

Studies need subjects. Potential subjects (patients, students, clients, employees) do not necessarily need studies.

Recruiting people to become subjects has developed into an art form that has progressed far beyond simple advertising. To be most cost effective, the right number of the right kind of people need to learn about the study and agree to participate without, at the same time, creating selection bias, unneeded work, and or hard feelings.

No regulations address recruitment although there are guidances about advertising and phone screens. Recruitment is reviewed under several different rubrics:

- Consent depends upon information much of which is transmitted via recruitment materials.
- Consent must be voluntary and without force, fraud, deceit, duress, coercion or undue inducements, all of which are possible to do within the recruitment timeframe.
- Studies should be designed to yield fruitful results; enrollment bias may so skew results that they are not evaluable.
- Selection of an inappropriate population can alter the risk calculus.

Two ethical principles within the Belmont Report can be related to recruitment issues:

- Respect for Persons requires truth in advertising
- Justice requires equitable selection of subjects.

REMEMBER: Advertising provides a first impression of the study.
It is the first information leading toward consent.

RECRUITMENT MATERIALS All of the materials involved in the process including advertising, scripts, messages, etc.

ADVERTISEMENT Recruitment material using the media, or other means, in a pre-planned way with the intent of informing potential subjects that a trial exists. Under this definition, any print, mailed, radio, television or computer advertisement targeting subjects is an advertisement.

RECRUITMENT METHODS - What is reviewable?

Competition for limited resources often inspires imaginative responses. Creative recruitment measures have been seen. Some are reviewable and some are not.

| <u>Reviewable</u> | <u>Not necessarily reviewable</u> |
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| Any materials directed to potential subjects: Ads - print, radio, TV, flyers, brochures | Materials targeting referring professionals: Ads in professional journals Flyers to other professionals |
| Talk show appearance media kits | Talk show dialogue - it cannot be pre-planned. |

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| Press releases | |
| Internet databases – any that are subjective or that you control | Internet databases – all objective information with simple lists of studies and features. |
| Health fairs, | Directories |
| Review of private databases (physician records, recruiter databases, etc.) | |
| 1-800 number ads | |
| Call waiting voice messages | |

IRB REVIEW PROCESS

Materials submitted with initial or continuing review or as a part of a modification request will be reviewed with that application.

Materials submitted separately will be presumed to be a minor modification to an already approved protocol and thus eligible for expedited review.

IRB REVIEW CRITERIA

Our general rules are:

- All recruitment materials must have tracking information such as a item number, version number or, at a minimum, a date.
- It cannot be misleading. It cannot make promises of safety or efficacy; benefits or financial rewards must be reasonably stated. (Outsized fonts emphasizing money are discouraged.)
- It must be quite clear that it is for research or for an investigation.
- It should give the name of a primary contact and a method of making contact.
- It may give some brief eligibility criteria such as disease, condition, or age limits.
- 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:

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

1-800 ADVERTISING

Each investigator needs approval for his or her recruitment materials. Many call centers will not refer to an investigator without IRB approval for the 1-800 ad. We have several rules of thumb.

- The scripts used should give information first, should ask questions second and obtain identifying information last
- Callers must be told whether the information will be retained for future recruitment and, if so, their verbal agreement is required.

