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Owner	Susan Kornetsky: Manager
Department	Research
Applicability	Boston Children's Hospital- Policies & Procedures

Recruitment: Methods Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

IRB

Clinical Research Executive Committee

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Policy Statements

This policy describes recruitment methods and provides guidance concerning the following:

1. Finders Fees, Bonuses, and Sponsor Coupons
2. Screening Boston Children's Hospital Medical Records for Recruitment
3. Recruitment Introductory Material
4. Follow-up Recruitment Introductory Material
5. Who May Invite a Patient/Family Receiving Care at Boston Children's Hospital to Participate in Research
6. EPIC MyChart Research Invitiations
7. Telephone Recruitment and Communication
8. Online/Internet/Social Media Recruitment and Clinical Trial Listings Website

9. Recruitment of Participants at External non-Boston Children's Hospital Institutes
10. Recruitment of Participants by a non-Boston Children's Hospital Investigator

Identification, initial contact, and recruitment of potential research participants is the beginning of informed consent process. The research team, study sponsor, and the IRB share the responsibility of creating an effective and ethical recruitment environment that complies with the federal regulations and institutional guidance. These responsibilities require consideration of the appropriate procedures for the initial identification, contact, screening, and recruitment of potential participants. Both screening and recruitment processes should demonstrate and reflect respect for the dignity and autonomy of the potential participants by avoiding any potential undue influence and by protecting both the privacy of the individual and the confidentiality of any information obtained for recruitment. The particular context of a protocol, participant population, and procedures may call for different recruitment methods.There is no one method for recruitment.

The timing, location, method, and the individual performing the recruitment must all be considered and approved by the IRB.

The procedure guidelines assure the appropriate human subject research protections while allowing flexibility as to when and how potential participants 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. The types and methods of recruitment are approved on a protocol-by-protocol basis.

Finders Fees, Bonuses, and Sponsor Coupons

Finders Fees and Bonuses

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 Boston Children’s Hospital employees 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 participant may add a strong element of undue influence 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 participants for a clinical investigation. House officers, staff, and Boston Children’s 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.

Sponsor Coupons

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.

Procedures

Screening Boston Children's Hospital Medical Records for Recruitment

Investigators who wish to query the Boston Children's Hospital medical record or other institutional databases such as EPIC or BCH360 for the purpose of identifying potentially eligible participants are required to submit to the IRB with a justification for a waiver of HIPAA Authorization to review records for recuitment purposes. The IRB Application in CHeRP will automatically branch to the Screening for Recruitment section if a waiver of authorization is requested for recruitment.

Recruitment Introductory Material

Providing Written Information Prior to Approaching a Potential Subject

Providing recruitment materials prior to being approached enables families to become familiar with research opportunities and give time to informed consideration to participating in the study. Prior notification may allow potential participants to be better prepared to ask questions when they are approached directly.

Whenever possible, the IRB recommends that potential participants receive written/electronic information about a study prior to being approached in person. This is not always possible, as it may not be practical for some protocols. Some examples of written/electronic information include: a letter sent to a potential participant's home, electronic communications through a method approved by the IRB, an EPIC MyChart recruitment invitation, a pamphlet or an information sheet that is presented to a potential participant at the start of a visit.

Introductory material should include information on how the potential participant/family may opt-out of further contact about the study. The research team may consider directing potential participants to use a return mail response card, or provide a telephone number or email address to opt out of further recruitment contact for the study. If a potential participant responds indicating they would like to opt-out, no further contact of that individual is to be attempted for the study.

Follow-up after Recruitment Introductory Material

When a potential participant does not respond to the intial recrutiment contact, it is highly recommended that follow-up attempts to reach the potential participant/family be limited to three attempts.

1. The IRB considers "contact" to include voice messages, emails, texts, etc.
2. When describing plans for contacting individuals multiple times in an effort to secure their enrollment into the study, it should be specified how many contact attempts will be made and the mode (e.g. voice messages, emails, texts, etc.).

