6.1.020

Human Subjects Research Policy

Date of last board of trustees review: March 12, 2025

The originator of this policy is the assistant director of Research and Surveys. Questions regarding this policy may be directed to the originator by calling 801-957-5106.

1. Policy

The Human Subjects Research Policy establishes Salt Lake Community College's compliance with the regulations outlined in 45 CFR 46 ("Common Rule") and the ethical principles outlined in the Belmont Report. This policy only applies to activities defined by the Common Rule as research involving human subjects conducted by any employee, student, or agent as part of their institutional responsibilities or when the college's name, symbols, property, or services are used in research activities. SLCC's Institutional Review Board ("IRB") ensures that human subjects research activities comply with federal and institutional regulations.

2. References

A. Basic HHS Policy for Protection of Human Research Subjects, 45 CFR §§46.101-124 (2018).

B. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979).

Salt Lake Community College

6.1.020

Human Subjects Research Procedure

Date of last executive cabinet review: January 14, 2025

The originator of this procedure is the assistant director of Research and Surveys. Questions regarding this procedure may be directed to the originator by calling 801-957-5106.

3. Definitions

A. Application: the submitted research design and any other necessary materials for review by the IRB.

B. Class Assignment: educational exercises or activities conducted within a course or academic program, which may include projects, experiments, or studies assigned to students that may involve human subjects.

C. Common Rule: the Federal Policy for the Protection of Human Subjects which outlines basic provisions for IRBs, informed consent, and assurance of compliance.

D. Confidentiality: the protection of research participants' privacy from disclosure of their personal, sensitive, or private information.

E. Consent: an agreement to participate in research activities that is only valid if given by the subject voluntarily and must be free of coercion and undue influence.

F. Consent Form: a clear explanation, whether in writing or read to participants, of the purpose, risks, benefits, and procedures of the study.

G. Direct Identifier: information that directly identifies an individual, such as name, student ID, date of birth, email address, or phone number

H. External: any researcher, event, or funding that is not directly affiliated with SLCC.

I. Faculty sponsor: an individual who represents SLCC in research conducted by external agents involving SLCC auspices or oversees a student-led research project to ensure compliance of research activities. These individuals include non-faculty members.

J. Generalizable knowledge: conclusions, findings, or results that contribute to a scholarly field or discipline, intended to be shared with other people through publications or external presentations, often expressed in theories, principles, and statements of

relationships meant to inform and benefit the broader field. Examples are located on the IRB Guidance Site.

K. Human Subjects: living individuals about whom an investigator conducting research obtains data through intervention, interaction, observation, or by gathering identifiable information about the individuals. Human subjects may also be referred to as participants.

L. Identifiable Information: any data or combination of data elements that could reasonably be used to identify an individual participant in a study. Including direct identifiers, such as student ID number or email, and indirect identifiers, such as gender, race or ethnicity, geographic information, occupation, or academic major.

M. Informed Consent: process of communication with potential human subjects that provides information about the study and allows for the person to have full knowledge in their decision to participate.

N. Institutional Review Board (IRB): the SLCC committee that reviews all research applications to ensure ethical practices and compliance with the Common Rule.

O. Minimal Risk: the probability and extent of harm or discomfort anticipated in research that is not greater than those ordinarily encountered in daily life or during routine psychological or physical examinations. Inadequate data handling practices can affect the extent of the risk if privacy breaches or unauthorized disclosures would result in harm to participants.

P. Principal Investigator (PI): the individual responsible for the overall conduct of the research study and acts as the primary point of contact.

Q. Research: a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

R. Student-Led Research: studies conceived, designed, and conducted primarily by students, requiring supervision and guidance by a faculty sponsor. Class assignments are not equivalent to student-led research.

S. Vulnerable Populations: individuals with diminished autonomy and others requiring additional protection. This includes, but is not limited to, minors, individuals who are pregnant, and individuals who are in prison.

4. Procedures

A. General

1. Salt Lake Community College (“SLCC”) recognizes the importance of protecting

human subjects in research conducted under institutional auspices.

2. SLCC's Institutional Review Board ("IRB") ensures that human subjects research activities comply with federal and institutional regulations and ethical principles. Roles, responsibilities, additional support, and other information regarding the IRB can be found on the IRB Guidance Site.

3. Researchers planning to conduct research involving human subjects must submit a complete application for IRB review and obtain approval before beginning any activities.

B. When Research is Human Subjects Research

1. According to the Common Rule research means systematic investigation and contributions to generalizable knowledge.

   a. A human subjects research project requires:

      (1) the data received from the participant to be about that participant; and

      (2) an intervention or interaction.

2. The following activities do not require IRB review unless the research focuses on vulnerable populations, involves risk to participants, or the research will be shared externally:

   a. Operational activities, such as studies for internal institutional purposes, program evaluation, quality assurance and/or improvement, or marketing studies.

   b. Case studies or anecdotes.

   c. Scholarly activities that do not require an intervention or interaction with human subjects.

   d. Student class assignments, such as those commonly used in courses covering research methods and ethics.

