

Guideline for Recruitment – RPG-09

Guideline

Purpose

This guideline provides an evidence-based approach for developing and implementing a successful recruitment plan for a research study. Previous literature has shown that successful recruitment can be attributed in part to careful planning and involvement of the entire clinical team. This guideline outlines important issues to consider in recruitment planning such as budget, audience, and CCI approval. This document is not meant to be exhaustive, but will provide a useful starting point for developing a recruitment plan.

Definitions

Recruitment

Recruitment is the process of identifying suitable subjects and assessing their interest in participating in a trial.

Enrollment

Enrollment is the process of entering subjects into a trial via informed consent, screening, and randomization.

Procedure

Develop a Recruitment Plan

Develop a plan for meeting your recruitment goals, realistically estimating your recruitment potential. Estimate subject availability taking into account the complexity of the study visits and procedures, inclusion/exclusion criteria, previous experience with the target population, expected screen failure and dropout rates, and referral, seasonal and other patterns that may affect availability. It may be helpful to work with a biostatistician to estimate the number of subjects that will need to be screened to achieve the expected enrollment target. Use this number to develop a timeline for screening per week or month. This will be used to guide recruitment efforts.

Determine the Audience

Age-Appropriate Advertising The age group being studied will determine who the target audience is for recruitment efforts. Adolescents and adults may be targeted directly, whereas children need to be recruited via their parent/guardian. When recruitment efforts are targeted to children or adolescents, parents or guardians will be required to provide informed consent for their participation, in addition to the subject providing assent. Exceptions may be made under special circumstances.

Availability of Target Patient Groups The availability of patients who meet the inclusion criteria for a protocol will affect the recruitment methods employed.

- **Narrow target groups**
Many studies require a very specialized group of patients (i.e., a rare genetic blood disorder). Recruitment efforts for these studies should be focused on areas where these patients are highly concentrated. Examples would include clinics where these patients are treated, or through foundations or support group publications specific to the disorder.
- **Broader demographic**
For studies that will include a broader group of patients (i.e., overweight adolescents or high school students), recruitment efforts should be more generalized, perhaps using several modalities.

Chronic versus acute conditions Different recruitment strategies may have to be used for studying acute conditions for which the subject can only be recruited at presentation and studying chronic conditions for which the patient population is known..

Choose Recruitment Methods

Below is a list of several recruitment methods. Choice of recruitment modality will depend on the audience as well as the recruitment budget. Keep in mind that large scale recruitment methods, such as TV or radio advertising, require sufficient resources to be put in place to respond to enquiries. Each advertising method employed must be approved by the CCI as an amendment to the protocol.

Small-budget recruitment methods

- [BCH advertising and marketing outlets](#)
- [Flyers, brochures](#) (in Related Content Section below)
Investigator's own practice database (review CHQuery, Epic, PowerChart, mail recruitment letters, and make recruitment calls)
- Outside physician referrals
- Health fairs or screenings
- Professional or community organizations
- Patient associations; advocacy and support groups
- [Newspapers](#)
- [Internet advertising](#)
- [BCH-Connect Volunteer Registry](#)

Large-budget recruitment methods

- Direct mail
- Radio
- TV
- Movie theaters (advertising screens before the start of the movie)
- Public transit
- Third-party recruitment firms

Develop the Content for Recruitment Efforts

Information to Motivate and Educate Participants While maintaining CCI standards, several factors should be considered when developing recruitment strategy messages. Some key factors that help to educate and motivate patients and their families include:

- Ability to help advance the state of medical practice and science
- Gain better awareness and understanding of the medical condition
- Seeking an alternative medical therapy
- Following a physician's advice
- Finding convenient volunteer opportunities
- Compensation

Appropriate Content

Trial specific advertising can begin only after the material has received CCI approval. Recruitment notices should contain enough information to inform a potential participant about the study and evoke interest. Generally speaking, it is best to compose all recruitment material in language geared towards sixth graders. Contact CCI for more information about using plain language in recruitment materials. Recruitment documents should be translated into appropriate languages, and should be culturally sensitive. Very specific study details are more suited to be addressed during the screening phone call or meeting.