3. If an investigator feels they cannot follow this guideline or there is a reason to include more attempts, the investigator should provide a justification in the protocol and CHeRP application.

Who May Invite a Patient/Family Receiving Care at Boston Children's Hospital to Participate in Research

Investigators who are involved in the clinical care of a patient may approach the patient for participation in research. The following guidance is provided to address investigators who are not involved in the clinical care of patients/families receiving care at the Hospital and wish to recruit them for research purposes. This guidance applies to all forms of recruitment.

Greater than MInimal Risk Research (i.e. interventions such as clinical trials of drugs/devices, surgical procedures

Many research protocols that are determined to be greater than minimal risk are interventional and may impact clinical care. For these studies, investigators who are not involved in the clinical care of the patients/families must obtain permission from a clinical provider of the patient before approaching patients/families for potential research. This requirement is essential to ensure the safety and welfare of the patient based on current and proposed clinical care.

Minimal Risk Research

For research the IRB has determined to be minimal risk, investigators who are not involved in care of the patients/families may initiate recruitment efforts after they NOTIFY the patient's clinical care provider/s that an individual patient/family, or group of patients/families may be approached for the research. Permission from the care provider/s is not required. Examples of notification methods include:

- Individual or group emails or other methods of communication with care providers
- Communication with Department/Division leadership
- Presentations at a Department/Division faculty or other meeting

It is important to note that some Departments/Divisions or locations in the hospital may require permission of the care provider before recruiting a participant. If so, this more stringent requirement of permission needs to be followed.

Additional Safeguards to Protect Confidentiality & Privacy in Recruitment

The IRB requires additional safeguards for confidentiality and privacy when patients are identified for recruitment based on their sensitive and confidential health conditions or treatments such as transgender/gender affirming care, substance use/abuse, family violence/abuse, psychiatric care, sexually transmitted disease, or illegal behaviors. This applies to research that is determined to be minimal risk and greater than minimal risk.

To protect patient privacy and confidentiality when patients may be eligible and are approached for recruitment based on the conditions or treatments noted above, the IRB will require that an individual from the patient's clinical care team contact the patient/family to determine if they are interested in learning more about the research and provide permission to be approached by the research team.

EPIC MyChart Research Invitations

All Boston Children's Hospital patients who have MyChart accounts are "opted in" to receive research invites unless they have specifically taken a step to opt out of receiving research invites. EPIC includes research tools that allow investigators to identify subjects who may be eligible for their research. Research invites are used to inform patients about research and allow patients to express interest through MyChart. The IRB has developed template research invites that are designed to provide limited information so a patient can decide if they want to be contacted and find out more about a study. Patients may then be contacted with further recruitment details if interest is expressed. Any investigator who utilize this method of recruitment will be required to clearly identify use of MyChart Research Invitation in the protocol application in CHeRP and include the research invite template with study specific information. **Researchers using the MyChart Research Invitation must follow procedures outlined in section above: *Who May Invite a Patient/Family Receiving Care at BCH to Participate in Research*.**

Telephone Recruitment and Communication

Telephone Calls

Telephone calls as an initial form of research recruitment should not be undertaken before recruitment information about the study (e.g. letter, information sheet, email etc.) is sent to potential participants. The materials should enable an individual to decline further contact. Investigators may send recruitment materials with instructions that unless an individual requests no further contact, they will be called at a later date. Individuals should be given clear instructions on how to "opt out" of subsequent phone contact and be provided with adequate time to respond. Typically, a week to 10 days should be offered. If there are reasons why phone calls are proposed without following these guidelines, a clear rationale should be provided in the protocol application

Initial Phone Contact Requirements

It is important that participants are aware that the call is a legitimate call from Boston Children's Hospital.

1. The IRB requires that any initial phone contact for recruitment purposes be made on a Boston Children's Hospital telephone.
2. The telephone must indicate that it is a Boston Children's Hospital on the caller ID.

