

Institutional Review Board (IRB) Policies & Procedures Manual



Document: irbm-010-001-recruitment-responsibilities.docx

Recruitment: Responsibilities and Requirements

Purpose

The policy describes IRB and PI responsibilities concerning recruitment. This also includes principles, requirements, and recruitment language that is not allowed.

Policy

The IRB recognizes an investigator's desire to optimize recruitment; however, the rights and welfare of the subject and the need to avoid undue influence and/or coercion are the IRB's priority.

IRB Responsibilities:

- Review and approve all recruitment processes and materials prior to use.
- Review all recruitment activities to ensure that recruitment practices do not unduly influence a subject or family member to participate.
- Review the status of individuals who approach and recruit a family/subject and the manner in which they determine that a subject is eligible. This includes consideration of privacy issues when an individual who is not involved in the participant's care approaches individuals for recruitment.

Principal Investigator Responsibilities:

- Submit all recruitment materials for IRB review and approval.
- Ensure that subjects are recruited at appropriate times.
- Provide potential research subjects ample opportunity to consider participation.
- Protect the privacy of potential subjects and the confidentiality of their medical/research records during any recruitment practice. To this end, investigators must limit their search for potential subjects to those whose records fall within the scope of their responsibility unless otherwise approved by the IRB.

Additional policies related to recruitment include: **Recruitment: Methods** and **Recruitment: Special Circumstances**.

Procedures

Research subjects are recruited at different times. Many are recruited while hospitalized or while visiting an ambulatory clinic or Boston Children's Hospital (BCH). Others are recruited after they are discharged from BCH or in locations outside of BCH (i.e. schools, homes, etc.). All efforts must be taken to avoid any type of undue influence or coercion.

The timing, location, method, and the individual performing the recruitment may all inadvertently influence a subject to agree to participate. For example, when potential subjects are asked by their care provider to participate in research, the subjects may be hesitant to choose not to participate for fear of disappointing or upsetting the care provider.

The following includes guidance and considerations when developing and evaluating recruitment practices:

General Recruitment Guidelines

To comply with federal requirements, the IRB requests as part of the protocol a complete description of all recruitment efforts. This includes who is responsible for recruitment, how and when subjects are approached, and the time commitment.

In addition, BCH reviews all materials used for soliciting participation in a study and they must be approved prior to use, regardless of the medium (i.e. newspaper, poster, flyer, e-mail, professional journal, newsletter, website, social media, audio/video taped announcements).

The IRB reviews recruitment practices and materials on a case-by-case basis and will take into consideration such variables as procedures, amount of compensation, the population, time commitment, location of postings.

Required Recruitment Elements for Notices/Advertisements

Any proposed notice or advertisement must contain the following information:

- The purpose of the study
- Clear statement that it is research
- Eligibility criteria in summary form
- Summary of procedures
- Contact Information that may include the name and address of the investigator or research facility
- Location of the research
- The amount of time required and/or the duration of the study
- Compensation provided, when applicable. Amounts of remuneration may be provided if the amount **is not** overemphasized in the manner in which it is presented.
- The use of investigational drugs or devices is explicitly stated, when applicable.

Recruitment Elements That Are NOT Allowed

- Claims about the safety or effectiveness of the investigational product.
- Claims that the test article or therapy is known to be equivalent or superior to other articles and therapies.
- Terms that may mistakenly lead a potential subject to assume that the methods of treatment are proven. These include: “new treatment,” “new program,” “new drug”
 - “free care,” “free drug,” and/or “free evaluation.”

Recruitment Criteria

The IRB will approve a recruitment method only if the following conditions are met:

- The form and method of advertising are not coercive and do not unduly imply the certainty of a favorable outcome or benefit.
- The advertisement is to be professional in appearance.
- The advertisement does not include exculpatory language

Related Content

IRB Policies

Recruitment: Methods

Recruitment: Special Circumstances

Document Attributes

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