

Cornell University
Office of Research Integrity and Assurance
Human Research Participant Protection Program

SOP 9 : RECRUITMENT AND PAYMENT OF HUMAN PARTICIPANTS

1. Subject of Policy & Procedure

The recruitment of human participants for a research study is seen by the IRB as the initial stage of the participant selection and informed consent process. *Before* the Protocol PI may begin to recruit human participants 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 participants and (2) the protections for participants 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, 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 participants and designed to encourage them to contact the investigator for further information about a specific study."

The following informational communications are not 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 not 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 participant opportunities. Examples include: (1) general information about being a human research participant, (2) non-study-specific recruitment of a participant pool, and (3) announcements that promote research generally to a community, even if designed to encourage future interest in serving as a research participant. 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.

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by Cornell faculty, staff, or students or by anyone conducting a research activity supported by Cornell or on property maintained by Cornell.

3. Terms and Definitions

All parties to whom this policy applies (e.g., faculty, students, staff, IRB members) should consult the IRB Glossary at <http://www.irb.cornell.edu/glossary/>.

4. See Also

Affected researchers and employees should also consult:

1. Cornell University Federal Wide Assurance Registration:
<http://www.irb.cornell.edu/regulations/fwa.htm>
2. Cornell IRB SOP 9: Informed Consent Options, Processes, and Documentation:
<http://www.irb.cornell.edu/policy>

5. Regulations Applicable to Recruitment of Human Participants

- 5.1. 45 CFR 46.111(a)(3), 21 CFR 56.111(a)(3): Criteria for IRB Approval of Research, stating 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.”

6. Permissible Methods for Identifying/Recruiting Participants

- 6.1. Advertisements: A Protocol PI may advertise for research participants. Advertisements include, but are not limited to, class announcements and sign-ups, newspaper ads, radio ads, bulletin boards, posters, flyers, and emails that are intended to be seen and heard by potential human research participants 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.
- 6.2. Private Medical Information: The Protocol PI may identify participants from resources such as medical records, clinical databases, patient registries, and psychosocial screening databases. The IRB must review and approve any method of obtaining private health information before the Protocol PI uses it.
- 6.3. Referring to Research Projects: A Protocol PI may provide physicians, faculty members, or other professionals with general information about a research project and contact information for potential participants 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 physicians, faculty members, or other professionals before the materials are sent.

7. Roles and Responsibilities of the Protocol PI in the Recruitment Process

- 7.1. The Protocol PI may not begin any recruitment measures before he or she receives IRB approval of the recruitment methods and materials. The Protocol PI shall submit such information with the protocol application or via a protocol amendment. Such materials include the final copy of printed advertisements and video and audio recordings. The Protocol PI may submit the wording of an advertisement prior to taping to avoid re-taping necessitated by IRB changes.
- 7.2. If a Protocol PI modifies a recruitment method or the text or appearance (*e.g.*, change in font size) 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.

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

If the text of a website ad is identical to text used in flyers or newspaper ads, the Protocol PI needs to provide the IRB only one ad with a statement of how and where the ad will be displayed.

- 7.4. When recruiting potential research participants, the Protocol PI must consider the risks and ethical aspects of the method of contact, as well as of the research study itself. The Protocol 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 Protocol PI 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, prisoner). Where the recruitment method involves privileged records or sensitive information, the Protocol 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 participants, the risks of the study, and the risks of the recruitment method(s) are in such balance as to allow approval of the recruitment method(s).

- 7.5. 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.
- 7.6. Payment to Participants: The IRB must determine that payment to participants is appropriate under the circumstances of the study. If so, the Protocol PI must provide all information

regarding payment, including the amount and schedule of the payments, in the informed consent documents.

The Protocol PI may not make payment contingent on the participant's completing the entire study. Instead, payment to participants must accrue as the study progresses and must be prorated based on the number of study visits, or other comparable milestones, completed by the participant.

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

For multi-institutional studies, participants at collaborating institutions should be compensated on the same terms for participation, unless different terms have been approved by the Cornell IRB.

8. Content of Advertisements, including Payment Information

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

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

8.2. 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 or other commitment required of participants
- 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
- Statement that Cornell University is an equal opportunity employer

9. Direct Contact with Potential Research Participants

- 9.1. A Protocol PI may propose for IRB review and approval a contact technique that minimizes the risk of intrusiveness and coercion.
- 9.2. Where potential participants are identified from sensitive information or private records, the initial contact with them must be made by someone with legitimate access to the information (and, in the case of medical patients, to those patients).

10. Criteria for IRB Review of Recruitment Methods and Advertisements

- 10.1. 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, also, may not promise free treatment, when the intent is only to say that participants will not be charged for participation.
- 10.2. The IRB shall pay particular attention to the potential coercive effects of recruitment methods and materials directed at vulnerable populations.
- 10.3. The IRB shall ensure that advertisements do not include language exculpating the investigators, sponsors, Cornell, or others, in the event of an adverse event or unanticipated problem.
- 10.4. 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 for participation.