Research Recruitment

Summary

Before starting any recruitment activities, you must first have IRB approval for your research project, including your recruitment plan. There are various methods you may use to identify potential research subjects.

Study Advertisements

Any advertisements, fliers, brochures, notices, posters, radio spots, etc. which are intended to advertise the study and aid in recruitment must be submitted to the IRB for approval prior to use.

Copies of letters to participants or potential participants for purposes of information or recruitment, must also be submitted to the IRB.

The following should appear (or not appear, in some cases) in any study advertisements or letters:

- The name and address of the researcher and/or research facility;
- The condition under study (if applicable) and/or the purpose of the research;
- In summary form, the criteria that will be used to determine eligibility for the study;
- A brief list of participation benefits, if any (e.g., a no-cost health examination, participation in a nutrition program, etc…);
- The time or other commitment required of the subjects; and
- The location of the research and the person or office to contact for further information.
- Compensation must not be highlighted/accentuated beyond the other information about the study.

For drug or device studies:

- No claims should be made, either explicitly or implicitly that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Such representation would not only be misleading to subjects but would also be a violation of the FDA's regulations concerning the promotion of investigational drugs and investigational devices.
- Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatment" implies that all study subjects will be receiving newly marketed products of proven worth."
- Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid.

For additional information, see the FDA Information Sheets.

Contacting Potential Research Subjects via phone, email or mail

- In order to review medical records to find potentially eligible subjects, you normally must first have IRB approval for your study. A Partial HIPAA Waiver is granted at the time of IRB approval.
- CHOA does not condone 'cold calling' of patients (or former patients) based on information contained in their medical records, due to sensitivity around privacy.
- Providers that have a treatment relationship with the patient are able to contact their patients about their research studies.
- If you do not have a treatment relationship with the patient/are not part of a treatment group that cares for the patient, you have the following options:
    - Ask the patient's treatment provider to inform the patient about the study and to provide the patient with study contact information. The provider can not discuss details of the study if not listed as study personnel.
    - Ask the patient's treatment provider to get permission from the patient for you to contact him or her about the study. This permission should be recorded in the patient's medical record by the treatment provider. Again, the provider would not be considered study personnel unless their study involvement went beyond this step.
- When contacting potential participants, it is best practice to limit phone calls, emails or letters to a total of 3 attempts.
- CHOA employees are not allowed to disclose patient contact information to outside researchers.

Contacting Potential Research via Social Media

The federal regulations do not explicitly address the use of social media in human subjects research. Under the regulations, social media recruitment is held to the same standards as other types of recruitment efforts, including the requirement for prospective IRB review. If a research study is planning to use social media or public websites/forums, etc. for recruitment the study team must provide the IRB with statement describing the proposed social media recruitment techniques, including:

- A list of the sites to be use.
- A description of whether recruitment will be passive and/or active.
- If utilizing active recruitment, a description of how potential participants will be identified and approached, and their privacy maintained.

Until further guidance is developed, the IRB will review these requests on a study by study basis.

Questions

Contact the IRB at irb@choa.org