

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD**

REVIEW OF ADVERTISEMENT / SUBJECT RECRUITMENT MATERIALS

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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. Not included are:

- (1) Communications intended to be seen or hear by health professionals, such as “dear doctor” letters and doctor-to-doctor letters (even when soliciting for study subjects;
- (2) News stories; and
- (3) Publicly intended for other audiences, such as financial page advertisements directed toward prospective investors.

HHS regulations state that “An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the

possibility of coercion or undue influence". Therefore, the UTHSC IRB reviews all advertisements and recruitment materials to ensure voluntariness of participation, that the possibility of coercion or undue influence are minimized, that the confidentiality of records identifying subjects will be maintained, and 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:

DHHS Regulations and References:

45, CFR 46.111, 45 CFR 46.116, and 45 CFR 46.117

[Office for Human Research Protections – Informed Consent FAQs](#)

FDA Regulations and References:

21 CFR 50.20, 21 CFR 56.111

[FDA Information Sheet - Recruiting Study Subjects](#) , January 1998

[FDA Information Sheet – Screening Test Prior to Study Enrollment](#), January 1998

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

IV. DEFINITIONS

Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access, or have their access affected, to needed health services if he or she does not participate in the research.

Compensation is payment, merchandise, class credit or other gift, service or item provided to research participants, their parents/legal guardians, or their legally authorized representatives to reimburse them for their time, effort, and/or for any out-of-pocket expenses associated with research participation. **Note:** Compensation is sometimes distinguished from an incentive or inducement, which is generally thought of as a payment or other offering that is “over and above” reimbursement and intended to encourage research participation.

Finder’s Fee is a payment made by an investigator or sponsor to an organization or individual (including non-research personnel or a research participant) for identifying and/or referring potential participants for research.

Note: UTHSC and its employees and students are prohibited from participating in the payment of finder’s fees to medical residents, physicians, nurses or other individuals or entities for the recruitment of patients as participants in clinical investigations involving human subjects.

Lotteries and raffles are games of chance. Raffle means a game of chance in which a participant is required to purchase a ticket, share, chance or similar record for a chance to win a prize, with the winner to be determined by random drawing. **Note:** Research projects may not include distribution of prizes to research subjects via games of chance in which human subjects participants are offered a chance to win a prize. Terms used for these purchased chance distributions

include but are not limited to “lottery”, “raffle”, or “reverse raffle”. TCA 3-17-102

Recruitment Materials are announcements; advertisements; flyers; posters; scripts for telephone or other oral communication; letters and email messages; bulletin board tear-offs; internet postings; newspaper, radio, television, or video broadcasts, or other media used to attract potential participants for research.

Recruitment Methods are materials, incentives, and other practices or procedures used to inform potential participants about research.

School Official is a person employed by the University in an administrative, supervisory, academic or research, or support staff position (including law enforcement unit personnel and health staff); contractors, consultants, volunteers and other outside parties to whom the institution has outsourced institutional services or functions instead of using University employees or officials (such as an attorney, auditor, or collection agent); a person serving on the Board of Trustees; or a student serving on an official committee, such as a disciplinary or grievance committee, or assisting another school official in performing his or her tasks.

Subject Pools/Databases are an aggregation of potential research subjects, that include private identifiable information, who have given permission for future contact.

Undue Influence/Undue Pressure occurs through an offer of an excessive, unwarranted, improper or inappropriate reward, the use of persuasion, authority figures or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. Undue influence may also be subtle. For example, patients might feel obligated to participate in research if their physician is also the investigator, or students might feel pressure to participate in research if everyone else in the class is doing so.

