



Recruitment

Policy

- Subjects are recruited for research protocols at many different times. Many are recruited while hospitalized, or while visiting an ambulatory clinic or the Hospital. Others are recruited after they are discharged from the Hospital or locations outside of Children's (schools, homes).
 - It is the investigator's responsibility to ensure that subjects are recruited at appropriate times, and that they are provided ample opportunity to consider research participation.
 - It is the Institutional Review Board's (IRB's) responsibility to review all recruitment activities to ensure that recruitment practices do not unduly influence a subject or family member to participate.
- Whenever possible, recruitment is to be avoided during stressful times for subjects.
- All efforts must be taken to avoid any type of undue influence. For example, when asked by their care provider, potential subjects may be hesitant to choose not to participate for fear of disappointing the care provider. The timing, the location, the method, and the individual performing the recruitment may all inadvertently influence a subject to agree to participate.
- There is no one method for recruitment. The particular requirements of the protocol, the subject population, or the research procedures may call for different recruitment methods. 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 are the IRB's priority.
- Investigators must 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. The status of the individual who approaches a family/subject and the manner in which he or she determines that a subject may be eligible are considered by the IRB. It may be necessary to secure a subject's permission to be contacted by an individual who is not involved in his or her care, or to ask another individual to assist an investigator in approaching subjects.

Procedures

The following are some specific guidelines to consider when developing and evaluating recruitment practices:

1. Review of Records for Recruitment Purposes

Investigators who wish to query medical records in order to find potentially eligible subjects for recruitment are required to justify a waiver of informed consent to review records for

recruitment purposes. The protocol application includes specific questions in order to justify a waiver for review of records only.

2. Recruitment by Mail Following the Receipt of Care At Boston Children's Hospital

In general, after potential subjects have left the hospital, they are to be initially contacted for recruitment by mail.

The IRB requires, whenever reasonably possible and feasible, that initial recruitment materials (letters, surveys, information sheets, etc.) to potential research subjects be signed/co-signed by a care provider known to the family or the chair/chief of a department with which the family is familiar. If an investigator feels they cannot follow this guideline, they will need to justify in detail why this is not possible for the intended study. Any letter sent to the family for recruitment should include

- How the potential subject's name was obtained (how and from where the list of names of potential subjects was generated).
- What information the investigator has obtained about the patient, and what was accessed
- When applicable, the fact that the medical record was *not* reviewed, and what was not accessed.
- When the investigator will not know the family's status to discern whether it is an appropriate time to contact them (i.e., child has died, stressful time), the correspondence should acknowledge this possibility.

Potential subjects must be given the option to request no further contact. It is suggested that a response card (and/or an alternative method by which they may opt-out i.e. telephone number, email) be included with the recruitment mailing for subjects to return if they do not wish to be contacted further. If a potential subject returns the response card (opts-out via other method), no further contact of that individual is to be attempted.

When a potential subject does not opt-out of further contact (return a response card/opt-out via other method), it is highly recommended that follow-up contact be limited to three attempts. The IRB considers "contact" to include voice messages. When describing plans for contacting individuals multiple times in an effort to secure their enrollment into the study, it should be specified how many contacts will be made and whether that includes leaving voicemail. If an investigator feels they cannot follow this guideline, they will need to justify in detail why this is not possible for the intended study.

Telephone surveys may not be undertaken before recruitment information (i.e. letter, information sheet) is sent to potential subjects that enables them to decline participation/further contact. The IRB does not consider "cold calling" an acceptable recruitment practice.

All recruitment materials are subject to IRB review and approval, and are to be submitted with the protocol application.

3. Providing Written Information Prior to Approaching a Potential Subject

Whenever possible, the IRB recommends that potential subjects receive written information about a study prior to being approached in person. This information may be in the form of a letter sent to a potential subject's home, or a pamphlet or information sheet that is presented to a potential subject

at the start of a visit. This is not always possible and may not be practical for some protocols; however, written materials are to be employed whenever possible. Such materials enable families to give informed consideration to participating in the study, and allow them to be better prepared to ask questions when they are approached.

