Guidance
Human Subject Recruitment and Use of Advertisements for Research

Introduction

Numerous methods to recruit potential research participants exist; however, all methods involve presenting potential subjects information about the study to establish a subject's interest and willingness to participate in research. An important ethical principle that is relevant to the recruitment process is Respect for Persons as described in the Belmont Report.

Recruitment is generally the first contact between researchers and prospective participants (whether through paper-based or online announcements, media communications, or face-to-face interactions) and is a prelude to the informed consent process. Per Federal regulations, recruitment is considered part of the informed consent process. Thus it is expected that this initial contact and recruitment, in any form, is done ethically and respectfully and that the information presented clearly and accurately represents the research and what the participant can expect so that a decision to continue on with the research consent process and possible enrollment is informed and voluntary.

The issues of greatest concern relating to recruitment campaigns may be summarized in terms of four Cs:

1. **Consent (ongoing or continuing)** – Research participation must be voluntary. Just as the consent process respects an individual's right to decline participation in a research project, this same respect must be present in the initial contact to introduce research to a potential subject. In approaching or contacting potential research subjects, before they are ever enrolled, there must be the opportunity for the potential subject/family to decline to even hear about a research project. They should be given the choice about whether they are comfortable or interested in hearing about the research or meeting with someone to present the research project.

2. **Coercion (of medium and message) -** Information should be balanced and free of misleading emphasis that makes the study excessively attractive (e.g., avoid wording such as "free medical treatment", "new and improved", "guaranteed…"). Any anticipated benefits should not be overstated and it must be clear if there are no direct benefits to participation.

3. **Confidentiality and privacy** – Approaching a potential research subject in person, or contacting them in another way (phone calls, mailings, etc.) involves privacy concerns and HIPAA considerations. The person approaching/contacting to inquire if a potential subject would be willing to hear about a project and meet with a member of the research staff should be someone for whom the subject expects would know their medical information, have access to their medical information, the reason for being seen by staff at Children's Wisconsin, etc. This means someone with a treating relationship with the potential subject.

4. **Completeness (accuracy as well as truthfulness versus deception). -** Information shared with potential participants should be **accurate and clearly presented**. Number of visits, expected time commitment, any eligibility criteria, etc., should fully align with the proposed research plan. Information must be clear and understandable, and free from technical or scientific jargon.

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All recruitment methods and materials used to recruit potential research subjects must have CW HRPP/IRB of record review and approval prior to utilization.

Definitions

Recruitment: Identifying or seeking individuals to enroll or participate in a research study.

Advertising: A public announcement usually by a printed notice or voice or data broadcast that describes a research study including contact information. Typically this is used for recruitment purposes for a research study. Advertisements can be in many forms and encompass many modes, such as flyers, posters, billboards, radio ads, website copy, social media posts, etc.

Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

Undue influence, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

Treating Relationship: An individual who has reason to interact with an individual for the purpose of medical/clinical assessment, treatment, or intervention; an individual who would, within the scope of their practice, have reason to know that a patient is being seen at Children's Wisconsin or by a Children's Wisconsin medical provider; an individual directly involved in a potential participant's clinical care, rather than unknown researchers; a person considered to be engaged in the patient's medical care.

Final Format: An advertisement which has been prepared and is ready for print or to be used for recording. An advertisement which is in "final format" has:

- Identified the mode of advertisement, i.e. print flyer/poster, radio script, video script, web or social medial posting;
- All text, font and style used is exactly how it will appear to potential subjects
- Incorporates all images to be used;
- Addresses whether posting will be interactive, for example, Facebook pages, submission of personal information to be sent to site for further contact, etc.

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- Address if advertisements will also be provided in different languages and attach a certified copy of the interpreted document.

When submitting a new research study, the PI should identify and describe in sufficient detail in the summary/application all methods of recruitment they will use to recruit and/or identify potential research subjects. The process and methods should be described from the first encounter with the subject/their data all the way through to the consent process and include (by role) which research team members will be involved.

Any method of recruitment to be used in a research study should be conducted in a fair and equitable manner while maintaining respect for the individual and his/her privacy and confidentiality and comply with HIPAA Regulations. Recruitment and consent material must be consistent with the level of data identification.

If the PI proposes to use advertisements such as approach letters/phone calls, flyers, posters or web postings, these documents/scripts must submitted for CW HRPP/IRB of record review and approval prior to use. For more information, see section below on *Use of Advertisements in Research*.

If the PI chooses to add or change a method of recruitment during the course of the research study, an amendment package must be submitted via eBridge with any revised or new advertising materials and/or recruitment methods for review. CW HRPP/IRB of record approval is required prior to utilization.

