explanation regarding why the study was rejected along with, if appropriate, steps that should be taken in order for the study to be approved. The principal investigator may request a meeting with the IRB to provide additional information.

Application Deadlines

Review Type	Submission Deadline	IRB Timeline for Review
Exempt	On-going	2 weeks from application submission
Expedited	On-going	4 weeks from application submission
Full	On-going	6 weeks from application submission

External Requests to Conduct Research on SCC Students/Employees

External researchers desiring to conduct research with SCC students or employees must submit a cover letter, IRB application, evidence of approval from the institutional review board or equivalent from the institution he or she represents, and proof of a formal affiliation with that institution.

Changes to Proposed Research

Changes in any aspect of the proposed research project must be reported to IRB for review through using the (Changes-Modifications) Application.

Researches conducted without IRB's approval

A non-compliance report will be sent to the Vice President of Academic and Students Affairs for further action against the Researches conducted without the approval of IRB.

Additional Investigator Reporting Requirements

The following reporting will be required by principal investigators of IRB approved research:

- Annual Progress Reports
- Completion/Termination Notice