Elements of advertising notices include:

- A statement that clearly identifies the study as research
The name of the organization that is conducting the research
- A brief objective of the study
- A brief listing of key inclusion and exclusion criteria
- What drug or device, if any, is involved in the study
- The duration of the study, including number of visits and estimated time commitment (i.e., "You will be asked to participate in one 90-minute focus group")
- What is required of the participant, such as keeping a diary or an overnight hospital admission
- The benefits of the study to the participant (i.e., free study-related visits and trial medications)

- Compensation, including transportation costs, giveaways, or stipends
- Specific contact information for the study.

It also may be appropriate to list risks, and to provide reassurance that participation or lack of participation will not affect participants' regular medical care. Care should be taken to ensure the suitability of any graphical representations used in advertisements to the target group and diverse ethnic and socio-economic groups. Content that may be considered coercive should not be included in any research advertising.

Element of advertising notices should avoid:

- Overstating the benefits of the study
- Use of phrases such as “new and improved” (“investigational” is a more appropriate descriptor)
- Overemphasizing free items and compensation as to entice participants
- Any claims that the purpose of the research is to treat the condition
- Any claims that the research will improve the subject's condition

CCI Approval

All recruitment materials require CCI approval before their implementation. This includes flyers, brochures, other media advertisements, recruitment letters and emails, telephone recruitment scripts, and anything else written or verbal to be used for recruitment purposes. Please refer to the [CCI website](#) for more information on submitting recruitment materials as an amendment to a protocol. Note that the BCH CCI requires that advertisements be approved for each venue in which they will be employed.

The HIPAA Privacy Rule and Recruitment

Physician referrals and patient recruitment letters fall under the scrutiny of HIPAA Privacy rule protections. Refer to the [HIPAA Project website](#) and [CCI Recruitment Policy](#) for information regarding HIPAA and recruitment.

Prepare for Subject Contacts

1. Develop a study-specific recruitment plan to be used in training and implementation of recruitment strategies. This plan should include strategies for dealing with non-response and refusals.
2. Develop a Screening Log for use in screening patients. This log should capture all of the information necessary for the initial screen. Some examples of information that may be collected on a screening log include subject name, date of birth, referral source, and disposition. Example screening logs may be found on the [EQuIP website](#).
3. Develop a call guide or a script to be used in screening phone calls. The script should contain information about the study, as well as screening questions to be asked of potential participants. This guide should be approved by the CCI before implementation.
4. Set up a voicemail or email account to receive responses from potential participants for screening. Note: Patient-study staff email contact must be approved by

CCI.

5. Train all study staff on the recruitment plan and related screening materials before the recruitment efforts begin to ensure standardization of procedures.

Implementation

Using the procedures outlined in the recruitment plan, respond to all participant referrals within 24 to 48 hours of receipt. At least three attempts should be made to reach potential participants; study staff may consider calling on different days of the week and during different times of the day. Care should be taken so that potential participants do not feel as if they are being harassed; it is recommended that the number of voicemails be limited.

Disposition

Each subject should be assigned a disposition that describes the outcome of recruitment efforts and screening. Examples of dispositions include No Contact, Not Interested, Does Not Qualify, and Enrolled. The disposition is an important piece in the analysis of recruitment modalities and is required when publishing results of clinical trials.

Related Content

BCH ADVERTISING AND MARKETING OUTLETS

1. BCH-Connect: Volunteer for Clinical Research

Audience: patients, families, visitors, hospital employees or other individuals from the community, who may be interested in participating in clinical research studies, including individuals with specific medical areas of interest and/or healthy volunteers.

About: Researchers with CCI approved protocols at Children's have access to the registry's database and can contact individuals in the registry for their interest in participating in specific studies.

Web site: Register to search and view information about registry participants at:
<http://crit-apps/HSR>

2. Find a Clinical Trial: Clinical Research Recruitment Site

Audience: patients, parents, hospital employees or other individuals from the community, who may be interested in participating in clinical research studies, including individuals with specific medical areas of interest and/or healthy volunteers.

