SJU Saint Joseph's University

IRB Standard Operating Policy and Procedures Number:	2
Title:	Submission Requirements and Procedures for Research Exempt from IRB Review
Effective Date:	January 1, 2023
Responsible Office:	Office of Research Services/IRB

Purpose

Research activities that meet Saint Joseph's University's definition of human subject research (SOPP 1), but do not require review and oversight by the Institutional Review Board (IRB) are known as "exempt" because they do not require IRB approval. The IRB Administrator in the Office of Research Services (ORS) will review and determine if the research project meets the eligibility requirements for exemption from IRB review. This policy describes the criteria under which an exemption may be granted and the procedures for applying for an exemption.

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.

Policy Statement

A Principal Investigator (PI) may not self-determine that their research protocol qualifies for exemption from Institutional Review Board (IRB) review. A PI requesting an exemption must submit an application through IRBNet. If the research activities are not eligible for exemption, the research protocol will receive either expedited or full committee review by the IRB (See SOPP 4).

Students may submit a Human Subjects Research Protocol Application as PI. All student PIs must work with a Faculty Advisor who will sign the submission. The Faculty Advisor, in signing, certifies: having reviewed the research plan/protocol documentation; continuing supervision of the conduct of the research to ensure compliance with applicable federal, state and institutional regulations/policies; and acknowledgement of ultimate responsibility for the conduct of the research following all written study procedures.

Requirements

In order for the IRB Administrator to begin considering exemption, the following must be present: appropriate electronic signatures, as indicated in the protocol application (i.e., PI, Faculty Advisor, Department Head, Dean, and/or VP) are required on the submission, and current CITI training certificates for all personnel and advisors named in the protocol.

Research activities may not commence until the PI receives written notice of exemption or approval. The IRB administrator must review changes to any exempt research activities or materials to verify that the project continues to be eligible for exemption from IRB review.

Investigators whose research has been determined to meet exemption criteria are responsible for reporting any unanticipated event or problems. Researchers are responsible for ensuring full and continuing compliance with all applicable Federal, State, University, and IRB regulations/policies in the conduct of their research.

Procedures

Submission

After determining that their research constitutes research with human subjects (see SOPP 1), a PI should submit a Human Subjects Research protocol application through IRBNet, along with all applicable study-related materials (e.g., training reports, **recruitment materials, consent forms, surveys, questionnaires, interview** scripts/outlines, etc.). Guidance on submission may be found in the Investigator Submission Guide on the IRB website.

IRB Review

The initial review process for exemptions typically takes up to 10 business days and will use the criteria outlined below.

Research Determined to be Eligible for Exemption

If the IRB Administrator determines that the research project is human subject research AND eligible for exemption, the IRB Administrator will issue a formal notice of exemption determination to the PI. A copy of the exemption notice and all submission documents will be archived in IRBNet indefinitely. The PI will have access to all documentation via personal login to IRBNet.

Protocols that meet the criteria for exemption do not require continuing IRB oversight (i.e., annual renewal of exemption is not necessary).

For each proposed change that may need to be made while conducting the research, the PI is expected to submit an Amendment for review by the IRB Administrator to determine whether the change affects the research project's continuing eligibility for exemption. The PI must receive a written notice acknowledging the Amendment before implementing the proposed change in the research activities.

Research Ineligible for Exemption

Research activities that are not eligible for exemption will be forwarded to the IRB for Expedited or Convened (Full Board) Review (See SOPP 3).

Criteria for Exemption

Research activities that do not qualify for exemption

Research involving Prisoners, research involving active collection of biological specimens or conducting biomedical/psychophysiological procedures.

Research activities that may be granted exemption:

Research conducted in established or commonly accepted educational settings, that specifically involve normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met**:** (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts an expedited IRB review to make the determination required by §46.111(a)(7).

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts an expedited IRB review to make the determination required by §46.111(a)(7). (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by

the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

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 agricultural chemical or environmental contaminant 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.

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts an expedited IRB review and makes the determinations required by §46.111(a)(8).

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; (iii) An IRB conducts an expedited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Regulation and Guidance

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 human subject research funded by the Public Health Service (PHS). By institutional policy, the same standards apply to all human subject research, regardless of funding support. OHRP has developed Decision Charts for guidance on eligibility for exemption. Eligibility of certain research protocols to be exempt.

Ethical Codes

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