

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

**I. PURPOSE**

To document the procedures for review of study advertisements and other subject recruitment materials submitted to University of Tennessee Health Science Center 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, and investigators.

**III. BACKGROUND**

Recruitment for research studies, including advertising directed toward potential subjects, is properly conceptualized as part of the informed consent and subject selection process. As part of the informed consent process, recruitment activities should contribute to a knowledgeable and voluntary consent by prospective subjects. That is, recruitment activity must support an accurately informed choice about participation in research, and it must assist subjects in making a voluntary choice, free from any element of coercion or undue influence. Facilitating a knowledgeable choice necessitates that key features of a research study be accurately described in recruitment materials. These basic elements include the purpose of the study, the types of subjects being recruited, the activities in which they must participate, the time commitment involved, major risks and benefits, and any compensation that subjects may receive. Recruitment materials must also encourage a voluntary choice on the part of prospective subjects. This requires that participation incentives are presented in a manner that does not undermine

careful consideration of the risks, discomforts and inconveniences associated with participation.

Recruitment activities must also contribute to fair selection of subjects. The content of these materials, the audiences to which they are geared, and the placement of advertisements in various media formats and outlets must be such as to promote fair representation of subjects with respect to gender, race, ethnicity, religion, and sociodemographic status. In some cases, assuring fair representation may necessitate special recruitment strategies to reach groups of prospective subjects who are generally more difficult to recruit for research studies.

There are also important pitfalls that must be avoided in the content of recruitment materials. First, FDA guidance on advertising and recruitment materials specifies that no claims should be made, either explicitly or implicitly, that a 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 mislead subjects, but would also violate the agency's regulations concerning the promotion of investigational drugs [21 CFR 312.7(a)] and investigational devices [21 CFR 812.7(d)]. Second, advertising for 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 established worth. Third, 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.

Recruitment strategies for research studies may also be directed to individuals other than prospective subjects, such as health professionals who might refer their patients for study participation or current research subjects who might recommend others as potential participants. For example, "dear doctor" letters might be sent to physicians to encourage referral of their patients to a study, and subjects might be asked to suggest friends or family who may be interested in participation.

**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](#)

[Clinical Trial Websites: When is IRB Review Required and What Should IRBs Consider with Reviewing? \(OHRP Guidance, 2005\)](#)

**FDA Regulations and References:**

21 CFR 50.20, 21 CFR 56.111

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

[FDA Information Sheet – Screening Tests 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**

**Advertisements and other recruitment materials** refer to, but are not limited to: materials to be published in local newspapers, broadcasts on television or radio networks, notices 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 in the definition are:

- (1) communications intended to be seen or heard by health professionals, such as letters from investigators to other physicians soliciting study subjects;
- (2) news stories about current research studies; and
- (3) information intended for audiences other than prospective subjects, such as financial page advertisements directed toward prospective investors.

**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 access to needed health care may be limited or lost if he or she does not participate in the research. Coercion always involves a threat to motivate the behavior of another, while inducements motivate behavior by the offer of benefits.

**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. There are two types of compensation in research:

- (1) Reimbursements are intended to cover out-of-pocket expenses that research subjects may incur during participation in research, such as expenses related to travel, meals, parking and overnight housing.
- (2) Incentives (such as cash payments, gift cards, etc.) are intended solely to encourage prospective subjects to accept the risks, discomforts and inconveniences associated with study 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. UTHSC **prohibits** 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.

**Games of Chance.** Games of chance are forms of gambling which, under Tennessee law is defined as "risking anything of value for a profit whose return is to any degree contingent on chance." Examples that are given in the statute include "slot machines [and] roulette wheels." Tenn. Code Ann. § 39-17-501. Lotteries and raffles are also games of chance. Lottery is defined as "the selling of anything of value for chances on a prize or state." TCA 39-17-501(5). Raffle means a game of chance in which a participant is required to purchase a ticket, share, chance or similar item for a chance to win a prize, with the winner to be determined by random drawing. The Tennessee Attorney General has opined that the crimes of gambling and lottery only occur if the participants risk loss of money when participating in the activity. As a result, lotteries or drawings as a form of payment for research subjects are permissible under state law provided that the participants do not risk their own money to gain a chance at any proffered reward.