Recruitment Methods

Record Reviews

Potential subjects may be identified by investigators/key personnel using medical records, clinical databases or research databases. This process is often identified as "a record review" or "screening" and requires CW HRPP/IRB of record and Privacy Board approval, and appropriate consent and HIPAA waivers granted, prior to accessing records.

The PI should provide the following information within the protocol summary/application:

- Do the investigators/key personnel have a treating relationship with the potential subjects?
- Which members of the research team have been delegated to review the records?
- What identifying information will be collected/viewed to assist with the recruitment process?

The CW HRPP/IRB of record may approve research in which the investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without first obtaining informed consent if either of the following conditions are met:

1. The information will be obtained through oral or written communication with the prospective subject, OR

2. By accessing records or stored bio-specimens.

Children's Wisconsin (Children's) is considered a covered entity and must abide by the federal regulations regarding Health Insurance Portability and Accountability Act (HIPAA).

- Investigators/key personnel should indicate in their eBridge submission in the protocol summary/application if they wish to screen or recruit subjects from review of medical records.
- A partial HIPAA waiver may be required.

<u>In Person (face-to-face) Contact for Recruitment (avoiding "Cold Approaching")</u>

This section applies to any areas of Children's Wisconsin in which a potential subject is physically present and applies regardless of the type or risk level of the research project.

Potential subjects who have been identified as possibly qualifying for a research project without their knowledge (via an IRB approved partial HIPAA waiver for screening) must be initially contacted by an individual with a treating relationship to the potential subject. First contact should be made by persons directly involved in prospective participants' care, rather than unknown researchers. Persons identified through a clinical record review should be contacted via an individual with a treating relationship with the patient. This expectation provides prospective subjects with the opportunity to participate in the research study while simultaneously respecting their autonomy and protecting their privacy and confidentiality. The process for approaching the potential subjects must be described in sufficient detail in the submission materials for the CW HRPP/IRB of record to assess the acceptability of the plan relative to this guidance and confirm the waiver requests are appropriate.

While this represents our expectation, it is recognized that on occasion exceptions to this may be appropriate. A researcher may propose an alternative approach to recruitment that may be more appropriate for the clinical area or the specifics of the study. Any alternative approach should be described in detail in the submission, with justification as to why this alternative is appropriate and include any supporting documentation to be used for the proposed recruitment approach. This will be assessed case by case within the context of a particular study, the clinical area, and the specific circumstances.

In addition, PIs who wish to approach and recruit Children's Wisconsin inpatients for their research studies must also obtain the permission from the attending provider. This permission must be documented in the regulatory file. PIs must describe this plan in sufficient detail in the protocol summary/application.

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Recruitment Letters, Emails, or Phone Calls (avoiding "Cold Contact")

Recruitment letters/emails/phone calls are seen as a first step of the informed consent process and the subject selection process and should contain the information as outlined in the section below *Use of Advertisements in Research.*

Children's does not allow "cold contact" of potential subjects. In order to respect a patient's autonomy and privacy, it may be necessary for the PI to enlist the cooperation of other professionals and organizations as intermediaries in contacting a potential subject and obtaining permission from the subject/family to release his or her contact information to the investigators/key personnel. This permission should also include subject/family preference regarding how they will be contacted (letter, email, or phone). This is appropriate when an investigator has not had prior contact with prospective research subjects and has not obtained their names from a publicly available source.

All email contact with patients/families must be encrypted and the patient/family must be able to respond in an encrypted fashion or clearly be made aware that any correspondence from the patient/family is not secure without being encrypted.

Approach letters should be printed on either departmental or project based letterhead and signed by the treating physician (the treating physician may also be the PI.). The letter should describe how the potential subjects were identified.

When obtaining names through a public list (e.g. telephone book), the PI should include the name of the source in the initial communication/contact (email, letter or phone call).

The PI should consider what the next course of action will be if prospective subjects do not respond to the recruitment contact. Many PIs choose to resend the request to those individuals who did not respond to the initial contact. If this will be the case, this should be stated in the initial recruitment materials.

Some PIs may choose to include return postcards with a mailing of their recruitment letters on which potential subjects may indicate their desire to participate in the research or not. The postcard **cannot** contain any diagnosis or medical condition. Please keep in mind, often times the name of the study reveals this information. In this case, the subject/family will know whom to contact for further discussion and clarification about the research study. If the study involves a sensitive subject, the PI may opt to have the postcard be vague in its identification of the study, or the PI may include an envelope in which subjects can return the postcard to keep the response private.

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Other Methods of Communication Regarding the Study (not intended for direct recruitment)

Written CW HRPP/IRB of record approval would not be required of these types of documents themselves, but serve as reference and information for the CW HRPP/IRB of record in approving the overall recruitment plan.

