UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE 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 the IRB administrative staff, IRB members, investigators and sponsors.

Personnel Responsible:

UTGSM IRB administrative staff, IRB members, investigators

III. BACKGROUND

Any advertising is considered a part of the informed consent process. UTGSM IRB will review all advertisements and subject information documents to ensure that the information provided to potential subjects accurately reflects the nature of the study and the procedures involved.

REFERENCES

FDA Guidance for Institutional Review Boards and Clinical Investigators 1998 Update located at 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 the IRB through iMedRIS, the electronic system.

   Advertisements and solicitations would include any of the following:

Radio advertisements	Television advertisements
Newsprint	Web pages
Posters	Emails
Flyers	Newsletters

2. The content of advertisements, solicitations, and/or recruitment materials should 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. Such representation would not only be misleading to subjects but would also be a violation of the FDA regulations concerning the promotion of investigational drugs [21 CFR 312.7(a)] and of investigational devices [21 CFR 812.7(d)].
   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. Generally, the 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 advertisements. It should be noted, however, that FDA does not require 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. For print advertisements, a copy of the print ad must be submitted in its planned format in order for the board to review the layout of the advertisement as well as the content.

4. For large multi-site studies, the sponsor's may provide a package of recruitment material to the sites for submission to the IRB for review and approval.

5. Radio and television advertisement scripts must also be first submitted to UTGSM IRB for approval.

6. A dated print copy of any Web pages used for recruitment must be submitted for approval. No changes to the web page may be made without further approvals.

7. All advertisements must be submitted before they are used, and advertisements cannot be used until they are approved by UTGSM IRB.

8. Advertisements provided in the original submission will be reviewed with the initial study submission. UTGSM IRB will notify the investigator of any revisions required in writing before approval can be granted. Approved advertisements will be marked with the approval stamp.

9. The IRB staff will notify the Investigator of any revisions required in writing before approval can be provided. UTGSM IRB will provide an expedited review of the submitted materials.

10. UTGSM IRB must review any revision(s) made to a previously approved advertisement that could affect its impact. These include content changes, as well as other changes such as images, pictures, font or size.

11. The IRB administrative staff is the contact person for investigators, to call for any questions regarding participant recruitment materials.

12. Subject educational materials, study posters or pamphlets are considered recruitment materials and must be reviewed and approved by UTGSM IRB prior to use.

13. A copy of all advertising / recruitment materials and IRB / investigator correspondence will be kept in iMedRIS.