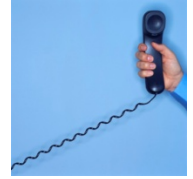


RECRUITMENT MATERIALS (Advertisements)



Federal regulations require that the IRB review and approve all recruitment materials for research subjects (e.g., advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study) **prior** to implementation. Recruitment materials include, but are not necessarily limited to:

- Newspaper Ads, Posters, Flyers, Pamphlets
- Radio
- TV
- Internet Web Sites
- Institutional e-mail and Publications
- Bulletin Boards
- Telephone Screening Scripts and/or Call Centers
- National Ad Campaigns
- Press Releases
- Organizational Listserv Mailings
- Physician to Patient Letters and Physician to Physician (Referral) Letters (e.g. Mass Mailings)
- Presentations to Describe Project to Local Support Groups, Social Groups, Clinic Sites, Health Fairs, Grocery Stores, etc.



Recruitment materials should be submitted to the North Texas Regional Institutional Review Board (IRB) for review along with the **initial** protocol submission.

Federal regulations consider advertising for study subjects to be the start of the informed consent process. Therefore, all advertisements (with the exception of those specifically approved for other health professionals) **must be at an 8th grade reading level.**

Recruitment materials should include the following information:

- The word “research”
- Statement of condition under study and brief description of the purpose of the research
- Brief summary of the eligibility criteria
- Brief list of the procedures involved
- A statement of the approximate time commitment required
- May include graphics or pictures appropriate to the purpose of the study
- The name and location of the institution and department conducting the research
- Contact person for further information, including telephone number
- When appropriate (and IRB approved), compensation for time and travel expenses (no specific dollar amounts)



Recruitment materials should NOT include the following information:

- Terms such as “new treatment”, “new medication” or “new drug” without explaining that the drug or device is *investigational*. A phrase such as “receive new treatments” leads study subjects to believe they will be receiving newly improved products of proven worth. An “IRB friendly” way to say this is: ***Volunteers with a diagnosis of (target disease) are being sought to participate in a research study testing an investigational drug.***



- Promise “free medical treatment” when the intent is only to say subjects will not be charged for taking part in the study. Ads may state that subjects will be “compensated for their time and travel expenses”. An “IRB friendly” version would be: ***Qualified volunteers will receive all study-related exams and lab tests at no charge and will be compensated for their time and travel expenses.***
- Enticing or inducing terms or phrases such as “free”, “new”, “exciting”, “limited enrollment”, “help us help you”, “you deserve to feel better”
- Emphasize the payment or the amount to be paid, by such means as larger or bold type
- Links to sites/resources that are not IRB approved



IRB Review Process

If your recruitment material is being submitted **after** IRB review of your initial protocol submission, you must attach a signed cover memo by the PI indicating how and where the ad will be used (e.g., run in the *Fort Worth Star-Telegram*, a flyer posted in UNTHSC or JPS clinics, etc.).

A “track changes” and clean version of your protocol synopsis must also be submitted for IRB review if your recruitment material adds a new type/form of recruitment not previously mentioned in the protocol.

You should allow at least 2-3 days for review and approval of your ad (and any other complementary research-related document).

Additional Guidance on Advertisements:

- UNTHSC:
 - For on-campus advertisement, UNTHSC Marketing requires placement of ads on designated bulletin boards or easel (including IRB-approved ads). Advertisement **cannot** be posted on places such as, but not limited to, elevators, restrooms or wall surfaces. For further information, please contact UNTHSC Marketing for appropriate locations before posting IRB-approved recruitment material.
 - For UNTHSC studies, advertisements that will be published outside of UNTHSC (e.g., local newspaper, community newsletters, etc.) must be reviewed and approved by UNTHSC Marketing.
- John Peter Smith Health Network (JPS): Please contact the appropriate officials to verify requirements (if any) for posting advertisement (e.g., appropriate location, etc.).