Descriptions regarding other types of methods should be explained in the submission application and included as reference materials for the CW HRPP/IRB of record. For example:

- Communications intended only to be seen or heard by health professionals, such as "dear doctor'' letters and doctor-to-doctor letters;
- News stories, as long as they are not intended for recruitment purposes (for example, do not include phone number at the end to contact for more information to participate in a particular research study, does not provide protocol-specific details, etc.);
- Publicity intended for other audiences (e.g., media releases regarding types of services available or offered by a particular clinic, institute or physician);
- Any communications or news stories (social media posts, blogs, etc.) must be reviewed by Children's Public Relations, as well as Children's Corporate Compliance.

Use of Advertisements in Research

Advertising for or soliciting subjects is considered to be the start of the informed consent process and subject selection process. As such, when advertisements are used as part of subject recruitment for human subject research, these must be reviewed and prospectively approved by the CW HRPP/IRB of record.

Any ads to be used must be included with the submission. These may be part of the initial approval in the new research study submission. When the PI decides after the initial approval to advertise for subjects or to change the advertisement(s) already approved, this is considered an amendment to the ongoing research study which requires CW HRPP/IRB of record review and approval.

Advertisements used to recruit subjects include, but are not limited to:

- Newspaper;
- Radio;
- Televisions;
- Bulletin boards;
- Posters;
- Flyers that are intended for potential subjects;
- Internet blogs;

- Social media posts (examples include but are not limited to: Facebook, Twitter, YouTube, Vimeo, Twitch, Instagram, etc.).

The CW HRPP/IRB of record will review the information contained in the advertisement and the mode of its communication to ensure that it is not coercive, unduly influential, and does not state or imply a certainty of cure or favorable outcome or other benefits beyond what is outlined in the informed consent document and the protocol. This is especially critical when a research study may involve subjects who are likely to be vulnerable to undue influence, such as children.

The CW HRPP/IRB of record must review the print advertisements in final format to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the CW HRPP/IRB of record must review the final audio/videotape prior to use.

The CW HRPP/IRB of record can review and approve the wording of the advertisement **prior** to taping for broadcast to avoid the necessity of re-taping because of inappropriate wording. The review of the final taped message prepared from CW HRPP/IRB of record approved text may be accomplished through expedited review of an amendment. Please plan sufficient time for the review of the amendment.

Approval from Children's Marketing and Communication Department must be obtained for use of the Children's logo. After an advertisement or press release has been approved by the CW HRPP/IRB of record review, it must also be submitted to the MCW Public Affairs Office for review and approval if the MCW logo will be included.

Content of Advertisements

When preparing an advertisement, website or social media posting or recruitment letter to be used to recruit potential subjects to their research study, the PI should ensure the content of the advertisement is appropriate and consistent with this procedure.

Advertisements used to recruit subjects should be limited to the information the potential subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements:

- The name and address of the PI or the facility where the research study will be conducted;
- The purpose of the research study unless otherwise justified;
- The criteria that will be used to determine eligibility for the research study;
- A brief summary of participation benefits, if appropriate;
- Time or other commitment required of the subject;
- Location of the research study and the person to contact for additional information.

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Advertisements used to recruit subjects should NOT include the following:

- Claims of safety, effectiveness, equivalence or superiority in reference to the drug, device or procedure under investigation;
- Use of the terms "new" or "exciting" in reference to a drug or device without explaining that the test article is investigational;
- Use of the term "free" in reference to treatment or procedures;
- Use of bold or enlarged print or other means to emphasize payment;
- The amount to be paid;
- Use of exculpatory language, or asking subjects to give up legal rights;
- Claims that the subject will receive therapeutic benefit from participation in the research study;
- The use of any inappropriate pictures or images that would be inconsistent with equitable subject recruitment;
- Offers of compensation from a sponsor that would involve a coupon good for a discount on the purchase price of the product once it had been approved for marketing;
- Exhibition of the ad in venues which are not in line with the research study's purpose or intent.

Scripts

For some research studies the first contact prospective subjects make may be with an individual who follows a script to determine basic eligibility for the specific research study. The CW HRPP and IRB of record must review the procedures and script/list of talking points to assure that they adequately protect the rights and welfare of the prospective subjects. The CW HRPP and IRB of record must have assurance that any information collected about prospective subjects will be appropriately handled. The plan must be described in the protocol summary/submission.

Internet or Social Media Recruitment

If a local PI chooses to post direct recruitment advertisements or material via the internet or social media, CW HRPP/IRB of record review and approval of the method and content is required. This method cannot be used to gather identifiable information from potential subjects. The PI must describe in the protocol summary/application where and what listing is being used. In addition, the PI must assure that the information shared for recruitment is in accordance with their signed clinical trial agreement or grant.

