SJU Saint Joseph's University

IRB Standard Operating Policy and Procedures Number:	1
Title:	Determination of Need for IRB Review and Approval
Effective Date:	January 1, 2023
Responsible Office:	Office of Research Services/IRB

Purpose

All research activities involving human subjects that are conducted under the auspices of Saint Joseph's University (SJU) must be evaluated to determine whether they constitute Human Subject Research (HSR) and require IRB review and approval. This policy provides guidelines for making these determinations and outlines the appropriate review requirements.

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

Research:

It is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The following activities are deemed not to be HSR:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order.
- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

Human Subject:

Is defined in 45 CFR § 46.102(e)(1) as a living individual about whom an investigator (whether professional or student) conducting research either obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the

information or biospecimens; OR Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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 de-identified publicly available data, such as public records (phone numbers, property values, etc.), or data found on unrestricted sites, in phone books, or in 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