

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
REVIEW OF ADVERTISEMENTS / SUBJECT RECRUITMENT
MATERIALS**

I. PURPOSE

To document the procedures for review of study advertisements and/or subject recruitment materials submitted to University of Tennessee Health Science Institutional Review Board.

II. SCOPE

This SOP applies to investigators and sponsors whose studies are reviewed and approved by the UTHSC IRB.

Personnel Responsible:

UTHSC IRB administrative staff, IRB members, investigators.

III. BACKGROUND

Under FDA regulatory guidance, advertising for research subjects is conceptualized as part of the informed consent and subject selection process. Advertisements and other recruitment materials refer to, but are not limited to: materials to be published in local newspapers, broadcast on television or radio networks, placed on the internet, or posted or distributed in pamphlets, posters, signs, brochures, announcements, or promotional materials; descriptions of financial rewards, enrollment fees, and payment to subjects for participation; and any other plans, procedures or materials designed to solicit the participation of subjects in research. The UTHSC IRB reviews all advertisements and recruitment materials to ensure that the information provided to potential subjects accurately reflects the nature of the study and the procedures involved therein.

Generally, FDA believes that any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisement, although inclusion of all items is not required:

- (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.

FDA guidance on advertising and recruitment materials specifies that no claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Such representation would not only be misleading to subjects, but would also be a violation of the Agency's regulations concerning the promotion of investigational drugs [21 CFR 312.7(a)] and of investigational devices [21 CFR 812.7(d)].

In addition, advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" may cause study subjects to believe they will be receiving newly improved products of proven worth.

Finally, 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. 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.

In accordance with:

Recruiting Study Subjects – Information Sheet
Guidance for Institutional Review Boards and Clinical Investigators
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>

Compliance with this policy also requires compliance with state or local laws or regulations which provide additional protections for human subjects.

IV. PROCEDURES

1. Requests for advertisements, solicitations, and/or recruitment materials must be submitted to and approved by the IRB prior to use. Such materials may be submitted at the time of initial review with the Form 1 Initial Application via iMedRIS. When an investigator decides at a later date to advertise for

subjects, a Form 6: Advertising/Recruitment Materials must be submitted for IRB review via iMedRIS.

2. The **content** of advertisements, solicitations, and/or recruitment materials must observe the following guidelines:
 - a. No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.
 - b. Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.
 - c. 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. 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.
 - d. When appropriately worded, the following items may be included in advertisements. It should be noted, however, that the FDA does not require the inclusion of all of the listed items.
 - i. the name and address of the clinical investigator and/or research facility;
 - ii. the condition under study and/or the purpose of the research;
 - iii. in summary form, the criteria that will be used to determine eligibility for the study;
 - iv. a brief list of participation benefits, if any (e.g., a no-cost health examination);
 - v. the time or other commitment required of the subjects; and
 - vi. the location of the research and the person or office to contact for further information.
 - e. Advertisements should not state, suggest or imply that all subjects will receive treatment for their condition if the study involves a placebo-control group.
3. **Receptionist Scripts** – The first contact prospective study subjects make is often with a receptionist who follows a script to determine basic eligibility for a specific study. In some cases personal and sensitive information is gathered about the prospective subject. If appropriate to the study, the investigator should explain in the IRB submission:
 - a. what will happen to the personal information if the caller ends the interview or simply hangs up;

- b. whether data will be gathered by a marketing company, and if so, whether names, etc. are sold;
 - c. whether names of non-eligible subjects will be maintained in case they would qualify for another study; or
 - d. whether paper copies of records are shredded or are readable copies put out as trash.
4. For **print advertisements**, a copy of the planned printed materials must be submitted in its planned format along with a written plan of utilization, explanation of the type of media to be used and how monetary rewards are to be administered in order for the board to review the layout of the advertisements well as the content.
5. For **large multi-site studies**, the sponsor may provide a package of recruitment material to the sites for submission to the IRB for review and approval.
6. **Radio, video, audio-taped, television, internet-based and mobile-based** recruitment materials must also be submitted for IRB review and approval.
7. IRB review and approval of **listings of clinical trials** on the internet is not required when the system format limits the information provided to basic trial information, such as:
 - a. title;
 - b. purpose of the study;
 - c. protocol summary;
 - d. basic eligibility criteria;
 - e. study site location(s); and
 - f. how to contact the site for further information.

Examples of clinical trial listing services that do not require prospective IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).

8. Advertisements included with the initial review of the Form 1: Initial Application will be reviewed with the initial study submission. The IRB will notify the investigator of any revisions required in writing before approval can be granted. Approved advertisements will be marked with a stamp indicating IRB approval. Note that the stamp can only be placed at the bottom of the document in the center; therefore, you will need to leave adequate space for the stamp in that area.

9. Advertisements submitted after the initial review may be reviewed by the IRB chair or designated IRB member by expedited means. When the reviewer has doubts about the acceptability of the submission or other complicating issues are involved, the advertising or recruitment materials will be reviewed at a convened meeting of the IRB. The IRB will notify the investigator of any revisions required in writing before approval can be granted. Approved advertisements will be marked with a stamp indicating IRB approval. Note that the stamp can only be placed at the bottom of the document in the center; therefore, you will need to leave adequate space for the stamp in that area.
10. The UTHSC IRB must review any revision(s) made to a previously approved advertisement that could affect its impact. These include content or media changes, as well as other changes such as images, pictures, font or size.
11. Following a decision by the IRB regarding the advertisement, the PI will be notified in writing of the decision. Approval of recruitment materials will be placed on the electronic meeting agenda and sent electronically to Board members before the Board meeting each applicable week when the agenda is finalized.
12. A copy of all advertising / recruitment materials and IRB / investigator correspondence will be kept in the electronic IRB files for the study.