Procedure Name: **Advertising Procedures**
Effective Date: **March 26, 2010**
Revision: **01**
Initiating Department: **Office of Clinical Trials**
Procedure Number: **OCT-008**
Application: **Advertising**

OBJECTIVE:

The objective of this procedure is to define the process for developing and submitting advertising materials for research subject recruitment for IRB approval.

REFERENCES:

OPHS-IRB Manual, Section 11.2	Recruitment: Advertisements
Office for Marketing and Communications, News Input Form	Memo dated January 28, 1997

SCOPE:

This procedure applies to all proposed clinical trial protocols governed by the Office of Clinical Trials (OCT).

BACKGROUND:

Federal regulations and UNTHSC policies require that the Institutional Review Board (IRB) review and approve all advertising materials for research studies (*i.e.*, advertising that is intended to be seen or heard by prospective subjects to solicit their participation in the study) **prior** to implementation. Advertising materials include but are not necessarily limited to:

- Newspaper ads, posters, flyers, pamphlets
- Radio
- TV
- Internet Websites*
- Institutional e-mail and publications
- Bulletin boards
- Telephone screening scripts and/or call centers
- National ad campaigns
- Press releases

- Organizational listserv mailings
- Physician to potential subject letters and physician to physician (referral) letters (*e.g.*, mass mailings)
- Presentations to describe project to local support groups, social groups, health fairs, clinic sites, grocery stores/pharmacies

*Investigators may use the internet as a recruitment tool in several ways. However, online research advertisements containing more detail (including those posted on the UNTHSC intranet) will require prior IRB review and approval.

Advertising materials should include the following information:

- The word "research"
- Statement or condition under the 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
- May include graphics or pictures appropriate to the purpose of the study
- The name and location of the institution and the 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)

The essential element in all subject advertising efforts is to make sure that the potential subject understands that they are being asked to be in a **RESEARCH** study . . . and that they not misconstrue the study as being a part of their regular, standard clinical care or treatment.

Advertising materials should *not* include 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 approved 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", or "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.

PROCEDURE:
Recruitment materials intended to be used for the purpose of recruiting research participants should be submitted to the IRB for review and approval along with the initial protocol submission. All advertisements (with the exception of those specifically approved for other health professionals) must be at an 8th grade reading level, since advertising for study subjects is considered the start of the informed consent process.

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

NOTE:
Advertising that will be published outside of UNTHSC (*e.g.*, local newspaper, community newsletters, and the like) must also be reviewed and approved by UNTHSC Marketing (see Marketing Memo cited on page 1).

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	10-108	Replacement of "policy" with "procedure"; addition of references and change history	MVWB