4. Advertising for Subjects

Federal requirements dictate that all materials used for soliciting participation in a study be subject to IRB review and approval prior to use, regardless of the medium (e.g., newspaper, poster, flyer, e-mail, professional journal, newsletter, web site, audio/video taped announcements). Only IRB-approved documents may be used. Any proposed notice or advertisement that requires IRB approval must contain the following information:

- The Purpose of the study
- Eligibility criteria in summary form
- Summary of procedures required
- 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, if applicable
- Person to contact for further information

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

- The form and method of advertising are not unduly coercive and do not imply the certainty of a favorable outcome or benefit.
- The use of investigational drugs or devices is explicitly stated, when applicable. Claims are not to be made about the safety or effectiveness of the investigational product.
- The advertisement does not make claims that that the test article or therapy is known to be equivalent or superior to other articles and therapies.
- The terms "new treatment," "new program" and "new drug" are not to be used. Such terms may mistakenly lead a potential subject to assume that the methods of treatment are proven.
- The terms "free care," "free drug" and "free evaluation" are not to be used.
- The advertisement is to be professional in appearance.
- The advertisement does not include exculpatory language.

Amounts of remuneration may be provided as long as the amount is not overemphasized in the manner in which it is presented. The IRB reviews recruitment postings on a case-by-case basis, and will take into consideration the procedures, amounts, population, time commitments, and determine what is most appropriate for the posting.

The IRB will consider where advertisements are to be placed. Advertisements that are to appear on television or other predominately public locations may be subject to review by the Public Affairs Office.

5. Use of the Internet for Recruitment

IRB review and approval of clinical trial listings on the internet are not required when the system format limits the information provided to basic trial information, such as the title; Purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. Examples of clinical trial listing services that do not require IRB approval include the National Cancer Institute's Cancer Clinical Trial Listing (PDQ), Clinicaltrials.gov and the government-sponsored AIDS Clinical Trials

Information Service (ACTIS). However, when the opportunity to add additional descriptive information is allowed by the database system, IRB review and approval are required as specified above.

6. Guidance on Use of Personal Cell Phones For Recruitment and Communication with Research Subjects

The Institutional Review Board often approves of the use of the telephone to recruit research subjects. In most cases, the IRB will require introductory recruitment materials (letter, info sheet, etc.) prior to a phone call; however, there are limited situations when just an initial call is acceptable. The types and methods of recruitment are approved on a protocol by protocol basis. The IRB requires that any initial phone contact for recruitment purposes be made on a Boston Children's Hospital telephone (one that will indicate it is Boston Children's Hospital on caller ID). It is important that subjects know (through caller ID) that the call is a legitimate call from Boston Children's Hospital. Once initial contact is made and you have established a relationship with the potential subject, it is acceptable to use other personal phones with the following guidelines.

It is highly recommended that when using a personal phone, the *67 feature be utilized when placing the call to prevent the actual cell phone number from being displayed.

In situations where there is concern that recipient phones will block all non-identified calls or the researcher wants the number to be displayed, subjects should be advised during initial contact as to how they will be contacted and by whom so they will recognize the calls.

It is important to remember to only use cell phones where appropriate confidentiality can be maintained. Calls should not be made in public locations where others may hear the conversations.

These guidelines assure the appropriate human subject research protections while allowing flexibility as to when and how subjects are recruited. If there are reasons to deviate from these practices, they should be addressed in the protocol and the IRB will review and approve them as appropriate.

7. Recruitment of Staff or Students

Investigators may not recruit as research volunteers staff or students under their supervision. It is generally suggested that such individuals be recruited outside the department of the investigator through the use of public postings. In this manner, interested individuals will approach the investigator, and will not feel coerced as they might if approached by the investigator.

8. Recruitment of Minorities

All potential subjects regardless of race, creed, color, religion, or economic status are to be treated equally. In the context of research, equal treatment requires that all individuals be accorded the autonomy to decide whether or not to participate in research. Minorities and non-English speaking individuals are not to disproportionately bear the burdens and risks of research, and they are to be assured that they share the benefits of the research. If the research protocol holds out the prospect of benefit, minorities and non-English speaking individuals are not to be excluded from the research unless there are sound medical or scientific justifications for such exclusion. Each protocol is considered on its own merits. The IRB is responsible for independently assessing the investigator's opinion of risk/benefit and

inclusion/exclusion criteria. The IRB has the right to require that minorities and non-English speaking individuals be included. Specifically, this may require that the written informed consent and the verbal consent for obtaining informed consent be rendered in a language and a manner that ensures the participant's understanding of what the consent involves. This may require the translation of informed consents and/or the use of interpreters with a short form translation.

9. Finder's Fees/Recruitment Bonuses/Bonus Payments/Sponsor Coupons

Clinical research is an important component of Boston Children's Hospital's commitment to providing the best quality of care to its patients. In pursuing this commitment, house officers, staff, and other personnel are expected to assist investigators in the performance of clinical research. The provision of a direct financial incentive to staff members or hospital personnel for enrolling a research subject may add a strong element of coercion to the recruitment and consent processes. For this reason, under no circumstances may house officers, staff members, and hospital personnel be offered or accept a monetary "finder's fee" or other incentive for recruiting or referring subjects for a clinical investigation. House officers, staff, and hospital employees are expected to observe this policy as one of their routine responsibilities at the Hospital. In addition no investigator or their research staff may accept any type of payment to accelerate recruitment that is tied to the rate or timing of enrollment. Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing is never allowed.