V. 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 *UTHSC IRB Form 1: Study/Project 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. In the *UTHSC IRB Form 1: Study/Project Application*, the investigator should explain recruitment methods and materials, including but not limited to:

- a. which key study personnel will be involved in screening and recruitment procedures;
 - b. the subject population(s) that will be included in the study/project;
 - c. how potential subjects will initially be identified;
 - d. the recruitment method(s) that will be utilized;
 - e. the screening procedure(s) that will be used;
 - f. the approaches that will be used to ensure the privacy and confidentiality of potential subjects;
 - g. whether subjects will receive compensation for participation;
 - h. whether information/data, including PHI, will be collected during recruitment;
 - i. whether identifying data collected during recruitment and/or screening will be retained; and
 - j. if the screening process involves review of medical/dental records, investigators must obtain prospective HIPAA authorization or request a waiver of the HIPAA authorization. See UTHSC SOP [HIPAA Authorization for the Use of PHI in Research](#).
3. 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.
4. **Telephone Scripts** – The first contact prospective study subjects make is often via telephone with key study personnel who follow a script to determine basic eligibility for a specific study. The telephone script should be submitted to the UTHSC IRB for review and approval. The telephone script should include:
- a. Identification of the study, the caller and his/her affiliation with UTHSC or one of the affiliate institutions;
 - b. The names of the investigator(s) responsible for the study;
 - c. An estimate of the time to complete the interview;
 - d. A question that allows the potential subject to opt out of the telephone interview, or schedule a more convenient time;
 - e. A description of the types of questions that will be asked especially the most personal and sensitive a subject can expect;
 - f. A statement that the subject's participation is voluntary and if he/she chooses not to participate or stop participating at any time, his/her decision will not result in a penalty or after his/her rights;
 - g. A request for verbal consent before proceeding with the questions, and a statement about what will be done with the screening data if the potential subject is not enrolled; and
 - h. The arrangement of an appointment or next step for those eligible potential subjects who wish to continue.

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.
5. **Electronic Media** – Examples of electronic media used for recruitment include advertising on a website or electronic bulletin board, text messages, email solicitation, chat rooms, instant messaging, banner ads, discussion forums, blogs, YouTube, and social media sites such as Facebook, Twitter, Instagram, LinkedIn, etc.

- a. Recruitment procedures and materials used with electronic media must follow the content guidelines outlined above.
 - b. Recruitment materials bearing the UTHSC name or logo should follow the UTHSC Branding Guidelines for guidance in the correct use of these elements and all items bearing any UTHSC logo should be submitted to the UTHSC Office of Communications and Marketing for approval prior to production.
 - c. Recruitment materials bearing the name or logo of an institution affiliated with the research should follow the appropriate institutional guidelines and procedures.
 - d. To utilize one of UTHSC's ListServes (e.g., Faculty, Staff, Student ListServes, etc.) contact Communications and Marketing at communications@uthsc.edu.
 - e. ResearchMatch.org is an online recruitment and education platform that securely matches people interested in participating in research with researchers throughout the US. Visit [ResearchMatch – For Researchers](#) for more information.
 - f. Enterprise Data Warehouse (EDW) is maintained by the Center for Biomedical Informatics at UTHSC and contains electronic medical data. For more information visit [CBMI website](#).
 - g. If standard texting rates will apply, this should be explained in the submission to the IRB.
6. **Print advertisements** – Examples of print media used for recruitment include but are not limited to advertisements, flyers, information sheets, posters, notices, bulletin boards, and recruitment letters.
- a. 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 compensation will be administered in order for the IRB to review the layout of the advertisements well as the content.
 - b. Recruitment procedures and print materials must follow the content guidelines outlined above.
 - c. Recruitment materials bearing the UTHSC name or logo should follow the UTHSC Branding Guidelines for guidance in the correct use of these elements and all items bearing any UTHSC logo should be submitted to the UTHSC Office of Communications and Marketing for approval prior to production.
 - d. Recruitment materials bearing the name or logo of an institution affiliated with the research should follow the appropriate institutional guidelines and procedures.
7. 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.

