UT Health San Antonio Institutional Review Board

GUIDELINES FOR ADVERTISING TO RESEARCH SUBJECTS

UT Health San Antonio interprets federal regulations, in accordance with the interpretation of the Office Human Research Protection and the Federal Drug Administration (FDA), to provide Institutional Review Board (IRB) authority and responsibility for review of study recruitment materials, including **advertisements**.

ADVERTISEMENTS FOR RESEARCH REQUIRING IRB REVIEW:

Direct advertising for study subjects initiates the informed consent and subject selection process and IRB review is required for direct recruitment materials that are intended to be seen or heard by prospective subjects to solicit their participation in a research study. Advertisements to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest.

The IRB must review:

- *The information contained in the advertisement.*
- *The mode of its communication.*
- *The final copy of printed advertisements.*
- *The final audio/video taped advertisements.*
- *Amount and schedule of any payments*

**IRB review of the above is required independent of whether the material/recruitment is created/conducted by the investigator, the sponsor, or a third party.*

Examples of direct advertisement include: posted notices, paid and unpaid newspaper solicitations or magazine advertisements (which may include public service announcements), websites, radio or television advertisements (which may include public service announcements), bulletin board announcements, recruitment posters, flyers, video recruitment tapes, Internet/website/social media postings and solicitations by electronic mail.

Examples of similar release of information that do not constitute advertisement requiring IRB review: Clinical Trials Websites under specific conditions; Press Release / News Stories under specific conditions; Communication intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting new subjects); and Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors. (Note: use of the term "dear doctor" letter is not meant as used in distributing important information about drugs under 21 CFR 200.5 (commonly referred to as "Dear Doctor Letters").

• **Clinical Trials Website:** When information posted on a clinical trial website goes beyond directory listings with basic descriptive information; such information is considered part of the informed consent process and therefore requires IRB review and approval. Basic descriptive information includes:

study title
purpose of the study
protocol summary
basic eligibility criteria
study site location(s), and
how to contact the study site for further information.

Information exceeding such basic listing information includes potential subject screening procedures, descriptions of clinical trial risks and potential benefits, description of potential incentives, or solicitation of identifiable information.

• **Press Release or News story:** University press releases that mention human volunteers for research studies are to be considered as "news stories."

1. News stories are not subject to the Common Federal Rule governing direct advertising for research subjects.
2. Stories should avoid creating a "therapeutic misconception" that just because this is a research study, it must provide benefit to the participant.
3. The word "research" should be included with "study" on first reference in stories, although it is not strictly required on later references.
4. Press releases in general should not overstate the benefits versus risks of participation in a research study.
5. It is advisable for release writers to point out when study participation is strictly altruistic versus providing actual benefit.
6. Consequently, evidence of approval is not necessary before distribution of university press releases mentioning human study volunteers.
7. However, external affairs writers are advised to avail themselves of the trusted counsel that the IRB is ready to provide

on stories mentioning human study volunteers.

8. This counsel may be provided by e-mail between writers and the IRB Director or Designee.

GUIDELINES FOR ADVERTISEMENTS FOR RESEARCH REQUIRING IRB REVIEW:

• Claims should not be made in recruitment materials, 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 or make any claims that are inconsistent with applicable FDA labeling.

• Recruitment materials for 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 prospective study subjects to believe they will be receiving newly improved products of proven worth, and is inappropriate.

• For clinical trial websites that exceed basic listing information above, the IRB will also assess the types of incentives, if any, that are being offered to prospective subjects. Monetary and non-monetary incentives (e.g., access to services or programs) can create undue influence on a potential subject's decision about research participation. The IRB will ensure it is clear that participation in a study is voluntary, and that incentives for participation are not so great that they compromise a prospective subject's assessment of the risks or affect the voluntariness of his or her choices. Recruitment materials should not promise “free medical treatment”, when the intent is only to inform subjects that they will not be charged for taking part in the investigation. Recruitment materials may state that subjects will be paid to compensate for their time and/or travel, but should not emphasize the payment or state the amount to be paid by such means as larger or bold type. Advertisements must not allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

• It is advisable to point out when study participation is strictly altruistic versus providing potential benefit.

• When recruitment materials are to be taped for broadcast, the IRB reviews the final audio/video tape or may review and approve the wording of the recruitment materials prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be reviewed through expedited procedures.

ADVERTISEMENTS MAY CONTAIN THE FOLLOWING INFORMATION:

1. the name and address of the investigator and/or research facility;

2. the purpose of the research and, in summary form;

3. basic eligibility criteria;

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. and the name, email, and phone number of the person to contact for further information.

INTENT OF IRB REVIEW:

1. Identify misleading or coercive language. Determine whether the amount of payment and the proposed method and timing of disbursement is neither coercive nor presents undue influence. The IRB considers whether any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
2. Ensure for treatment protocols, that no claims, either explicitly or implicitly, are made that a proposed treatment is safe and effective or equivalent or superior to any other treatment. IRBs also ensure all information concerning payment, including the amount and schedule of payments, is set forth in the consent document.

3. The IRB reviews the final copy of printed advertisements to evaluate the relative size of type used and other visual effects.
4. The IRB ensures that advertisements do not state or imply a favorable outcome or other benefits beyond what is outlined in the consent document and the protocol or include exculpatory language.
5. The IRB reviews payments to determine that credit for payment accrues as the study progresses and is not contingent upon the participant completing the entire study.

USE OF SOCIAL MEDIA FOR RECRUITMENT

Research team members are prohibited from using personal social media accounts to recruit subjects.

It is the responsibility of the research team, when designing recruitment procedures to understand privacy and data security provisions of the social media site(s) that will be used for recruitment. Considerations should be made to determine if use of social medial for recruitment of the research population is appropriate.

Type of recruitment involving social media

1. Static – This is a post or advertisement where there is no anticipated interaction (e.g., liking, commenting, sharing) and is recommended for vulnerable populations.
2. Interactive – This is a post or advertisement where interaction is anticipated (e.g., liking, commenting, sharing). Using this method should include a note indicating that depending upon your personal privacy settings, comments placed on the post may be viewable by the public.
3. Recruiting through a group – This method involves the recruiting of participants by interaction with public and private groups maintained on the social media platform. Typically access to the group requires approval from the group's moderator if such exists.
4. Private messaging – This is two-way communication between the research team member and a prospective research participant using a private message within the social medial platform.

Social Media Management Plan

1. A list of social media sites that will be used for recruiting must be included as part of the IRB application.
2. If public or private groups will be used, provide approval from the group's moderator or confirmation that there is no moderator.
3. The process for responding to group member messages must be included as part of the IRB application. A note that this will be managed by the UTHSA Marketing team may be appropriate.
4. Submission of all recruitment materials to be utilized, including static/interactive posts:
    a. Advertisements
    b. Posts
    c. Images
    d. Banners
    e. Tags
5. If links to additional sites will be used, a screenshot of the landing page is required.

a. If the landing page includes a survey, ensure the screening process has been incorporated and approved as part of the IRB application.

6. A plan to address privacy, confidentiality, data security and identity verification for private messages on the social media platform must be included as part of the IRB application.
7. Include a description of any identifiable data to be collected through the social media site, how it will be stored and used.
8. Include the individual/role responsible for posting, monitoring, and responding to recruitment related communication on the social media site-- this may be a service provided by a third party through a contract.