**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.

**Undue Inducement** occurs when benefits external to the study activities themselves may cause a prospective subject to not consider with sufficient care the risks, discomfort and/or inconveniences associated with study participation. Undue inducement most frequently involves offer of an excessive financial incentive for participation. Unlike coercive threats, inducements motivate behavior by the expectation of benefits, rather than threats of harm.

## V. PROCEDURES

1. Requests to use advertisements, solicitations, and/or other 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 individually identifiable information/data, including PHI, will be collected during recruitment; and
  - i. whether individually identifiable data collected during recruitment and/or screening will be retained.

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 other 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.
  - 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.
  - d. 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.

- e. When appropriately worded, the following items may be included in advertisements. It should be noted, however, that the inclusion of all of the listed items is not required.
    - 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.
  - f. 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** – If the first contact with prospective study subjects occurs via telephone with key study personnel who follow a script to determine basic eligibility for a specific study, then 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 name(s) 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 those generally considered personal and sensitive;
  - f. A statement that the subject's participation is voluntary and if he/she chooses not to participate or to withdraw at any time, his/her decision will not result in any penalty or affect his/her rights;
  - g. A request for verbal permission 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 might qualify for another study; and
  - d. whether paper copies of records are shredded or readable copies are 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 regarding 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 other institutions affiliated with the research should follow the appropriate institutional guidelines and procedures.
  - d. If you will utilize text messages to recruit subjects and standard texting rates will apply, this should be explained in the submission to the IRB
  - e. To utilize one of UTHSC’s ListServes (e.g., Faculty, Staff, Student ListServes, etc.) contact Communications and Marketing at [communications@uthsc.edu](mailto:communications@uthsc.edu).
  - f. ResearchMatch.org is a nonprofit program funded by the National Institutes of Health (NIH) that helps connect people interested in research studies with researchers. UTHSC is a one of the participating institutions. For more information about utilizing this platform for your study visit [ResearchMatch – For Researchers](#)
  - g. Enterprise Data Warehouse (EDW) is maintained by the Center for Biomedical Informatics at UTHSC and contains electronic medical data that may be utilized to recruit potential research subjects. For more information visit [CBMI website](#).
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 an explanation of the type of media to be used in order for the IRB to review the layout, content and placement of the advertisements.
  - 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 regarding 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 other institutions affiliated with the research should follow the appropriate institutional guidelines and procedures.
  - e. The use and posting of print advertisements should follow the appropriate guidelines and procedures of the institutions in which they are placed.
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. **Games of Chance**, including lotteries, raffles and drawings, are permissible as forms of incentives for prospective subjects to participate in research, provided the following conditions are satisfied:
    - a. Subject participation in a game of chance may occur upon enrollment in a study or may be contingent on compliance with the protocol and completion of the study;
    - b. The opportunity to participate in the game of chance must not be contingent on the subjects risking their own money to secure a chance to win;
    - c. The prize offered must not be of such a magnitude that it would constitute an undue inducement, i.e., it must not cause prospective subjects to fail to consider with sufficient care the risks, discomforts and/or inconveniences associated with study participation;
    - d. All subjects participating in the study must have the same fair chance to win the lottery and the prize at stake (such as a gift card, iPad, etc.) must be the same for all participants; and
    - e. The only exception to the fair chance requirement is when the study is designed to evaluate the impact of different forms of payment on some desired dependent variable, such as treatment compliance.

- 11. Employee Recruitment** – Employees who participate in research may be vulnerable to undue inducement and coercion. Employee participation raises questions about the ability of employees to exercise free choice because employees may believe that the decision to participate could positively impact performance evaluations and job advancement, or that refusal to participate might result in loss of benefits, such as salary increases or time off. The free choice of employees may be unduly affected by these beliefs even if they have no basis in fact. Research involving employees may also raise concerns about the confidentiality of data recorded about them during the research. The investigator should describe in the submission to the IRB:
- a. A justification for the inclusion of employees;
  - b. Procedures for assuring that the investigator(s) or key study personnel will not impose any occupational penalty, direct or implied, on those individuals who do not volunteer;
  - c. Procedures for assuring that the investigator(s) or key study personnel will 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;
  - d. Procedures for notifying prospective subjects who are employees that their employment status will not be affected in any way by the decision about participation; and
  - e. A plan for the recruitment process that will not include anyone who may be in the employee's direct chain of command, or a satisfactory explanation as to why this condition cannot be satisfied.

