# Recruitment and Selection of Participants

**Table of Contents: Recruitment and Selection of Participants**



## Policy Statement

Recruitment and selection of study participants is the start of the informed consent process and must have prior IRB review and approval. It is the responsibility of the Principal Investigator to follow the guidelines outlined in this policy and to submit all advertising and recruitment materials for review and approval by the IRB, prior to use. It is the responsibility of the IRB to review these materials, ensuring that participant selection is equitable and that a coercive situation does not exist. When making an assessment about whether selection is equitable, the IRB will take into account the purposes of the research, the setting in which the research will be conducted, whether prospective participants will be vulnerable to coercion or undue influence, the selection (inclusion/exclusion) criteria, participant recruitment and enrollment procedures, and the influence of payments to participants.

## Description and Procedures

### A. Selection of Participants: Ethical Standards

The Belmont Report describes how the principles of respect for persons, beneficence, and justice are relevant to research involving human subjects. Justice in particular relates to the selection of research subjects. The selection process needs to be scrutinized in order to determine whether some classes (e.g., welfare recipients, racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Whenever research leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

The selection of subjects must be fair. Potentially beneficial research should not be offered only to some subjects who are pleasant to work with; likewise, higher risk or research with no potential benefit to the subjects, should not be targeted only at "undesirable" populations. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential

subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only under exceptional conditions.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

## B. Screening Studies to Identify Eligible Subjects

Minor procedures involving little or no risk, may be performed for the purpose of identifying a population of research subjects. If a procedure obtaining information or biospecimens is to be performed solely for the purpose of screening, recruiting, or determining eligibility of prospective subjects, informed consent is not required if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative.
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

If neither of the above conditions are met, it is appropriate for the screening to be presented in a separate consent document describing the screening procedure and stating that its purpose is to determine eligibility for participation in further studies. A separate consent document for the actual study would then be signed by individuals found to be eligible. In such situations, at the time the subject is enrolled for the screening procedures, the prospective subjects should be shown the document they will be asked to sign if they meet the criteria for further study.

## C. Solicitation of Subjects Through Advertisements

The use of advertisements (e.g., notices on bulletin boards, paid and unpaid newspaper solicitations, solicitation by electronic mail, websites, letters to private practitioners, signs, or pamphlets, etc.) soliciting volunteers for research must have prior IRB approval. Such advertisements are an extension of the informed consent and subject selection process.

The IRB reviews advertisements to determine that (1) they are neither misleading nor coercive to potential subjects; and (2) no claims are made, either explicitly or implicitly, that a proposed intervention is effective or equivalent or superior to any other intervention.

Advertisements should contain the following:

1. the name and address of the investigator;
2. the purpose of the research;
3. in summary form, the eligibility criteria;
4. a straightforward, truthful description of the benefits, if any; and
5. the location of the research and the person to contact for additional information.

Submission and Approval Procedures

1. Identify method(s) of advertisement for research subjects in the protocol.
2. Submit bulletin board notices for IRB approval prior to posting. The IRB will return the advertisement with a dated IRB approval stamp. Subsequent changes in the content of an advertisement must be approved by the IRB.
3. If you plan to advertise in a newspaper, a WEB site, or other media advertisements, submit the text or a printed copy of the WEB information or other item for IRB approval. Solicitation of subjects within the context of a published or broadcast "news" release is not appropriate.
4. Submit other forms of advertisement (e.g., electronic mail, letters to private practitioners, letters to potential subjects, etc.) for IRB approval.

### D. Finder's Fees

A proposed recruitment method which involves offering cash and/or tangible non-cash incentives to others (i.e., finder's fees) is not permitted by institutional policy and cannot be approved by the IRB.

## Effective Date

August 24, 2020

## Revision History