



SAN JUAN COLLEGE

Guidelines for Research Activities Protecting Human Subjects in Research

San Juan College has an obligation to protect human research participants. This applies to a broad range of research activities. This document provides guidance on when Institutional Review Board (IRB) review and approval is necessary.

A. How does the IRB determine that federal definitions of “human research” are met?

1. The IRB first looks to see if activities meet the US Department of Health and Human Services (HHS) definitions of “research.”
 - ✓ Is the study a systematic investigation that utilizes one or more predetermined scientific methods for studying a specific topic, answers a specific question, tests a specific hypothesis, or develops theory?
—AND—
 - ✓ Is the study designed to develop or contribute to generalizable knowledge?
Generalizable knowledge is produced when information or data are collected about a given population sample and the results are used to describe, explain, interpret, or make predictions about those and other members of that population. The information may be generalizable to many people (society) or to very few. However, if information is collected for purposes other than generalization (such as a collection of facts, to diagnose illness, or to locate the source of a disease outbreak), the activity would not be considered research, even if the data were obtained via a "systematic investigation."
 - ✓ If the answer to *both* questions is “yes,” the IRB then looks to see if the study meets the HHS criteria for the conduct of research involving human subjects.

B. What kinds of activities DO fit the federal definitions of human research, and DO require IRB review?

Directed or independent research projects conducted by SJC students or employees, or by outside researchers on the SJC campus, which employ a systematic process for collection of data with the *intent* to contribute to generalizable knowledge are considered to meet the HHS definition of research. THE IRB must review and approve these projects prior to data collection, as long as the definition of “human participant” is also met. Only the IRB is authorized to make this determination.

Excluded from this requirement are course projects that require students to interact, intervene, or observe living individuals in which the purpose is to train students in research method (see C3 below).

C. What kinds of activities may NOT meet Federal definitions of human research and may not need IRB review?

Certain activities have the characteristics of human research but do not specifically meet the federal regulatory definitions of research. Below are several examples of activities that do not meet the federal definitions and therefore do not need IRB review.

1. Data collection for internal departmental, school, or other College administrative purposes.
Examples: course evaluations, employee satisfaction surveys

- Surveys issued or completed by SJC personnel with the intent and purpose of improving SJC services and programs or for developing new services or programs for SJC students, employees, or alumni are not considered human research and do not require IRB review. Nonetheless, care should be taken to ensure that: (i) the privacy of the individuals is protected; (ii) confidentiality of the individual responses is maintained; and (iii) participation is voluntary.

Note: If at a future date, an opportunity arose to present previously collected survey data outside of SJC, or to apply previously collected identifiable or coded survey data to a new study with the intent of contributing to generalizable knowledge, the IRB must be consulted before the data may be used.

2. Fact-collecting interviews of individuals where questions focus on services, procedures, or policies and do not gather information about living individuals.

Examples: canvassing librarians about inter-library loan policies or rising journal costs, asking employees in the workplace about organizational policies and procedures

3. **Course-related activities designed specifically for educational or teaching purposes where information is collected from human participants as part of a class exercise that is not intended for use outside of the classroom.**

Note: Presentation outside of the classroom and/or publicizing student-prepared documents in any manner is considered research. Students and/or Instructors of research methods courses are encouraged to consult with the IRB chair (listed at the end of this document) before presenting or publishing results.

4. Research involving a living individual, such as a biography, that is not generalizable beyond that individual.
5. Procedures carried out under independent contract for an external agency or organization to evaluate human performance where results will not be generalized outside of that specific organization.

Examples: some quality assurance evaluations, program effectiveness evaluations, efficiency studies, and ergonomics

6. Research involving deceased individuals.

For assistance in determining whether IRB review is required for your project, contact:

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