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# Recruitment of Research Subjects

## Purpose of this document

This guidance document provides information about different methods of recruitment and issues related to the protection of subjects in research.

Recruitment of subjects is a challenging aspect of research involving human subjects. Recruitment of subjects must be equitable and include racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition that is studied. All recruitment efforts must respect personal rights to privacy and confidentiality, be compliant with Health Insurance Portability & Accountability Act (HIPAA) regulations, when applicable, and avoid coercion of subjects.

The IRB requires that special protections are put in place when investigators recruit vulnerable subjects, such as children, prisoners, cognitively impaired individuals, or economically and educationally disadvantaged persons.

Selecting appropriate recruitment methods depends upon how the potential subject was initially identified. Potential subjects can be identified in several ways. This document outlines areas to consider when developing recruitment methods. All recruitment methods and materials must be submitted for IRB review and approval.

## Identifying Potential Subjects

There are several ways an individual may be approached to determine their interest in participating in a research study, including through direct contact, general advertisements, media sources and social media, records, or referrals.

### Indirect contact

Investigators are encouraged to advertise their study to subjects via flyers, recruitment letters, or information sheets. Recruitment materials used for indirect contacts should describe the study in sufficient detail and provide contact information of investigators. Potential subjects should be invited to contact the investigator if they are interested to participate in the study.

### Direct contact with new research subjects

Direct solicitation of subjects is permitted in some situations, but precautions must be taken to ensure subject privacy and confidentiality, and to avoid coercion.

Studies involving subjects who are directly supervised by the investigator(s) or who are the investigator's students should be avoided and will usually be disapproved by the IRB. In this setting, there are confidentiality problems and issues of coercion or obligation (either real or perceived) which are best avoided entirely. It is acceptable to advertise for volunteers in approved areas in the investigator's department or within the hospital (following hospital guidelines) and allow individuals in the department who are not directly supervised by the investigator(s) to participate in research studies.

### Direct contact with prior research subjects

Investigators who have previously obtained full consent and authorization to contact a research subject as a result of a previously approved research project, may contact his or her former research subjects provided that the subject agreed to be contacted for information on future research conducted by the same principal investigator or co-investigator(s).

## Use of records and referrals

Academic records, medical records, patient registries, clinical databases, and referrals can be useful resources to identify potential subjects. When using this method of recruitment it is essential to take precautions in ensuring subject privacy. Privacy is an important aspect of human subject protection and is one of the required regulatory findings made by IRB. Detailing the method of recruitment will be an important factor that will impact IRB review.

Any form of contact, including telephone contact, advertising, use of records or referrals, or direct mailings must be approved by the IRB.

## Recruitment Materials

### Recruitment Letters

Recruitment letters should explain the purpose of the research, and provide a brief description of the nature and extent of involvement, e.g., duration of participation and study procedures, and contact information of investigators. Potential subjects must be allowed to "opt in", depending upon the nature of the research. When the research involves sensitive or personal information, such as illegal behavior, drug or alcohol use, mental illness, sexual behavior or other sensitive issues, the IRB may require more stringent "opt in" procedure be followed when recruiting subjects.

### Advertising

The message content of all direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects, must be reviewed and approved by the IRB prior to distribution, posting, publication, or broadcasting. Direct advertising includes, but is not limited to newspaper, radio, TV, bulletin boards and the internet. Similar to recruitment letters, direct advertisements should explain the purpose of the research, and provide a brief description of the nature and extent of involvement, e.g., duration of participation and study procedures, and contact information of investigators.

### Recruitment using social media

IRB review and approval prior to implementation of social media or online advertising is required. The recruitment section of the study protocol should describe specific platforms intended for use. Investigators must identify and follow procedures of any social media platform or online advertising venue. Privacy policies, prohibited content, and limitations on location and frequency of postings are sometimes found in the user instructions or Frequently Asked Questions (FAQ) instead of the TOU (e.g., Craigslist FAQ).

## IRB Review of Recruitment Methods and Materials

IRB review will evaluate all documents and methods of recruitment to ensure recruitment methods will not be coercive, will not unduly influence potential subject and will protect the privacy of potential subjects. To address these requirements a protocol must include a recruitment section that describes:

- How potential subjects will be identified,
- How and by whom subjects will be approached about participation,
- What will be said to subjects (use of advertisements, verbal scripts etc.)
- Whether third parties will assist with recruitment of subjects.
- Any documents that will be used (letters, telephone scripts, in person introduction scripts, advertisements, emails, etc.)

## Alternative Recruitment Approaches

The guidelines listed above may not be applicable to every situation that arises in the research process. Carefully justified alternative approaches will be considered on a case-by-case basis. The IRB Office staff will offer guidance to investigators upon request.