Recruitment and Advertising for Research

Purpose

This document provides guidance on the use of recruitment and advertising materials and/or activities for the purposes of human subjects' research. his document provides guidance on how to communicate with research participants electronically. There are two types of electronic communication: one-on-one directed personal communication and general non-directed research recruitment activities. This guidance document focuses specifically on directed personal communication, which may include email, text messages, and social media.

General guidance on how to communication with research participants electronically, is discussed in more detail in the Spectrum Health IRB guidance document entitled, "Electronic Communication with Research Participants."

Regulatory Guidance

- 45 CFR 46.111 (a)(3) – Selection of subjects is equitable
- 21 CFR 56.111(a)(3) – Selection of subjects is equitable
- 45 CFR 46.111 (b) – Protections for coercion and/or undue influence
- 21 CFR 56.111(b) – Protections for coercion and/or undue influence
- 21 CFR 312.7 - Promotion of investigational drugs.
- 21 CFR 812.7 - Prohibition of promotion and other practices
- U.S. Food and Drug Administration Information Sheets: "Recruiting Study Subjects," 1998 Update
- The HIPAA Privacy and Security, 45 CFR Parts 160 and 164

Discussion

Recruitment and Advertising materials and activities are often effective tools for increasing screening and enrollment numbers in research. The IRB must assure that appropriate safeguards exist to protect the rights and welfare of research participants. In fulfilling these responsibilities, the IRB must review all of the research documents and activities that bear directly on the rights and welfare of the participants of proposed research, including the methods and materials that Investigators propose to use to recruit participants.

There are some activities that **do not** constitute recruitment and/or advertising materials for human subject's research, including, but not limited to:

1. Communications intended only to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters;
2. News stories, so long as they are not intended for recruitment purposes (e.g. a phone number at the end to contact for more information to participate in a particular study, full details of inclusion/exclusion criteria of a particular study, etc.); and

3. Publicity intended for other audiences (e.g., media releases regarding types of services available or offered by a particular clinic, institute or physician).

In addition, the following **do not** require IRB approval:

1. Information, pictures, videos and links to other websites posted by a research participant themselves do not require IRB review.
2. Websites that contain only minimal information such as study title, purpose, protocol summary, basic eligibility criteria, site locations and who to reach for more information do not require IRB review (i.e. clinicaltrials.gov postings, SH Internal Research Websites).
3. Websites about research in general or general information on signs and symptoms of a disease that potential subjects are referred to does not require IRB review since it is not specific to the study.

Advertising or soliciting for study participants is the first contact that study teams will have with potential participants to start the informed consent and subject selection process. The IRB reviews the advertising to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve participants who are likely to be vulnerable to undue influence.

The IRB must review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. The IRB must review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects.

When advertisements are to be taped for broadcast, the IRB must review the final audio or video tape. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures.

Recruitment and/or Advertising Material should be specific to the intended protocol and include information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements:

1. The name, address, and facility or institution of the Investigator or study coordinator (e.g. Spectrum Health);
2. If applicable, include “investigational, meaning non-FDA approved”;
3. The condition under study and the purpose of the research;
4. In summary form, the criteria that will be used to determine eligibility for the study;
5. A brief list of participation benefits, if any (e.g., a no-cost health examination);
6. The time or other commitment required of the participants;

7. The location of the research and the person or office to contact for further information; and
8. Payment or compensation, but the payment or the amount to be paid is not emphasized by such means as larger or bolded type

Recruitment and/or Advertising materials should **not** include the following:

1. Claims, either explicitly or implicitly, that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
2. Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention;
3. Terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational, meaning non FDA-approved; or
4. Promises of "free medical treatment," when the intent is only to say that participants will not be charged for taking part in the investigation.

Researchers who utilize the services of the Spectrum Health IRB comprise a very talented and diverse clinician base with numerous centers of clinical excellence. These Clinicians, whom are also Researchers, are frequently invited to take part in advertising and/or promotional activities of their clinical centers of excellence. Clinician researchers are cautioned to take special care in these types of promotional activities, including special interest news stories, to avoid the appearance of Recruitment and/or Advertising for human subjects' research. This can be accomplished by discussing research interests in a broader context while discussing clinical interests or practice.

It is extremely important to **never** make the following statements regarding ongoing research initiatives:

1. Claims, either explicitly or implicitly, that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
2. Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention;
3. Terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational, meaning non FDA-approved; or
4. Promises of "free medical treatment," when discussing research initiatives.

Participants may discuss their research experiences or outcomes from their own personal perspective, however, when the clinician researcher is requested to comment he/she should be sure to strike a balance of objectiveness and avoid any undue influence or coercion or appearance of improper promotion of an investigational product (See 21CFR 312.7 [Investigational Drugs] and/or 21 CFR 812.7 [Investigational Devices])

MyChart is a useful tool for recruitment purposes. The IRB should review and approve the use of MyChart if a study team wishes to utilize it for recruitment purposes. MyChart does allow for attachments to be sent to patients using the In-Basket function, but the study team should consider if the study is appropriate for MyChart use. For example, at this time only adult studies, where consent is being obtained (without an LAR) are approved for MyChart recruitment.

Additionally, study teams should make sure that MyChart is an appropriate recruitment tool by looking at other variables, such as the study population, the study inclusion/exclusion criteria, etc. If a study team wishes to use MyChart for recruitment they should follow clinical team standard work and SOPs for appropriate use of MyChart (for example, no more than 2 contacts are permitted per patient) and a request for this use should be reviewed and approved by the IRB.

Conclusions

- Recruitment and/or Advertising materials and activities for research:
- Are primary tools to increase screening and enrollment in research;
- Must have prospective IRB review and approval prior to use;
- Should avoid undue influence or coercion; and
- Should include enough information for a prospective participant to determine their eligibility and interest.
- Not all forms of advertising or promotional activities are classified as Recruitment and/or Advertising for Research. However, it is important to be cognizant of FDA regulations
- Clinician researchers must use caution during clinical promotional activities when discussing research interests or during interviews for news or special interest stories to avoid conducting Recruitment and/or Advertising for research without prospective IRB approval or creating undue influence or coercion.
- Utilize MyChart to send secure electronic communication to research participants if appropriate for your study and approve by the IRB.