3. Under the Common Rule, the IRB Chair retains final judgment regarding whether this policy covers a particular activity. This judgment shall be exercised in a manner consistent with the ethical principles of the Belmont Report.

C. Student-Led Research Activities

1. Class assignments and course requirements

   a. IRB application submission is required if the class assignment or course requirement involving human subjects research activities meets any of the

following:

(1) participation involves more than minimal risk for human subjects;

(2) activities are not within the exempt categories;

(3) involves vulnerable populations; or

(4) the study data will be used for external purposes such as publications.

b. IRB review is not typically necessary if a student conducts research activities involving human subjects as part of a class assignment or course requirement. Examples of class assignments not requiring IRB approval may include:

(1) activities designed to fulfill course requirements of learning research methods;

(2) investigations conducted by a student for a class assignment designed to teach human subject research methodology;

(3) projects that are not intended to produce findings that will be applied more broadly to the population at large; or

(4) projects not intended to produce findings that will be presented external to the college.

c. Faculty are responsible for ensuring students' research activities comply with the Common Rule and ethical principles.

d. The appropriate faculty must submit a course-level IRB application if one or more students in the course will be presenting on the assigned project at the college, outside of the classroom. If the assignment changes after IRB approval, the appropriate faculty is responsible for submitting a modification to the application for IRB review.

e. If a student's class assignment requires IRB submission, the faculty must act as a faculty sponsor.

f. IRB approval cannot be granted retroactively. An IRB application should be completed if a student is considering potential external use of the study.

2. Student-led Human Subjects Research

a. Students conducting research that meets the federal regulation's definition of human subjects research must have IRB approval to begin activities.

b. Students are required to have a faculty sponsor serve as Principal Investigator.

c. Faculty sponsors are ultimately responsible for ensuring students' research complies with federal regulations, ethical principles, and college policy.

D. Principal Investigator ("PI") Role and Responsibilities

1. PIs are accountable for assuring the study's compliance with federal and state regulations, ethical principles, and college policies and requirements.

2. External researchers must have a faculty sponsor to conduct a study. The external researcher must establish a faculty sponsor before submitting the IRB application.

3. The IRB Guidance Site describes the roles and responsibilities of PIs, including requirements for human subjects research training, study design, selection and recruitment of subjects, informed consent, IRB application submission, data management, data privacy for participants, and communication with the IRB.

E. Categories of IRB Review

1. Review category is assigned by the IRB during the application review process. All three review categories require approval before beginning any activities.

2. Exempt Review

a. Research may be deemed exempt if it poses no more than minimal risk to participants and falls into one of the six categories listed in 45 CFR 46.104.

b. Exempt studies only require review by one IRB member.

c. Studies granted exempt status do not expire, and continuing review is not required. The IRB reserves the right to audit and/or terminate any studies found to be in noncompliance.

d. The IRB must review any modifications to a previously reviewed study to ensure it continues to meet exempt status.

e. Exempt studies may require an informed consent form. The PI remains responsible for providing the following information to any potential participant before involvement in any activities:

(1) That participation is voluntary, and subjects may leave the study without negative consequences.

(2) That the activity involves research.

(3) A brief description of study procedures.

(4) The name and contact information of the study's PI.

3. Expedited Review

    a. Research that poses no more than minimal risk, involves only procedures listed in one or more of the categories outlined by the U.S. Department of Human and Health Services, and is not classified may be deemed expedited. The activities included in the list are an indicator of eligibility for expedited review.

    b. Expedited Review requires review by at least two IRB members.

    c. Expedited Review may be considered for research falling into an exempt category if the IRB is concerned that the identity of human subjects may be ascertained directly or indirectly; or for modifications to previously approved research.

    d. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

    e. Standard requirements for informed consent must be met.

4. Full Review

    a. A full review by the IRB committee at a convened meeting is required for any studies that do not qualify as exempt or are not eligible for expedited review.

    b. At least two members of the IRB committee must perform a review before the committee meeting.

    c. A majority of IRB members must be at the committee meeting to consider whether regulatory requirements are met.

    d. A majority of the IRB members present at the meeting must approve the research.

F. IRB Application Submission

1. Complete IRB applications are required for IRB consideration.

2. IRB application submission requirements are available on the IRB Guidance Site.

G. IRB Review Process

1. Every submission will be considered in the order they are received. It is recommended to submit IRB applications at least two months before the study's

intended start date.

2. The PI will be contacted if the IRB has questions or requests edits to any aspect of the study or its materials.
3. The PI must communicate promptly with the IRB.
4. After completing the review, the IRB will notify the PI of the review outcome.
5. If a PI plans to change an already approved study, they must contact the IRB, and submit appropriate documentation for IRB approval before proceeding.
6. The IRB may decide to audit a current study or implement a continuing review at any time.