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 Committee on Clinical Investigation's (CCI's) responsibility to review all recruitment activities to ensure that recruitment practices do not unduly influence a subject or family member to particpate.
- Whenever possible, recruitment is to be avoided during stressful times for subjects .
- All efforts must be taken to aovid 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 particpate.
- There is no one method for recruitment. The particular requirements of the protcol, the subject population, or the research procedures may call for different recruitment methods. The CCI 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 CCI'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 CCI. 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. Recruitment by Mail Following the Receipt of Care At Children's Hospital

In general, potential subjects, after they have left the hospital, are to be initially contacted for recruitment by mail. Potential subjects must be given the option to request no further contact. Any letter sent to potential subjects following discharge or a visit must be signed or co-signed by the primary physician who cared for the child. If this is not possible, the letter must at least be signed by a representative from the department/division that cared for the child. It is suggested that a response card 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, no further contact of that individual is to be attempted. All recruitment letters are subject to CCI review and approval, and are to be submitted with the protocol application.

In most situations, telephone surverys may not be undertaken before a letter is sent to potential subjects that enables them to decline further contact. The CCI does not consider "cold calling" an acceptable recruitment practice.

2. Providing Written Information Prior to Approaching a Potential Subject

Whenever possible, the CCI 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 phamplet 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.

3. Advertising for Subjects

Federal requirements dictate that all materials used for soliciting participation in a study be subject to CCI 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 CCI-approved documents may be used. Any proposed notice or advertisement that requires CCI approval must contain the following information:

- The Purpose of the study
- Eligibility criteria in summary form
- Summary of procedures required
- Name of the investigator or institution (Children's Hospital Boston) or research facility
- Location of the research
- The amount of time required and/or the duration of the study
- Compensation provided, if applicable
- Study contact for further information

The CCI 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 is which it is presented. The CCI 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 CCI 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.

4. Use of the Internet for Recruitment

CCI 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 CCI 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, CCI review and approval are required as specified above.

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

The Committee on Clinical Investigation often approves of the use of the telephone to recruit research subjects. In many cases, the committee will require an introductory letter 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 by basis. The Committee requires that any initial phone contact for recruitment purposes be made on a Children’s Hospital telephone (one that will indicate it is Children’s Hospital on caller ID). It is important that subjects know (through caller ID) that the call is a legitimate call from 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 personal phone you should use the *67 feature when placing the call to prevent your actual cell phone number from being displayed.

In situations where you are concerned that recipient phones will block all non-identified calls or you want your number to be displayed, you should advise subjects during initial contact as to how they will be contacted and by whom so they will recognize the calls.

Please remember to only use cell phone 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 humans 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

6. Recruitment of Staff or Students

Investigators may not recruit as research volunteers staff or students under their supervision. Whenever possible such individuals should be recruited outside the department of the investigator through the use of postings. However the IRB will permit staff or students under the supervision of a PI to participate only if public postings are used and the PI does not directly and actively recruit. In this manner, interested individuals will approach the investigator, and will not feel coerced as they might if approached by the investigator.

7. 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 CCI is responsible for independently assessing the investigator's opinion of risk/benefit and inclusion/exclusion criteria. The Committee 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.

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

Clinical research is an important component of 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 "finders 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.

9. 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)

10. Recruiting Foreign Populations

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, the 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 CCI must make extraordinary efforts to ensure that the rights of these populations are protected in accordance with culturally and socially acceptable standards. The CCI 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*)

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

Requests to recruit 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 Children's Hospital investigators to assist in identifying and recruiting patients for studies conducted at other institutions.

In determining whether CCI 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 CCI 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 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 Children's Hospital CCI or arrangements for a reliance agreement must be made. This is necessary because a Children's Hospital investigator is actively performing activities that may be viewed as engagement in research. It is possible that Children's Hospital will rely on another institution's IRB approval, however the CCI office must be notified and make this decision.

12. 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

Document Attributes

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