

GUIDE TO CREATING AND SUBMITTING ADVERTISEMENTS

The IRB must review the methods and material that investigators propose to use to recruit subjects. All clinical trial advertisements for the Medical Center must be approved by the Office of Marketing and Communications and the Office of Legal Affairs before submission to the IRB for approval. Call the Office of Marketing and Communications at 942-8708 to begin the approval process.

Direct advertising for study subjects is considered to be the start of the informed consent and subject selection process.

The following types of advertising for research subjects, **must be reviewed and approved** by the IRB: newspaper, radio, TV, bulletin boards, posters, and flyers that are intended for prospective subjects.

The following types of advertising **are not included**: (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 and (3) publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

IRB review and approval of listings of **clinical trials on the internet** is not required when the system format limits the information to the following:

- a) the title
- b) purpose of the study
- c) protocol summary
- d) basic eligibility criteria
- e) study site location(s)
- f) how to contact the site for further information.

Examples of clinical trial listing services that do not require prospective IRB approval are:

- a) National Cancer Institute's cancer clinical trial listing (PDQ)
- b) government-sponsored AIDS Clinical Trials Information Service (ACTIS).

The IRB will review the information contained in the advertisement and the mode of its communication. You must inform the IRB of every mode of communication you will be using the text of the ad for. If you change modes, you must receive IRB approval.

The IRB will consider the following points:

- a) Advertisements cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- b) The final draft of printed advertisements to evaluate the relative size of type used and other visual effects.
- c) The audio/video tape and word choices used.
- d) No claims should be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation.
- e) No claims should be made either explicitly or implicitly that the test article is known to be equivalent or superior to any other drug, biologic or device.
- f) Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug". A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.
- g) 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.
- h) 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.

- i) Advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.

The following items may 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.

When submitting any type of recruitment materials for IRB review and approval:

Submit **TWO** copies of the flyer, booklet, brochure, letter or other copy.

Submit one copy of the audio/video tape.

Once approved, your advertisement will receive either a letter of approval or a stamp of approval or both. Flyers that will be printed on white or colored paper using black ink for posting on Rush property must bear the approval stamp of the Rush IRB. All other types (colored ink, posters, press announcements) of advertisement require that you have the approved copy on file.

If you have any questions regarding advertisements, please call the Office of Research Affairs at 312-942-5498.