HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL GUIDANCE

4.2 GUIDANCE FOR ADVERTISING TO RESEARCH SUBJECTS

RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD) **EFFECTIVE DATE: June 7, 2021**

I. RATIONALE AND TEXT

A. UT Southwestern Institutional Review Board (IRB) interprets federal regulations and Institutional policy, in accordance with the interpretation of OHRP and FDA, to provide IRB authority and responsibility for review of study recruitment material, including advertisements.

B. Because recruitment is considered part of the informed consent process, this guidance applies to the UT Southwestern IRB and the HRPPD who must review and approve all recruitment methods, as well as the content of the recruitment materials. Recruitment activities cannot be initiated until approval is received from the IRB. In addition, any changes to an approved recruitment tool must be submitted to the IRB for review as an amendment prior to implementing the changes (See 2.3 MODIFICATIONS TO RESEARCH).

II. SCOPE

A. This guidance applies to all materials intended for use to solicit or otherwise recruit participants into research studies reviewed by a UT Southwestern IRB.

III. GUIDELINES

A. 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

B. ADVERTISEMENTS MAY CONTAIN THE FOLLOWING INFORMATION**:**

- the name and address of the investigator and/or research facility;
- A summary of thepurpose of the research;
- basic eligibility criteria;
- a brief list of participation benefits, if any (e.g., a no-cost health examination);
- the time or other commitment required of the subjects; and
- the name and phone number of the person to contact for further information.

C. ADVERTISEMENTS FOR RESEARCH REQUIRING IRB REVIEW:

1. Direct advertising for study subjects is the start of 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.

    - 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.
    - IRBs reviewing advertisements, including clinical trial websites that exceed basic listing information above, also should 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. IRBs must 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. IRBs review advertising to ensure that advertisements do 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 recorded for broadcast, the IRB reviews the final audio/video or may review and approve the wording of the recruitment materials prior to recording to preclude re-recording because of inappropriate wording. The review of the final recorded message prepared from IRB-approved text may be reviewed through expedited procedures.

D. **INTENT OF IRB REVIEW:**

a. 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.

b. 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.

c. The IRB reviews the final copy of printed advertisements to evaluate the relative size of type used and other visual effects.

d. 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.

e. When such 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.

f. The IRB reviews payments to determine that credit for payment accrues as the study progresses and not be contingent upon the participant completing the entire study.

E. **Examples**

2. **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 postings and solicitations by electronic mail.

3. **Examples of similar release of information that do not constitute advertisement requiring IRB review:** Clinical Trials Websites under specific conditions (see below); 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").

4. **Clinical Trials Website:** When information posted on a clinical trial website goes beyond directory listings with basic descriptive information (or information listed in clinicaltrials.gov), 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),
- how to contact the study site
- Information exceeding such basic listing information includes descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information.

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

   g. News stories are not subject to the Common Federal Rule governing direct advertising for research subjects.

   h. Stories should avoid creating a "therapeutic misconception" that just because this is a research study, it must provide benefit to the participant.

   i. The word "research" should be included with "study" on first reference in stories, although it is not strictly required on later references.

   j. Press releases in general should not overstate the benefits versus risks of participation in a research study.

   k. It is advisable for release writers to point out when study participation is strictly altruistic versus providing actual benefit.

   l. Consequently, no IRB stamp of approval is necessary before distribution of university press releases mentioning human study volunteers.

   m. 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.

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

IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

V. REFERENCES

Resource
21 CFR 50 – PROTECTION OF HUMAN SUBJECTS
45 CFR 46 – PROTECTION OF HUMAN SUBJECTS
45 CFR 164 – SECURITY AND PRIVACY (HIPAA PRIVACY RULE)
21 CFR 56 – INSTITUTIONAL REVIEW BOARDS

VI. REVISION AND REVIEW HISTORY

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures