

Standard Operating Policy and Procedure (SOPP) 8
RESEARCH INVOLVING SAINT JOSEPH'S UNIVERSITY STUDENTS

1. Introduction

- 1.1. This document sets forth requirements for obtaining IRB approval for research involving Saint Joseph's University (SJU) students. There are no federal regulations that specifically address the inclusion of students in research protocols. However, students are vulnerable to being unduly influenced by the expectation that participation or non-participation in a protocol may place them in good favor (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (i.e., by seeming "uncooperative," not part of the scientific community). They may also be vulnerable to undue influence to participate from being approached multiple times for participation in research because their presence on campus makes convenient their recruitment. Confidentiality and security of data also may be of special concern to potential student subjects, especially in light of the closeness of the university community.
- 1.2. The IRB, therefore, will pay special attention to ensuring that the research protocol and associated recruitment methods and informed consent avoid coercion or the appearance of coercion when including SJU students in research.
- 1.3. While special attention by the IRB is warranted, students have the same rights as any other potential subjects to participate in research, regardless of the degree of risk.

2. Policy Statements

- 2.1. Protocols involving SJU student subjects submitted to the SJU IRB will be reviewed in accordance with SJU IRB [SOPP 2: Submission Requirements and Procedures](#) and [SOPP 3: Initial and Continuing Review](#). The conduct of research involving SJU students is subject to all SJU IRB policies set forth in regard to research involving human subjects.
- 2.2. When Saint Joseph's University students are being recruited as potential subjects, researchers must ensure that there are appropriate safeguards in place for these vulnerable subjects. The voluntary nature of participation must be primary and without undue influence (coercion). Researchers must emphasize to subjects that neither their academic status nor grades will be affected by their participation decision.
- 2.3. When a faculty researcher wishes to conduct research with current

students, measures must be taken to allow for consent without real or perceived coercion. The PI must design the consent process and conduct of research in such a way that the faculty PI is unaware of students' participation decision until after final grades have been issued.

- 2.4. The IRB may require that the PI implements specific precautions to ensure the confidentiality of participation and security of data files for SJU student subjects.

3. Considerations in Research Involving SJU Students

3.1. Protecting Against Coercion

- 3.1.1. A PI may offer extra credit as an incentive to students to participate in a research project. The amount of such credit, however, should not be so significant as to be coercive. Investigators are discouraged from directly recruiting individuals they supervise or selecting subjects on such basis.
- 3.1.2. To avoid the appearance of coercion, the IRB may elect to require that the PI utilize one or more of the following measures:
 - 3.1.2.1. To offer the same amount of extra credit for non-participating students who complete an assignment requiring equivalent time and effort such as a short paper or presentation or attendance at a research colloquium.
 - 3.1.2.2. To advertise for subjects generally (e.g., through notices posted in the school or department) rather than to recruit individual students directly or individually.
 - 3.1.2.3. To allow students to withdraw from participation at any time without losing the extra credit.
 - 3.1.2.4. To give students several studies to choose from, rather than requiring them to volunteer for a particular study, especially where participation is a course requirement.
 - 3.1.2.5. To provide justification for including student volunteers from courses for which they are the instructor.
- 3.1.3. In light of the limited financial resources of most students, PIs should be cautious about offering excessive monetary compensation to students. The IRB may deem that other incentives, such as limited free food, are more appropriate.

3.2. Informed Consent

- 3.2.1. The IRB will give special consideration as to who is responsible for obtaining consent from students, in order to avoid the appearance of coercion by a faculty member of a student.
- 3.2.2. Depending on the risk level of the project, the IRB may consider whether a member of the IRB, ORS, or some other third party

affiliated or unaffiliated with SJU should observe/monitor the consent process.

3.3. Confidentiality of Data

- 3.3.1. As with research involving human subjects generally, research involving the collection of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to subjects of which they should be made aware and from which they should be protected, to the greatest extent possible.
- 3.3.2. Because SJU is a relatively small community, the IRB may also require that the data collection process be designed to be equally sensitive to individuals' privacy. For instance, a study on sensitive topics as described above should not involve subjects waiting in a public space where fellow students may readily deduce their participation in the study.