Established Relationship and Personal Phone Use

Once initial contact is made and the research team has established a relationship with the potential participant, it is acceptable to use other personal phones with the understanding of the following recommendations:

1. 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.
2. In situations where there is concern that recipient phones will block all non-identified calls or the researcher wants the number to be displayed, participants should be advised during the

initial contact as to:

a. How they will be contacted **and**
b. By whom so they will recognize the calls.

3. 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 privacy cannot be maintained.

Online/Internet/Socia Media Recruitment and Clinical Trial Listings

Online/Internet/Social Media Recruitment

Internet and social media recruitment is subject to the same regulatory and ethical norms as traditional recruitment, including the requirements of prospective review and approval by an IRB compliance with all applicable federal and state laws, fair and equitable subject selection, respect for the privacy and other interests of potential participants, sensitivity to the norms and values of different communities, and consideration for the impacts of different recruitment techniques on public trust in the research enterprise.

Investigators proposing internet social media recruitment should approach it in substantially the same way they do traditional recruitment methods. Investigators should:

1. Ensure that social media recruitment methods comply with all pertinent laws and federal regulations, including HIPAA and HITECH.
2. Ensure that proposed social media recruitment techniques comply with the policies and terms of use of the relevant websites
3. Ensure that the proposed recruitment strategy:
    a. Is sensitive to the privacy of potential participants;
    b. Is respectful of the norms of the community being recruited; and
    c. Will not undermine public trust in the research enterprise, including via deceptive practices or lack of transparency.

The Boston Children's Hospital IRB may ask investigators to work the Hospital's Social Media department to ensure that all institutional policies are followed.

Clinical Trial Listings Websites

IRB review and approval of clinical trial listings on the internet/websites 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 following:

1. National Cancer Institute's Cancer Clinical Trial Listing (PDQ),

2. Clinicaltrials.gov
3. Departmental websites listing active protocols.

Recruitment of Participants at External non-Boston Children's Hospital Institutions

Requests to post a notice on a bulletin board, leave pamphlets in a clinic/procedure/inpatient waiting area, or have individuals distribute information regarding research conducted at an external non-Boston Children's Hospital institution is permitted.

In these situations, a parent or child may read the information and decide whether they wish to contact the Boston Children's Hospital investigator. However, it is necessary to assure that all policies regarding this type of recruitment are in accordance with the external institution. In addition, this plan should be disclosed in the protocol application.

Recruitment of Participants at Boston Children's Hospital for non-Boston Children's Hospital Research

If a Boston Children's Hospital investigator is asked to participate in recruitment activities for a non-Boston Children's Hospital Investigator, that consist of:

1. Identifying eligible participants and/or contacting potential participants to either assess interest in the research or screen for eligibility; and/or
2. 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 human subject research. It is possible that Boston Children's Hospital will may decide to rely on another institution's IRB approval, however the IRB office must be notified to make this decision and ensure a reliance is documented in accordance with regulatory and institutional requirements.

If activities are limited to solely distributing information about the research and it is up to the potential participant to contact the external investigator, Boston Children's Hospital IRB approval is not required, as this does not represent engagement in human research.

For more information, see the IRB Policy: ***Single IRB Review***

1. The IRB considers "contact" to include voice messages, emails, texts, etc.
2. When describing plans for contacting individuals multiple times in an effort to secure their enrollment into the study, it should be specified how many contact attempts will be made and the mode (e.g. voice messages, emails, texts, etc.).
3. If an investigator feels they cannot follow this guideline, they will need to provide a justification in detail within their protocol on why this is not possible for the intended study.

Related Content

- IRB Policies
    - Recruitment: Responsibilities and Requirements
    - Recruitment: Special Circumstances
    - Single IRB Review

Approval Signatures

Step Description	Approver	Date
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Applicability

Boston Children's Hospital- Policies & Procedures