Recruiting Human Subjects for Participation in Research Studies

Advertisement Guidelines

Any advertisement directed at the recruitment of potential human research subjects should be limited to the information that the subject needs to determine his or her eligibility and interest. Per Food and Drug Administration guidelines (FDA Information Sheets for IRBs and Clinical Investigators, 1998 Update), advertisement statements should be limited to:

1. The name of the clinical investigator and/or research facility;
2. The condition under study and/or the purpose of the research;
   1. No claims should be made, either explicitly or implicitly, that a test article (e.g., drug, biologic, device) or procedure is safe or effective for the purposes under investigation, or that it is known to be equivalent or superior to any other approved article or procedure.
   2. Advertisements for recruitment into investigational drug, biological or device studies should not use terms such as "new treatment", "new drug", "new device", or "new procedure" without explaining that the test article or procedure is investigational. (Such terminology may be interpreted that the research subjects will be exposed to newly marketed articles or new procedures of proven worth.)
3. In layperson’s terminology and in summary form, list the criteria that will be used to determine eligibility for the study;
4. A brief list of participation benefits (e.g., a no-cost health examination), if any;
   1. Advertisements should not promise "free medical treatment" when the intent is only to say that subjects will not be charged for taking part in the research study.
   2. Advertisements may state that subjects will be paid for participation and the amount to be paid, but this information should not be emphasized (i.e., by such means as larger or bold type).
5. The time or other commitment required of the subject; and
6. The location of the research (if not previously addressed) and the person or office to contact for further information.