

PARTNERS HUMAN RESEARCH COMMITTEE POLICIES AND PROCEDURES

Recruitment Of Research Subjects

Under Federal regulations, the Human Research Committee must review and approve methods used to recruit subjects to ensure that the methods are not coercive and that the confidentiality and privacy of potential subjects are protected. Every protocol must include a recruitment section that clearly describes:

- How potential subjects are identified
- How and by whom subjects are approached about participation
- When consent is obtained in relation to the start of the study procedures
- Whether third parties (calling centers/centralized screening centers) will assist with recruitment of subjects for Partners' sites

Selecting appropriate recruitment methods depends upon how the potential subject was initially identified. Potential subjects can be identified:

- I. through private medical information about individuals who are NOT patients of the investigator(s) (e.g., medical records, clinical databases, patient registries or by referring physicians),
- II. from among the patients of the investigator(s),
- III. by advertisements in various media, and
- IV. from among the employees/students of the investigator(s).

Please refer to the applicable section [I., II., III., or IV. below] for a description of the appropriate procedures for each recruitment method.

I. RECRUITMENT OF SUBJECTS IDENTIFIED THROUGH PRIVATE MEDICAL INFORMATION

Recruitment efforts frequently target individuals known to have a specific medical condition. Medical records, patient registries, clinical databases and referrals from treating physicians can be useful resources to identify potential subjects; however it is essential to take special precautions to ensure that patient privacy is protected and that the individual patient is appropriate to participate in the research. It is not appropriate for investigators to make the first contact with potential subjects identified through their private health information. Rather, active participation by the patient's primary/specialist health care provider in the recruitment process ensures that consideration is given to the appropriateness of an individual patient's participation in the research prior to recruitment and that the patient's privacy is respected.

- The primary/specialist health care provider, usually a physician, who is known to the potential subject and has first hand knowledge of the patient's medical history must (1) give approval for his/her patient to be contacted for research purposes, (2) initially introduce the study to the patient AND (3) obtain the patient's permission to be contacted by study staff.

- The primary/specialist health care provider can introduce the study and obtain the patient's permission to be contacted by study staff either (1) verbally during the course of providing medical care OR (2) through the use of a recruitment letter (refer to guidelines for use of recruitment letters below).

Guidelines For Use of Recruitment Letters

Although recruitment letters are frequently prepared by the study staff, they must be signed by the patient's physician, or the patient's physician and the investigator, but not the investigator alone. In some cases, it may be appropriate for a physician representative on behalf of an entire practice/clinic staff to sign the letter rather than the potential subject's primary/specialist physician. It is never appropriate for recruitment letters to come from study staff, such as research assistants or data managers.

In the letter, the primary/specialist physician should indicate that one of his/her medical colleagues is conducting a research study. The letter 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.

Potential subjects must be allowed to "opt out" or "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 HRC may require that the more stringent "opt in" procedure be followed.

OPT OUT Procedure: The recruitment letter should include a telephone number to call or a postcard to return if the subject is not interested in participating in the study. If no telephone call is received or postcard returned, the subject may then be contacted by the investigator to determine whether or not the subject is interested in learning more about and/or participating in the study.

OPT IN Procedure: The recruitment letter should include a telephone number to call or a postcard to return if the subject is interested in learning more about and/or participating in the study. The investigator may not contact subjects who have not called or returned a postcard indicating interest in learning more about the study.

In either case, care should be taken to ensure that letters are properly addressed to avoid delivery to an incorrect party, and return postcards must not contain information regarding the patient's medical condition, medication or diagnosis.

Recruitment letters must be submitted for review and approval by the HRC.

II. RECRUITMENT OF SUBJECTS FROM AMONG THE INVESTIGATOR'S OWN PATIENTS

When recruiting potential subjects from among their own patients, investigators must consider the possibility that their patients may feel obligated to participate because they are being asked by their treating physician. For the investigator, maintaining a dual role as investigator and treating physician may create subtle conflicts and ethical tension,

while for the patient/subject it may create some uncertainty. Investigators should reinforce with their patients that participation is voluntary, that they do not have to participate, and the decision not to participate will not affect their care, now or in the future. Further, the Committee asks researchers to describe any plans that are in place to minimize the possibility that patients will feel obligated to participate, e.g., initially contacting patients about the research in writing and allowing patients to make further inquiries if they are interested, etc.

III. RECRUITMENT OF POTENTIAL SUBJECTS THROUGH ADVERTISING

The text 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 HRC prior to distribution, posting, publication, or broadcasting. Direct advertising includes, but is not limited to newspaper, radio, TV, bulletin boards and the internet. Please refer to the Partners Guidelines for Advertisements.

Unlike potential subjects identified through private medical information, those responding to advertisements have initiated the first contact and therefore, have implicitly given their permission to be contacted by study staff.

IV. RECRUITMENT OF EMPLOYEES/STUDENTS IN INVESTIGATOR'S DEPARTMENT

Studies of volunteers 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 Human Research Committee. 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.

V. 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 Human Research Office staff will offer guidance to investigators upon request.

VI. OTHER RECRUITMENT CONSIDERATIONS

Recruitment of Harvard Medical School Students

For the mutual protection of the student, investigator, and the Medical School, any protocol in which Harvard Medical School students are recruited must be submitted to the Dean's Office for review and approval before activation.

Incentives and Rewards for Recruitment of Patients and Referral to Clinical Investigators

Timely enrollment of patients into approved trials is desirable, but care must be taken to ensure that the interests of patients are not jeopardized during the recruitment process. Cash payments or other financial or non-monetary incentives to physicians for referral of patients, otherwise known as "finder's fees", pose a conflict of interest and are not permissible. Financial incentives to physician-investigators to accelerate enrollment of their own patients in their own clinical trials pose a similar conflict of interest and are not acceptable. The HRC requires full disclosure of any financial arrangements that may encourage physicians to recruit patients for research participation that may not be in the patient's best interests. In some special circumstances, physicians who are not formally listed on the protocol may be performing specific research-related activities (such as conducting screening examinations or tests, or participating in the consent process), but solely in the role of service providers. These physicians may be reasonably compensated for their time and effort. Such arrangements should be clearly detailed and justified in the research protocol.