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).

- 12. Student Recruitment** – Students who participate in research are vulnerable to undue inducement and coercion with respect to their academic standing. Undue inducement may occur when students are offered extra credit for participation in research without being provided alternative ways to secure the same credit. Coercion may occur if students are led to fear that failure to participate in research will label them as less cooperative or less motivated academically, perhaps affecting the overall assessment of their performance. In addition, if the research involves the review of academic records, the legal privacy rights of students under The Family Educational Rights and Privacy Act (FERPA) must be fully respected. Therefore, the following requirements apply to recruitment of student subjects in research:
- a. Investigators must explain how the decision about research participation will not impart any competitive academic or occupational advantage or disadvantage. Reasonable levels of extra credit or rewards may be offered for participating in research. However, 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.. If participation in research is a course requirement, students must be provided with non-research alternatives involving comparable time and effort to fulfill those requirements. Moreover, students must not be penalized or perceive that they might be penalized in any way for refusing to participate in research.

- b. Investigators proposing to enroll their own students should carefully explain how they will mitigate any perception on the part of prospective student participants related to undue inducement or coercion.
- c. If the Family Educational Rights and Privacy Act (FERPA) is applicable because the research includes the review of student records for the purpose of identifying, contacting, recruiting, and/or studying students, then:
  - i. If the University determines that the researcher who is making the request to use individually 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 granting approval for the research study using individually identifiable education records is not required;
  - ii. A UTHSC student researcher is considered a school official only if:
    - 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. If a UTHSC student researcher does not meet the above 3 requirements/situations on a research application without a UTHSC school official also being named on the application, then he/she must secure and submit to the IRB a written agreement with the University permitting the use of the individually 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 must secure and submit to the IRB a written agreement with the University permitting the use of the individually identifiable education records before the IRB can approve the research study.

**13. Family Member Recruitment** – When a family member is asked to recruit another family member or members for a research study, the investigator should consider how best to protect the free choice, privacy and confidentiality of family members who may be identified as potential subjects. As applicable, the investigator should explain in the submission to the IRB:

- a. Whether medical information will be collected from individuals who are current subjects about other family members who may qualify for study participation;
  - b. Whether current subjects will be asked for the names of other family members without first securing the approval of other family members to disclose their names to investigators;
  - c. Who will be responsible for contacting other family members to determine their interest in study participation;
  - d. What procedures investigators will use to assure that other family members are not unduly influenced by the current subject when deciding about participation in the research;
  - e. How investigators will assure that the data secured from various family members remains confidential, unless disclosure to other family members who are subjects is permitted by the terms of the consent agreement;
  - f. Why it would not be practicably possible to conduct the study if only alternative recruitment strategies not relying on current family members were utilized.
14. IRB review and approval of **Listings of Clinical Trials on Websites** is not typically required when the system format limits the information provided to basic trial information, such as the study title, the purpose of the study, a summary of the protocol, the basic eligibility criteria, study site location(s), and 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 listings, the government-sponsored AIDS Clinical Trials Information Service (ACTIS), and the ClinicalTrials.gov website.

When information posted on a clinical trial website exceeds directory listings with basic descriptive information, such information is considered part of the informed consent process and therefore requires IRB review and approval. Information exceeding basic listing information includes descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information.

15. 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.
16. Advertisements submitted after the initial review may be reviewed on an expedited basis by the IRB chair or designated IRB member. If the reviewer

is not able to approve the application due to concerns about whether IRB requirements are satisfied, then 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.

17. The UTHSC IRB must review any revision(s) 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.
18. 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.
19. A copy of all advertising / recruitment materials and IRB / investigator correspondence will be kept in the electronic IRB files for the study.