10. Recruiting in Schools

All conduct of research by Hospital staff at schools or using school populations requires the written permission of the school board and/or superintendent of the school system involved before the study may begin. It is the investigator's responsibility to obtain approval from the individual school system. Investigators must also consider special arrangements for recruiting subjects, obtaining parental consent, teacher involvement, and feedback on individual results. These issues are to be addressed in the protocol application. Investigators are advised that school system requirements vary, and that ample time must be allowed to address these issues. (see *Guidelines for School Based Research* for further information about recruitment and how it relates to informed consent in school based research).

11. Recruiting Foreign Populations

Boston Children's Hospital has long been recognized as a significant force in medical care and research, both in this country and internationally. Owing to their expertise, staff may be provided opportunities to study foreign populations with unique disease entities (e.g., tropical diseases, malaria).

As a leading research institution, Boston Children's Hospital recognizes that there exist cultural differences and varying standards of medical care, and that it is not always possible to ensure that researchers will be subject to the same regulations that apply in the United States. In such situations, the investigator and the IRB must make extraordinary efforts to ensure that the rights of these populations are protected in accordance with culturally and socially acceptable standards. The IRB requires evidence that the investigator considered the regulations and the needs of the host country. Proposed procedures must be sensitive to the population and compliant with the sponsoring government. Federally funded studies that involve a foreign population are required by regulation to negotiate an assurance of compliance between the foreign site and the Office of Human Research Protections. (see

additional guidelines *International Research and Cross Cultural Issues and Community Based Participatory Research*).

12. Policies for Recruitment of Boston Children's Hospital Patients for Research Conducted at Other Institutions

Requests to recruit Boston Children's Hospital patients for research conducted at other institutions may be made as follows:

- Posting notices on bulletin boards or in waiting areas that contain information about the studies conducted at other institutions; or
- Asking Boston Children's Hospital investigators to assist in identifying and recruiting patients for studies conducted at other institutions.

In determining whether IRB review is required, the following guidelines are to be observed:

1. Requests to post a notice on a bulletin board or leave pamphlets in a clinic/procedure/inpatient waiting area regarding research conducted at another institution may be honored without IRB review of the protocol. In these situations, a parent or child may read the information and decide whether he or she wishes to contact the investigator. Before such requests may be honored, however the investigator must get approval from the Department Chair/Division Chief or director of the clinic/procedure/inpatient area.
2. If a Boston Children's Hospital investigator is asked to participate in recruitment activities that consist of:
 - Assisting in recruiting procedures by discussing information about a study or
 - identifying eligible subjects or assisting in the informed consent process.

A research protocol from the other institution must be reviewed and approved by the Boston Children's Hospital IRB or arrangements for a reliance agreement must be made. This is necessary because a Boston Children's Hospital investigator is actively performing activities that may be viewed as engagement in research. It is possible that Boston Children's Hospital will rely on another institution's IRB approval, however the IRB office must be notified to make this decision.

13. Recruitment of an Investigator's or Research Team Member's Children.

An investigator may involve his/her own child in their research project only in accordance with all the following criteria and stipulations For research when there is no potential for direct benefit. The research must be minimal risk. The child must be of age and mind to provide assent. The other parent/ guardian provides parental permission*. The consent process is conducted by an individual other than the PI For research that presents a potential for direct benefit The other parent/ guardian provides parental permission*. Child assent is obtained if the child is capable, if required by the IRB.

An investigator may involve the children of other research team members only in accordance with all the following criteria and stipulations. For research when there is no potential for direct benefit. The research must be minimal risk. The research team member must approach the PI about participation based on knowledge of the research , the PI must not directly or actively recruit The other parent/ guardian provides parental permission * Child assent is obtained if the child is capable For research that presents a potential for direct benefit The research team member must approach the PI about participation based on knowledge of the research , the PI must not directly or actively recruit Child assent is obtained if the child is capable, if required by the IRB.

*If there is only a one parent/guardian family, the IRB office should be contacted for approval.

Related Content

IRB Policies

Guidelines for School Based Research

International Research and Cross Cultural Issues and Community Based Participatory Research

Document Attributes

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Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05 6/20/05 12/12/05 08/03/09 04/23/2010 10/11/2011 05/02/2012
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