SJU Saint Joseph's University

IRB Standard Operating Policy and Procedures Number:	4
Title:	Initial and Continuing Review: Requirements for Submission, Approval for Expedited and Full Board Review, and Post-Approval Procedures
Effective Date:	January 1, 2023
Responsible Office:	Office of Research Services/IRB

Purpose

Research activities that meet Saint Joseph's University (SJU)'s definition of human subjects research (SOPP 1), but do not meet criteria for exemption must be reviewed and approved by the IRB. Once approved by the IRB, research protocols are subject to continuing review. This policy describes the criteria under which approval may be granted, and the procedures for applying for IRB approval and continuing review of previously approved research.

Scope and Applicability

SJU's Institutional Review Board (IRB) Standard Operating Policies & Procedures (SOPPs) apply to all research activities involving human subjects conducted by SJU faculty, staff, or students or by anyone conducting research in which the participation of SJU meets the definition of "engagement" as indicated by the Office of Human Research Protections (OHRP)*. These policies rely on and reference the Department of Health and Human Services (DHHS) Regulations pertaining to the Protection of Human Subjects in Research (hereinafter referred to as 45 CFR § 46). The guidance document on "engagement" may be found here.

Definitions

Principal Investigators (PIs)

The PI is ultimately responsible for assuring compliance with applicable federal regulations as well as University IRB policies and procedures. The PI is also responsible for the oversight of the research study and the informed consent process. The PI may delegate tasks to other IRB-approved research personnel, but the PI must uphold the ultimate responsibility for the conduct of the study. Due to the nature of a PI's role (i.e., direct interaction with research participants), this individual must be a faculty member, staff, or student of the University.

- *Faculty PIs*
  All SJU faculty, including full- and part-time faculty, may serve as the PI on an SJU IRB-approved research study.
- *Staff/Administrator PIs*
  If appropriately qualified, SJU staff and administrators may serve as the PI on an IRB-approved research study.
- *Student PIs*

Undergraduate, graduate and doctoral students may serve as the PI under an SJU IRB-approved research study. Each student PI must have their research study overseen by an SJU faculty research advisor.

Co-Principal Investigators (Co-PIs) & Additional Research Personnel

Appropriately qualified individuals may serve as a co-PI or as additional research personnel on an SJU IRB-approved research study. Such individuals may perform tasks delegated by the PI, but they are not ultimately responsible for all facets of the research study.

Faculty Research Advisors

Each student investigator must have their research overseen by an SJU faculty member. Such advisors must have adequate knowledge of the research area with which the student is affiliated.

Policy Statement

Researchers are responsible for ensuring full and continuing compliance with all University and IRB policies in conducting research involving human subjects. They are expected to consult with the Research Compliance Coordinator in the Office of Research Services (ORS) to determine if their research activities constitute research involving human subjects.

Regardless of whether or not the research activity meets the definition of HSR, thus requiring IRB oversight, it is expected that all research activities involving human subjects (whether the knowledge is generalizable or not) be designed and conducted in accordance with the ethical standards set forth by federal, state, and University policy.

Secondary Data Analysis involving data obtained by the researcher without access to direct or indirect identifiers (i.e. responses are coded and a key exists that may allow researchers to connect an individual to their responses) does not meet the criteria for HSR. In the event that subjects may be directly or indirectly identified, secondary data analysis may meet the criteria for HSR (see section 4.3. below for details).

Research conducted as a pedagogical exercise within the context of a particular course, or for internal assessment purposes does not constitute Human Subjects Research. However, if the data collected will be reported as part of a Thesis or Dissertation, or if the results will be shared outside of SJU, the activity is deemed “generalizable” and meets the criteria for HSR.

Researchers who intend to conduct HSR are expected to submit an HSR Protocol Application for review by the Research Compliance Coordinator and determination of Exemption. If the protocol does not meet the exemption criteria, the application will be referred to the IRB for Expedited or Full Board review.

Research activities may not commence until the researcher receives written notice of exemption determination or a letter of IRB approval.

Procedures

Research Activities Not Involving Human Subjects Research:

If the Principal Investigator determines that the activity does not meet the definition of HSR, the investigator may initiate the project without submitting a protocol for review, and is not required to complete the CITI Human Subject training.

In the event of changes to a research protocol, the investigator is expected to consult with the Research Compliance Coordinator to determine whether the proposed change affects the classification of the project as "not HSR".

Research Activities Involving Human Subjects Research:

If the activity does meet the definition of HSR, the investigator must complete and submit an HSR Protocol Application and the supporting documentation required for review, through IRBNet. Investigators should refer to the submission guides, Submission Checklist, and IRB SOPPs 2 and 4 for submission requirements.

Secondary Data Analysis:

Certain types of secondary data analysis do not meet the criteria for HSR. However, data that may be identifiable is classified as "restricted use" or "licensed data" and may require IRB oversight. "Restricted or restricted access data" must be used with appropriate confidentiality protections as specified in a formal written data use agreement between the University and the data provider. "Licensed or limited use data" are used within an agreement that protects the provider's intellectual property (e.g., copyright), and may or may not include adequate steps to assure the confidentiality of participants.

An investigator planning to obtain data under contractual terms, such as a restricted access data agreement or a licensed data agreement, must contact the Office of Research Services (ORS). ORS will negotiate the terms of that agreement with the data provider on behalf of the University. Investigators are not authorized to sign data use agreements themselves. Investigators must include with their IRB application 1) a copy of the fully executed data use agreement and 2) an approved data security plan. When the sponsor or provider of the data requires IRB approval before the data agreement can be finalized, the IRB office can issue a conditional approval for the project.

If secondary data analysis falls under HSR, researchers must complete the Secondary Data Form, which is in lieu of the general HSR application. This form may be found under "Forms & Templates" on IRBNet. If the PI is unsure whether his/her research activity is classified as HSR, he/she should contact the Research Compliance Coordinator.

Secondary data analysis that does not require IRB oversight:

1. Data about individuals who are no longer living (i.e., historical records of deceased individuals or death records)

2. Identifiable or deidentified publicly available data, such as public records (phone numbers, property values, etc.), or data found on unrestricted sites, in phone books, or publications

Secondary data analysis that may require IRB oversight:

1. Analysis of private, identifiable data, or restricted access or licensed data requires IRB oversight if information is about a living individual, but may qualify for exemption if no identifiers are recorded, retained, or used by the researcher;
2. Analysis of private, identifiable data (where the researcher records, retains, or makes use of identifiers) must be overseen by the IRB if the information is about living individuals

Regulation and Guidance

Federal Regulations

SJU has a Federal-wide Assurance (FWA) with the Office for Human Research Protections (OHRP) of the U.S. Department of Health & Human Services guaranteeing its application of the federal policy for the protection of human subjects in 45 CFR § 46 when engaging in HSR funded by the Public Health Service (PHS). By institutional policy, the same standards apply to all HSR, regardless of funding support. SJU's appointment of an appropriately constituted IRB is included in the FWA.

Requirement for IRB review and approval of HSR before its initiation: 45 CFR §46.108.

Ethical Codes

- The Nuremberg Code (1948)
- The Belmont Report (1974)
- Declaration of Helsinki (last revised in 2000)

Referenced IRB SOPPs

- SOPP 2: Submission Requirements and Procedures for Research that is Exempt from IRB Review
- SOPP 4: Initial and Continuing Review by the IRB