The FDA requires 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. This includes recruitment and/or direct advertising materials.

**Recruitment materials** (direct advertising) *intended for prospective subjects* are reviewed by the IRB and must be submitted with the Initial Request for Review and Approval. If an investigator decides at a later date to advertise for subjects, the advertising is considered a protocol amendment and must be submitted to the IRB for review and approval. **TIP: The FDA considers direct advertising for study subjects to be the start of the informed consent process.**

**Recruitment materials include, but are not limited to:**
- Newspaper,
- Television,
- Radio,
- Bulletin boards,
- Posters,
- Flyers
- E-mail

**Recruitment materials DO NOT include:**
- Communications intended to be seen or heard by health professionals (e.g., dear doctor letters and doctor-to-doctor letters; *even when soliciting for study subjects*).
- Internet listings, 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, and
  - how to contact the site for further information.
- News stories
- Press releases or publicity intended for other audiences, such as financial page advertisements, directed at prospective investors.
## A Guide to Do’s and Don’ts for Recruitment Materials (Advertising)

### DO Include:
- A clear statement indicating that it concerns a research study. (e.g., the use of words such as “investigational,” “experimental,” “clinical trial,” and “research”).
- Generally the FDA believes that any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded the following items may be included in the advertisements, however the FDA does not require inclusion of all of the listed items.
  - Name and address of the investigator and/or research facility.
  - The location of the research and the person or office to contact for further information.
  - The condition under study and/or the purpose of the research.
  - A summary of the criteria that will be used to determine eligibility for the study.
  - A brief list of participant benefits, if any (e.g., a no-cost health examination).
  - CAUTION: Care should be taken not to promise free medical treatment.

### DON’T Include:
- Do not state or imply that the FDA or IRB has approved the research.
- Do not refer to investigational drugs, devices, or procedures as “new,” “safe,” “effective,” “a cure,” “treatment” or “therapy,” without qualifying them as “investigational,” “experimental” and so forth; for example “new investigational drug.”
- Do not call the investigational medication simply “medication” or “drug”; qualify each use appropriately with “investigational” or “study” as in “investigational medication” or “study medication.”
- Do not include statements of implied safety and/or effectiveness of the drug, biologic or device OR that the test product is known to be equivalent or superior to any other drug, biologic or device.
- Do not emphasize payment or amounts of the payment to subjects or the word “free” (e.g., bold, large font, dollar signs).
- Do not include payment amounts for studies involving underage subjects.
- Do not promise free medical treatment.
- Do not use the terms “confidential” or “completely private.”
- Do not include inappropriate promises of benefit or exaggerated statements about the potential benefits of participating in the research, receiving treatment from the investigator, or the organization.
- Do not use the phrases “Enrollment limited,” “Study ends soon,” or “Call today!”
- Do not include the statements “You deserve to feel better,” “Join this study and take charge of your life,” or similar phrases or logos.
- Do not include references to website recruitment content that has not been reviewed and approved by an IRB (except the clinicaltrials.gov website and other such public registries).
- Do not use potentially coercive visual effects (e.g. reassuring picture, graphics, fonts or symbols).
Receptionist Scripts:
The first contact prospective study subjects make is often with a receptionist who follows a script to determine basic eligibility for the study. The IRB should review receptionist scripts to ensure the procedures adequately protect the rights and welfare of the prospective subjects. In some cases personal and sensitive information is gathered about the individual. The IRB should 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.

Examples of issues that should be addressed during IRB review include:
- What happens to personal information if the caller ends the interview or hangs up?
- Are the data gathered by a marketing company? If so, are names, etc. sold to others?
- Are names of non-eligible subjects maintained in case they would qualify for another study?
- Are paper copies of records shredded or are readable copies put out as trash?

The acceptability of the procedures would depend on the sensitivity of the data gathered (e.g., personal, medical, and financial information).

References:
- U.S. Food and Drug Administration, Recruiting Study Subjects – Information Sheet, nd.