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- If the proposed recruitment website will collect any personal identifiable information from potential subjects, there should be a description of how the information will be collected, and protected from breaches of privacy.
- Management and control of the platform must be described. For example: who will manage the content? Who can post (visitors or only administrators)? If visitors can post who will be vetting and managing? What are the parameters for posting comments and content? Will it be closed (request to join or log in) or public and open?

Federal guidance regarding website recruitment states that if a research study's recruitment material (e.g. website or web posting) contains only basic descriptive information, IRB approval is not required. Children's HRPP considers the following posting services not to require prospective CW HRPP/IRB of record approval (although the use of websites for recruitment should be described in the recruitment procedures of the protocol summary/submission for the research study):

- The National Cancer Institute's cancer clinical trial listing (PDQ),
- The government-sponsored AIDS Clinical Trials Information Service (ACTIS), and CliniclTrials.gov

Sponsor Recruitment Campaigns

When the overall campaign and other tools (such as radio and phone screening scripts) are not under the direct control of the local site and are intended to recruit potential subjects at a national level, the local IRB would not be responsible for review and approval of these sponsor-specific recruitment methods and materials, since the persons viewing the campaign would not yet be considered Children's subjects.

This method should be described in the protocol summary/submission for the research study; however, local IRB acknowledgement would solely represent that the local IRB is (1) aware that local site plans to participate in this recruitment campaign and use these materials; (2) aware of the content of the tools, and (3) is comfortable with the local site receiving potential subject referrals obtained via this method. It is the CW HRPP/local IRB's expectation that when this method of recruitment is proposed, the sponsor has obtained appropriate IRB of record's approval of the content of these recruitment materials and methods to be used.

When recruitment involves individuals in registries who have consented to be contacted for future studies, any email communication should address each potential subject individually – study teams should not send out "group" emails to multiple individuals in the registry.

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Compensation

Acceptable compensation methods for subjects:

- PIs may choose to provide compensation to subjects for the time, effort or inconvenience associated with participating in their research study. Reimbursement may also be offered for expenses incurred. Compensation is not a requirement for a research study and should be evaluated by the PI and CW HRPP/IRB of record to determine if appropriate for each specific research study and subject population.
- The following compensation or reimbursement methods may be acceptable:
    - Monetary compensation (includes check, cash, gift certificates, and prepaid debit cards);
    - Parking reimbursement;
    - Meal coupons;
    - Items such as bags, blankets, pens, coolers, calendars, magnets, etc.;
    - Medical Equipment – if provided to the subjects by the sponsor during the course of the research study, and allowed to keep it after participation has ended. Examples include, but are not limited to:
        - Blood pressure cuffs;
        - Glucose meters;
        - Portable electronic devices.

The CW HRPP/IRB of record will review and evaluate all compensation plans proposed on a study by study basis. In their review the CW HRPP/IRB of record will evaluate the following components:

- If compensation has been pro-rated on a per research study visit basis;
- If there is a "completion bonus" offered for the final visit (completion bonuses are often an amount which totals greater than 40% of the total compensation for the research study);
- If the total compensation being offered in the research study and the plan and timing of disbursement to subjects is not unduly influential.

Unacceptable compensation methods for investigators or subjects:

- Sponsors may offer to pay investigators or research personnel an additional fee to encourage subject recruitment efforts and the timely or accelerated opening of research studies. In most situations, these payments are prohibited. Each situation should be

disclosed and reviewed to be sure that it complies with Federal regulations, ethical opinions, and Children's HRPP policy.

- Investigators may not receive payment for referrals of potential subjects, or offer recruitment bonus to other physicians who refer individuals to a research study, or offer to provide additional compensation for submitting data or addressing queries.
- Subjects may not receive escalated payments for the purposes of accelerating recruitment or to encourage participation multiple times.
- It is impermissible to pay or accept **finder's fees**. Additionally, it is impermissible for faculty, employees or students to accept personal payments from sponsors or other researchers in exchange for accelerated recruitment or referrals of patients.
- It is impermissible to accept **bonus payments**.

Acceptable compensation methods for investigators:

- It is acceptable to receive compensation for recruitment and screening related activities that are unrelated to whether the subject ultimately enrolls in or completes the research study (such as advertising, administrative and personnel costs). PIs should be sure to determine a reasonable budget amount that is directly related to the value of the services provided to the research study, and to document how that amount was determined. For example, individuals could be paid on a flat hourly basis for the time spent recruiting and screening potential subjects (regardless of whether they are successful in recruiting those subjects) and time sheets should be kept documenting this effort. Staff should not be paid a fee for every successful recruitment (e.g., $10 for every subject who signs the consent document to participate in the research study). Further, this amount should be reflected in a written agreement that is reviewed by the Office of Grants and Contracts.

This guidance is not intended to prohibit renegotiation of contract fees when recruitment is progressing much more slowly than anticipated such that additional time and effort are required for recruitment activities than initially anticipated.