Recruitment & Advertising for Research: Quick Guidance

A Tallahassee Memorial HealthCare IRB Guidance Document

Purpose

This document provides guidance on the use of recruitment and advertising materials and/or activities for the purposes of human subjects' research. Contact the TMH IRB Office at 850-431-2522 or IRBOffice@tmh.org if you have additional questions or need assistance regarding the use of recruitment and advertising materials.

Quick Points

- 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. It is important to be aware of the 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. External Advertising is also required to be reviewed by the Public Relations Office at TMH.

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.

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, favorable outcome, or other benefit beyond what is outlined in the consent and the protocol.

The IRB must review the final copy of printed advertisements, and the final audio or video tape when advertisements are to be taped. The Public Relations Office at TMH should be informed about these products as well.

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:

- The name, address, and facility or institution of the Investigator or study coordinator (i.e., Tallahassee Memorial HealthCare)
- If applicable, include "investigational, meaning non-FDA approved",
- The condition under study and 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, in any (i.e., no cost health examination),
- The time or other commitment required of the participants,
- The location of the research and the person or office to contact for further information,
- Payment or compensation, but the payment or the amount to be paid is not emphasized by such means as larger or bolded type

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

- Claims, either explicitly or implicitly, that the drug, biologic, device, or other type of intervention is safe or effective for the purposes under investigation
- Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, device, or intervention
- Terms such as “new treatment”, “new medication”, or “new drug” without explaining that the test article is investigational, meaning non-FDA approved
- 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 are frequently invited to take part in advertising and/or promotional activities of their clinical centers (i.e., Cancer Center). 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. 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 (21 CFR 312.7 and 21 CFR 812.7).

There are some activities that do not constitute recruitment and/or advertising materials for human subjects’ research, including, but not limited to:

- Information, pictures, videos, and links to other websites posted by a research participant themselves to not require IRB review.
- 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).
- 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 as it is not specific to the study.
- News stories, so long as they are not intended for recruitment purposes (i.e., do not include 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.).