Standard Operating Policy and Procedure (SOPP) 11

RECRUITMENT AND PAYMENT OF HUMAN SUBJECTS

Introduction

The recruitment of human subjects for a research study is the initial stage of the participant selection and informed consent process. *Before* the Protocol PI may begin to recruit human subjects for a specific study, both the recruitment methods and materials are subject to IRB review and approval.

In evaluating the recruitment methods and materials, the IRB will consider (1) the degree of risk and likelihood of benefit to the subjects and (2) the protections for subjects from coercion or undue influence. The IRB will pay close attention where investigators seek to recruit and enroll themselves, students, employees, or members of vulnerable populations such as children, pregnant women, institutionalized persons, and educationally or economically disadvantaged persons.

One recruitment method is advertising. The IRB defines advertising as "any outreach effort intended to be seen and heard by potential human research subjects and designed to encourage them to contact the investigator for further information about a specific study."

The following informational communications are <u>not</u> recruitment methods or advertisements subject to IRB review and approval: (1) news stories or interviews that do not provide any recruitment information; and (2) publicity intended for non-participant audiences, such as financial page advertisements directed at investors.

IRB review and approval is also <u>not</u> required for general non-study-specific advertising because such materials do not relate to a specific study requiring IRB approval. Such materials would include communications designed to raise awareness and knowledge of human participation in research and providing links to specific subject opportunities. Examples include: (1) general information about being a human research subject, (2) non-study-specific recruitment of a subject pool, and (3) announcements that promote research generally to a community, even if designed to encourage future interest in serving as a research subject. However, if any of these advertisements includes information about specific research protocols, they must be reviewed and approved by the IRB before they can be utilized.

1. Policy Statements

1.1. This policy applies to all ongoing and future human subject research projects conducted by SJU faculty, staff, or students or by anyone conducting a research activity supported by SJU.

2. Permissible Methods for Identifying/Recruiting Subjects

2.1. Advertisements: A Protocol PI may advertise for research subjects. Advertisements include, but are not limited to, class announcements and sign-ups, newspaper ads, radio ads, social media ads, bulletin boards, posters, flyers, and emails that are intended to be seen and heard by potential human research subjects and designed to encourage them to contact the investigator for further information about a specific study. The Protocol PI must submit exact copies of all advertisements, before using them, to the IRB for review and approval, as part of the protocol application or, if applicable, as a protocol amendment.

2.2. Referring to Research Projects: A Protocol PI may provide faculty or other professionals with general information about a research project and contact information for potential subjects to learn more about the project and whether they might be eligible to participate. The IRB must review and approve all materials to be sent by the Protocol PI to the referring faculty member, or other professionals before the materials are sent.

2.3. Privileged Records: The IRB must review and approve any method of obtaining private information before the Protocol PI uses it, including identifying subjects from privileged records such as student, personnel or medical records.

3. Roles and Responsibilities

3.1. The Principal Investigator may not begin any recruitment measures before he or she receives IRB approval of the recruitment methods and materials. The PI shall submit such information with the application or via a protocol amendment. Such materials include the final copy of the advertisements and video and audio recordings. The PI may submit the wording of an advertisement prior to taping to avoid re-taping necessitated by the IRB changes.If a Protocol PI modifies a recruitment method or the text or appearance of an advertisement, he or she must submit an amendment request to the IRB for review and approval before use.

Note: Minor Modifications, such as updating contact information or changes in basic formatting, may simply receive administrative approval, while more substantive changes may require IRB review and approval.

3.2. Regarding the placement of the recruitment materials, the PI must inform the IRB of the type of medium/media (e.g., newspaper) and the target audience (whether the general public or a specific ethnic, gender, or cultural group).

3.3. When recruiting potential research subjects, the PI must consider the risks and ethical aspects of the method of contact, as well as the research study itself. The PI should choose the least intrusive and coercive method of recruitment that is consistent with successful research and should explain in the protocol application to the IRB why such a method is appropriate.

The Principal Investigator should state how he or she will guard against coercion, intrusiveness, and violations of privacy, especially where the potential participant is a member of a vulnerable population (e.g., child, pregnant woman, institutionalized

persons). Where the recruitment method involves privileged records or sensitive information, the PI must also be prepared to explain how breaches in confidentiality will be avoided.

