Advertising/Recruitment

Any advertisement that will be seen or heard by prospective subjects to solicit their participation in a study is considered Direct Advertisement for Research Subjects.

This includes, but is not necessarily limited to: e-mail announcements, online advertisements, newspaper, radio, TV, bulletin boards, posters, and flyers that are intended for prospective subjects.

Not included are:

1. communications intended to be seen or heard by health professionals, such as “dear doctor” letters and doctor-to-doctor letters (even when soliciting for study subjects)
2. news stories
3. publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process. Advertisements should be reviewed and approved by the IRB as part of the package for initial review. However, when the clinical investigator decides at a later date to advertise for subjects, the advertising may be considered a modification to the ongoing study.

When direct advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects 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.

Generally, 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 must be included in advertisements.

1. the name and address of the clinical investigator and/or research facility;
2. the condition under study and/or the purpose of the research;
3. in summary form, the criteria that will be used to determine eligibility for the study;
4. a brief list of participation benefits, if any (e.g., a no-cost health examination);
5. the time or other commitment required of the subjects; and
6. the location of the research and the person or office to contact for further information.