

Section 16: Recruiting Trial Participants

The FDA requires that an IRB review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109(a)]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. In fulfilling these responsibilities, an IRB is expected to review all research documents and activities that bear directly on the rights and welfare of the subjects of proposed research, such as the protocol, the consent document, and for trials conducted under the IND regulations, the investigator's brochure. The IRB should also review the methods and material that investigators propose to use to recruit subjects.

(Source: FDA Information Sheets)

The DFCI IRB is required to review:

- The process to be used to solicit participation in the study
- Advertisements/postings of any kind
- Letters for prospective participants, regardless of the sender
- Internet/database postings for which the opportunity to add additional descriptive information is not precluded by the data base system

IRB review of this material is to assure that: the language is appropriate for the audience; the information provided is true and clearly presented; and it does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

The DFCI IRB is *not* required to review:

- Communications intended to be seen or heard by health professionals only, such as "Dear Doctor" letters and Doctor-to-Doctor letters (even when soliciting for study participants)
- News stories
- Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors
- Listings of clinical trials on the internet ONLY when the system format limits the information provided to basic trial information, such as the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. [For example, the National Cancer Institute's Physician Data Query (PDQ), ClinicalTrials.gov, or the government-sponsored AIDS Clinical Trials Information Service (ACTIS)]

Recruitment Procedures

Any bonus payments to investigators as incentives for participant recruitment must be disclosed to the

appropriate institutional COI official and the IRB.

Potential study participants may be identified through any of these methods.

16.1 Private Medical Information

A common method of identifying potential trial subjects is to review medical records, clinical databases, and patient registries. This method allows members from the study team to review records and identify eligible individuals for a specific trial. However, the privacy and confidentiality of all individuals must be carefully protected. The recently enacted privacy rules under the Health Insurance Portability and Accountability Act (HIPAA) require this protection. The IRB must review and approve all such methods of obtaining private medical information prior to initiation.

16.2 Referring Physicians

Referrals from treating physicians can also be useful in identifying potential trial subjects. Treating physicians are most familiar with an individual's medical status and can therefore be quite helpful in recommending a proposed trial as an alternative to his or her patient. For example, referring physicians who have been provided with general information about the trial may inform their patients that the trial is available and provide the patients with contact information to learn more about the trial and whether they might be eligible. However, the referring physician *cannot* check eligibility or obtain consent.

16.3 Advertisements

Advertisements (i.e., posters, flyers) should be limited to the information necessary for potential trial subjects to make an informed decision. They should not make any claims regarding the safety and effectiveness of the investigational agent. Such representation would not only be misleading to participants but would also be a violation of the regulations concerning the promotion of investigational drugs [[21 CFR 312.7\(a\)](#)] and of investigational devices [[21 CFR 812.7\(d\)](#)].

Furthermore, advertisements should not promise “free medical treatment” when the intent is only to say participants will not be charged for taking part in the investigation. Advertisements may state that participants will be paid but should not emphasize the payment by such means as larger or bold type.

Terms such as “new treatment,” “new medication,” or “new drug” should be excluded, and explanations of the test agent being investigational should be avoided. A phrase such as “receive new treatments” may lead trial participants to believe they will be receiving newly improved products of proven worth.

Generally, the FDA takes the position that any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements (note that the FDA does not require inclusion of all of the listed items):

- Name and address of the clinical investigator and/or research facility
- Condition under trial and/or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the trial
- A brief list of participation benefits, if any (e.g., a no-cost health examination)

- The time or other commitment required of the participants and
- The location of the research and the person or office to contact for further information

All advertising materials must be reviewed and approved by the IRB prior to distribution.

16.4 Recruitment Letters

Recruitment letters provide another means for informing potential study participants about ongoing or new research projects and inviting them to learn more about these trials. The following should be included in the letter:

1. A statement that a research trial is being conducted
2. An explanation of the purpose of the research
3. A brief description of what is involved in the research
4. The expected duration of participation
5. An “opt-out” or “opt-in”
 - a. **Opt-out:** Either a telephone number to call or a postcard to return if the participant is *not* interested. If neither is returned, the investigator may then attempt one final contact to determine whether the participant is interested in learning more about participating in the trial. The “opt-out” must be justified due to the required effort of the potential participant.
 - b. **Opt-in:** Either a telephone number to call or a postcard to return if the participant *is* interested in learning more about participating in the trial. In this case, the investigator may *not* contact participants who have not called or returned the postcard.

The study team must take special precautions to ensure that the letters are properly addressed to the correct individual. Also, the return postcards should never contain information regarding a medical condition, medication, or diagnosis of those being contacted.

Note: The DFCI IRB does not allow investigators to recruit their employees, students, or anyone working under them to be volunteers in their research trial. There is the appearance of conflict of interest as well as the appearance of coercion or undue influence. Employees and students from other departments may be recruited to participate in such trials.

16.5 Scripts

A phone call, whether initiated by the research team or the potential participant, may be the first contact prospective study participants have with the research team. Calls are used as part of a recruitment process in order for people to obtain information about the study or determine basic eligibility for the study. The procedures followed must adequately protect the rights and welfare of the prospective participants.

In some cases personal and sensitive information is gathered about the individual. The IRB must have assurance that the information will be appropriately handled. A simple statement such as “confidentiality will be maintained” does not adequately inform the IRB of the procedures that will be used. In the proposal to the IRB, what happens to personal information if the caller ends the interview or hangs up

should be specified.

16.6 Unacceptable Language and Suggested Alternatives

Unacceptable: “We are very excited to be able to offer...”

Alternative Language:

- “We are conducting a research study that may be of interest to you...”
- “You may be interested in...”
- “We hope to learn a great deal from this study...”

Unacceptable: “You may benefit from participation in...”

Alternative Language:

- “Although there may be no direct benefit to you, your participation in this study will help us learn...”
- “It is unlikely that you will receive direct benefit from taking part in this study...”
- “It is unknown whether or not participants in this study will receive any direct benefit...”

Unacceptable: “You may qualify for...”

Alternative Language:

- “You may be eligible for...”
- “The entry criteria for this study are...”
- “This study is open to people with...”
- “We are looking for people with...”