About: The website allows clinical trial principal investigators or their study staff to electronically submit, modify, and post recruitment notices.

Note: You will need your approved CCI number to enter.

To post on the site: email Irine Breytburg to obtain access to the Clinical Research Recruitment site. After obtaining access to the website, follow website directions to post a

clinical trial, or to remove or modify a posting.

To view postings: Postings may be found on the Find a Clinical Trial web site:
www.childrenshospital.org/research/clinical/Search.cfm

CMS training: NetLearning

Contact: Irine Breytburg Email: irine.breytburg@childrens.harvard.edu

3. Children's Hospital Boston Intranet Children's Today

Audience: Hospital employees

Provide: Headline, message text and hyperlinks to applicable hospital Web pages

Timeframe: Messages can be placed for a 2 week period

Contact: Public Affairs Phone: 617-919-3110 (ext. 4-3110) Email:
public.affairs@childrens.harvard.edu

4. Children's Hospital Boston Children's News

Audience: Hospital Employees

Frequency: Monthly

Note: Children's News is available in print and online.

Information:

<http://web2.tch.harvard.edu/newspubs/mainpageS2730P2.html>

5. Television screens throughout the hospital (digital messaging)

Audience: Patients, families, visitors, hospital employees

Note: The digital messaging system allows users to create and submit their own bulletins after completing Net Learning training.

Information:<http://web2.tch.harvard.edu/publicaffairs/mainpageS2627P38.html>

6. Pediatric Views

Audience: 8,000+ referring physicians

Provide: A description of the study and a hyperlink to the study's 'Find a Clinical Trial' Web page

Frequency: Distributed bi-monthly (Feb, Apr, June, Aug, Oct, Dec)

Timeframe: News notes can be placed in the next issue. The publication is distributed bi-monthly.

Notes: Pediatric Views is distributed by mail and e-mail.

Contact: Editors Email peditric.views@childrens.harvard.edu

INTERNET ADVERTISING RESOURCES

1. Craigslist

Craigslist is an online community where users can place community-based classifieds.

For more information visit: <http://boston.craigslist.org/>

2. Thomson CenterWatch

CenterWatch is a Boston-based publishing and information services company. It provides information services used by patients, pharmaceutical and medical device companies, CROs, and research centers involved in clinical research around the world.

For more information visit: www.centerwatch.com and www.centerwatch.com/clinical-trials/post

NEWSPAPER ADVERTISING

a) Regional newspapers

- Boston Globe
 - a) Includes regional sections: City Weekly, North, Northwest, West, and South
- Boston Herald
- Free newspapers
 - a) Metro
 - b) Boston Phoenix
 - c) The Weekly Dig

- Select local/township papers
 - a) Milford Daily News (Milford)
 - b) The Patriot Ledger (Quincy) c. The Enterprise (Brockton)
 - c) Old Colony Memorial (Plymouth)
 - d) Telegram & Gazette (Worcester)
 - e) Daily News Tribune (Waltham)
 - f) MetroWest Daily News (Framingham)
 - g) Daily News Transcript (Dedham)
 - h) The Daily Item (Lynn/North Shore)
 - i) www.wickedlocal.com (several New England communities)

- Hispanic/Latino community (Spanish language) newspapers
 - a) El Planeta
 - b) El Siglo 21

- Brazilian community (Portuguese language) newspapers
 - a) Brazilian Times
 - b) Folha Online

- Chinese community (Chinese language) newspapers
 - a) Sampan

References

D. L. Anderson. A Guide to Patient Recruitment and Retention. Boston, MA: CenterWatch; 2004.

The Clinical Investigation Policy and Procedure Manual. “Recruitment” 14. September 2009. Children's Hospital Boston

Goberville, Maria. “Role of ICH GCP and recruitment strategies training of clinical sites staff in successful patient recruitment rates.” IBPA Association Blog. Accessed April 6, 2005

HIPAA Privacy Rule Information for Researchers, U.S. Department of Health and Human Services. 12 March 2009.

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