Mass General Brigham

Title:	Recruitment of Research Subjects
Department:	Human Research Affairs
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
Approved by:	Chief Academic Officer
Original Approval Date:	August 1, 2008
Original Effective Date:	August 1, 2008
Revision Approval Date(s):	N/A
Current Revision Effective Date:	October 1, 2021
Next Review Date:	October 1, 2022
Contact Person:	Director, Human Research Office

Under Federal regulations, the IRB 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 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 PRIVATEMEDICAL

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.

Guidelines For Use of Recruitment Letters and Research Notifications

Recruitment letters may be used by study staff to recruit patients or non-patients to research. The IRB provides templates that may be customized with study-specific information. Letters or research notifications, called Research Invitations, may be sent to patients through the EPIC Patient Navigator system. Study staff must ensure that patients have not opted out of receiving Research Invitations. Letters may also be mailed hard copy (e.g. through US Mail) to patients and/or non-patients.

Patients may opt out of receiving Research Invitations directly in Patient Gateway, through the Rally recruitment website, or by contacting the Mass General Brigham Research Navigator Office. Patients who opt out of receiving Research Invitations may not be contacted by mail or through Patient Gateway to be recruited for research studies and their clinical provider cannot override this decision. Researchers may continue to recruit in-person or through public advertisements regardless of a patient's opt-out decision.

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 and research notifications must be submitted for review and approval by the IRB.

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 IRB 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 IRB 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 Mass General Brigham IRB Guidelines for Advertisements for Recruiting Subjects.

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 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.

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 Mass General Brigham IRB 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 IRB 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.