8. **Radio, video, audio-taped, television, internet-based and mobile-based** recruitment materials must also be submitted for IRB review and approval. Some audio or video files may be too large for the IRB electronic system, iMedRIS. In such situations, the script of these materials may be submitted to the IRB for review and approval.
9. **QR Code** – Quick Response (QR) code is a specific two-dimensional code, which can be read by QR barcode readers or a camera phone. The use of a QR code should be explained in the submission to the UTHSC IRB. In addition, the materials to be accessed (“behind”) via the QR code should be submitted to the UTHSC IRB for review and approval.
10. **Employee Recruitment** – Employees who participate in research may be vulnerable to undue influence and coercion. Such research may also raise concerns about confidentiality. Employee participation raises questions about the ability of employees to exercise free choice, for example, because of the possibility that a decision to participate could affect performance evaluations or job advancement, even if it is only the employee’s perception that this is the case. In the case of coercion, refusal to participate might result in a loss of benefits (e.g., salary increases, time off). In the case of undue influence, a decision to participate could result in a job promotion. Employees are likely to view their employers as authority figures to whom they must show deference, which could undermine the freedom of their choice. If appropriate, the investigator should explain in the submission to the IRB:
 - a. A justification for the inclusion of employees;
 - b. Procedures to mitigate coercion or undue influence;
 - c. The investigator(s) or key study personnel must not impose any occupational penalty, direct or implied, on those individuals who do not volunteer;
 - d. The investigator(s) or key study personnel must not indicate to any potential subjects that research participation imparts any competitive occupational advantage, direct or implied, over other individuals who do not volunteer for research; and
 - e. Avoid the involvement of anyone in the recruitment process who may be in the employee’s chain of command.

If a research study will include UTHSC employees and these subjects will receive study compensation via their University paycheck, this should be explained in the *UTHSC IRB Form 1: Study/Project Application* and consent form(s).

11. **Student Recruitment** – Students who participate in research may be vulnerable to undue influence and coercion. Investigators should consider that student participation in research may not be voluntary because of a desire on the part of the students to appear cooperative or highly motivated.

Reasonable levels of extra credit or rewards may be offered for participating in research. If extra credit or rewards are offered for participation, students must be provided with and informed of non-research alternatives involving comparable time and effort to obtain the extra credit in order for the possibility of undue influence to be minimized. However, if participation in research is a course requirement, students must be informed of non-research alternatives involving comparable time and effort to fulfill those requirements in order for the possibility of undue influence to be minimized. Moreover, students must not be penalized for refusing to participate in research

If appropriate, the investigator should explain in the submission to the IRB:

- a. Students participation is voluntary;
- b. Student participation in the research will not impart any competitive academic or occupational advantage;
- c. Investigators who propose enrolling their own students should carefully consider the appropriateness of enrolling individuals they directly supervise or instruct;
- d. The Family Educational Rights and Privacy Act (FERPA) is applicable if the research includes the review of student records for the purpose of identifying, contacting, and recruiting subjects.
 - i. If the University determines that the researcher making the request to use identifiable education records without student consent is a “school official” with a “legitimate educational interest”, then a written agreement between the University and the school official in order to grant approval for the research study using identifiable education records is not required;
 - ii. A UTHSC student researcher is not considered a school official unless:
 - he/she is also employed by UTHSC and is conducting research with student education records under his/her employed UTHSC position; OR
 - he/she is serving on an official committee and is conducting research with student education records under that position; OR
 - he/she is assisting a school official in performing his/her tasks (which means that the school official must also be listed on the research application).
 - iii. A UTHSC student researcher who does not meet the above 3 requirements/situations on a research application without a UTHSC school official also being named on the application, he/she will need a written agreement with the University to be able to access and use the identifiable education records before the IRB can approve the research study;
 - iv. A non-UTHSC researcher who is listed on an application with a UTHSC school official will need a written agreement with the University to be able to access and use the identifiable education records before the IRB can approve the research study.

12. IRB review and approval of **listings of clinical trials** on the internet is not always 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), the government-sponsored AIDS Clinical Trials Information Service (ACTIS), and the ClinicalTrials.gov website

13. Advertisements included with the initial review of the *UTHSC IRB Form 1: Study/Project 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:** the IRB approval stamp can only be placed at the top left of the document; therefore, you will need to leave adequate space for the stamp in that area.
14. 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:** the IRB approval stamp can only be placed at the top left of the document; therefore, you will need to leave adequate space for the stamp in that area.
15. 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.
16. 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.
17. A copy of all advertising / recruitment materials and IRB / investigator correspondence will be kept in the electronic IRB files for the study.