The IRB will then decide if the merits of the research, the potential benefits to subjects, the risks of the study, and risks of the recruitment method(s) are in such balance as to allow approval of the recruitment method(s).

3.4. Investigators and other study personnel, including students and referring professionals, may not provide or accept bonus payments from sponsors or from one another as incentives for participant recruitment.

3.5. Payment to Subjects: The IRB must determine that payment to subjects is appropriate under the circumstances of the study. If so, the PI must provide all information regarding payment, including the amount and schedule of the payments, in the informed consent documents. The PI may not make payment contingent on the subject's completing the entire study. Instead, partial payment to subjects must be provided if the subject withdraws from the study.

Bonuses paid for complete participation should be reasonable and not so large as to unduly influence subjects to remain in the study when they might otherwise choose to withdraw.

4. Content of Advertisements, including Payment Information

4.1. The following are standard requirements for the content of advertisements:

- Principal Investigator's name and contact information
- Words that effectively communicate the purpose of the research and summarize the subject selection criteria (e.g., condition, age limits, gender)
- Clear indication that the study is for research or investigation, not treatment
- Payment Information: If the subjects will be paid, advertisements may so state, but they may not unduly emphasize payment or the amount of payment. Advertisements may state that subjects will be compensated for their time and travel.

4.2. The IRB may elect to require any of the following elements for advertisements, depending on the risk level and other characteristics of the research study:

- Location of the research study
- Duration of the study
- Time and other commitment required of subjects
- Contact information of the person designated to provide further information about the study
- Brief, clear description of the benefits of participation (no promises or implications of safety or efficacy) in keeping with what is stated in the informed consent documents.

5. Direct Contact with Potential Research Subjects

5.1. Any direct contact with potential research subjects, a Principal Investigator must minimize the risk of intrusiveness and coercion.

5.2. When potential subjects are identified from sensitive information or privilege records, the initial contact with them must be made by someone with legitimate access to the information

6. Subject Compensation

6.1. Saint Joseph's University balances a responsibility to maintain various levels of confidentiality for information about human subjects research with record keeping requirements of SJU, the grantor agencies, and the Internal Revenue Service.

6.2. Payments to subjects from a university budget will be recorded as a form of compensation.

6.3. Payment may be a type of remuneration including, but not limited to: check, cash, gift cards, personal property and other items of value.

6.4. Saint Joseph's University has adopted procedures to assure that these transactions will be reported in accordance with state and federal income reporting requirements with the appropriate level of confidentiality.

6.5 Subjects will be asked to provide the basic information including name, mailing address and social security number. The subjects should be informed that the information allows the University to meet government reporting obligations and precautions are in place to keep this information secure. Subjects may be given the opportunity to waive receipt of payment should they wish not to provide identifying information. The Institutional Review Board requires this notification in the language of the consent form.

6.6.If the research study requires anonymity of the human subjects, the PI may request permission to offer cash or gift cards as payment without collecting identifiable information. When completing the Request for Funds, the IRB approval letter indicating subject anonymity is needed and must be attached to the request.

7. Criteria for IRB Review of Recruitment Methods and Advertisements

7.1. The IRB shall review recruitment materials to ensure that they are not unduly coercive or misleading. For instance, advertisements may not overstate the potential benefits of the study beyond what is outlined (and approved) in the consent materials and

protocol. Nor may advertisements imply that the research or investigator offers a unique or special skill, remedy, or treatment. Advertisements may not promise free treatment.

7.2. The IRB shall pay particular attention to the potential coercive effects of recruitment methods and materials directed to vulnerable populations.

7.3. The IRB shall ensure that advertisements do not include language exculpating the investigators, sponsors, SJU, or others, in the event of an adverse event or unanticipated problem.

7.4. The IRB shall ensure that payment information is accurate and not unduly emphasized. Moreover, the IRB shall ensure that the amount of payment does not constitute a coercive reward or inducement to participate.

8. Regulations and Guidance Applicable to Recruitment and Payment of Human Subjects

8.1. 45 CFR 46.111(a)(3), 21 CFR 56.111(a)(3): Criteria for IRB Approval of Research requires that "[s]election of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons."