RECRUITING, ADVERTISING AND PAYMENTS TO SUBJECTS

Recruitment methods, including advertisements, and participant payment arrangements affect the equitable selection of participants and an appropriate consent process, and therefore relate to two criteria for IRB approval.

A research study may have fair selection criteria, but use recruitment methods or payment arrangements that lead to inequitable selection. For example, recruitment methods, advertisements, or payment arrangements that target economically disadvantaged participants can lead to unfair selection of participants despite reasonable selection criteria. Therefore, the IRB should evaluate whether recruitment processes, advertisements, and payment arrangements affect the equitable selection of participants.

Recruitment methods, advertising materials and payment arrangements also represent a part of the consent process. Recruitment methods and advertisements are the beginning of the consent negotiations; payments for participation are provided to reimburse participants for their time, effort, or other expenses. Recruitment methods, advertisements, or payment arrangements that are misleading, inaccurate, exculpatory, coercive, or unduly influential violate the regulatory requirements for consent. Therefore, the IRB should review proposed recruitment processes and advertising materials to judge whether they fulfill the regulatory requirements for consent.

FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process. Generally, advertisements should be reviewed and approved by the IRB as part of the package for initial review. The FDA expects IRBs to review the advertising to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.

When direct advertising is to be used, the IRB should 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. In the recruitment materials, no claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Such

representation would not only be misleading to subjects but would also be a violation of the Agency's regulations concerning the promotion of investigational drugs

Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" *without explaining that the test article is investigational.* A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.

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

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 may be included in advertisements. It should be noted, however, that FDA does not require inclusion of all of the listed items:

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.

Please see the PHRC advertisement guidelines for more information: http://healthcare.partners.org/phsirb/advert.htm

References:

FDA Information Sheets for IRBs
AAHRPP Evaluation Tool