

ADVERTISING FOR SUBJECTS

FEDERAL REQUIREMENTS: Although neither the FDA nor the DHHS regulations require IRBs to review advertising, each agency has required review. They cite two ethical principles from the Belmont Report: Respect for Persons (truthful advertising) and Equitable selection of subjects (equity in recruitment). Neither agency has defined advertising. FDA has published a guidance on it.

IRC REQUIREMENTS: IRC defines advertising as *"any outreach effort designed to encourage potential subjects to contact the investigator's site requesting information."* FDA has unofficially limited advertising to anything directed toward the potential subject; they do not include information directed to those who might refer potential subjects such as other physicians.

Our general rules are:

- a. It can not be misleading. It can not make promises of safety or efficacy; benefits or financial rewards must be reasonably stated. (Oversized fonts emphasizing money are discouraged.)
- b. It must be quite clear that it is for research or for an investigation.
- c. It should give the name of a primary contact and a method of making contact.
- d. It may give some brief eligibility criteria such as disease, condition, or age limits.
- e. It may give brief procedural information such as the location of the research, duration of participation, mode of administration and name of the test article.

As advertising will attract various subsets of the desired population depending on placement, the IRB will also consider placement of any advertising. For each advertisement, the IRB wishes to know:

- a. the name or type of the media (e.g., the San Francisco Times)
- b. The targeted audience of the selected media.
- c. Whether the medium selected is available to primarily a specific group. (e.g., Hispanics, gays, or wealthy)

INVENTIVE ADVERTISING TACTICS: As competition for limited numbers of patients increases, investigators are becoming more creative in recruitment measures. These are reviewable:

- health fair materials about the study
- computer bulletin boards or Internet
- 800 number ads
- disease databases (PDQ)-if you have any control over the content
- talk show appearance media kits
- posters and flyers
- press releases
- web sites
- phone "hold" messages
- video or other media

These do not require review:

- Ads in professional journals targeted to referring doctors
- Flyers to referring agencies that are not to be seen by patients
- talk show dialogue (cannot be preplanned)

PROCESSING AN APPLICATION: Advertising is reviewed using the expedited process. Although usually faster, please plan time to allow for a 4-day turnaround.

