DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Institutional Review Board: Subject Recruitment and Review of Advertisements	Policy #: CRP-1060
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DEPARTMENT: DHR Health Institute for Research & Development	EFFECTIVE: 03/22
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 03/22

Purpose: Investigators involved in the conduct of human subject research that falls under the authority of the Office of Human Research Protection Program will be provided with instructions and guidelines for the recruitment of subjects and development of advertisement for IRB review and approval. The following are procedures for the investigator in developing and for the IRB in reviewing subject recruitment procedures and advertisements.

Applies To:
This policy applies to the following: staff and members of the Institutional Review Board; potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

General Recruitment Policies
Recruitment plans for research projects should be designed to fully encompass racial, ethnic, and gender diversity. Efforts to identify and recruit potential human research subjects should be designed to respect personal rights to privacy and confidentiality. Everything possible should be done to avoid coercion of subjects in their recruitment for research study participation. Recruitment of vulnerable subjects should be done with respect to the regulations at 45 CFR 46, Subparts B, C or D, as appropriate.

The IRB will evaluate the recruitment methods to ensure compliance with federal regulations as well as HIPAA Privacy rules. All print, video, and audio advertisements used to solicit prospective research subjects (‘directed advertising’) must be reviewed and approved by the IRB prior to dissemination.

The IRB prohibits cold-calling of potential research subjects. "Cold-calling" is the practice of investigators or research staff, unknown to the potential research subject, initiating contact with the potential subject based on their prior knowledge of private information. To avoid a cold-calling scenario, the research study should be introduced to the potential research subject by an individual who, by virtue of his/her position, would normally have access to the potential subject’s confidential information (e.g., the personal physician of the potential subject or a member of the clinic or practice staff). If the potential research subject indicates an interest in study participation, s/he should be instructed to either (a) contact the investigators directly or (b) permit the individual who initiated this contact to share with the research team the person’s interest in study participation so that the researchers can subsequently contact the potential subject and provide more information about the study.

Examples of acceptable methods of contacting and/or recruiting potential research subjects include:

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- Direct discussion of the study during a face-to-face interaction with a potential research subject.
- Mailings sent to the prospective subject from their provider, clinic, or program representative. Mailings can describe the purpose of the study and request that the subject return a postcard or make a telephone call indicating his/her agreement to participate. If no response is made within a specified time period, the subject may then be contacted by the investigator or a member of the research team. For studies involving children, the letter introducing the study should be sent to the child's parents and parental permission obtained prior to enrolling the child in the research study.
- Public advertisements or notices posted in public places.

Directed Advertising
Directed advertising includes, but is not limited to, newspaper, radio, TV, Internet ads, audio/video tapes, bulletin boards, posters, and flyers that are intended for prospective subjects.

The following are not considered to be 'direct advertising' and do not require prospective IRB review:

- Communications intended to be seen or heard by health professions, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects);
- News stories, so long as information is not provided regarding recruitment;
- Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors;
- Directories of clinical trials on the internet when the system format limits the information provided to the most basic trial information, such as the title, basic eligibility criteria, and how to contact the study site for additional information.

Examples of clinical trial listing services that do not need IRB review and approval include the National Institutes of Health (NIH) ClinicalTrial.gov website, the NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query [PDQ]), FDA Clinical Trials, and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).

When information posted on a clinical trial website goes beyond directory listings, such information is considered part of the recruitment and informed consent process and requires IRB review and approval. Examples of information which would exceed basic listing information include descriptions of clinical trial risks and potential benefits or solicitation of identifiable information (e.g., name and contact information).

Submission of Advertisements Directed at Potential Research Subjects
Advertisements directed at potential research subjects should be reviewed at the time of initial IRB review of the protocol. Advertisements directed at potential research subjects not reviewed at the time of initial IRB review must be submitted as a modification through the IRBNet system and reviewed in an expedited manner by the IRB Chair, Co-Chair or IRB staff.

- The IRB will review a final formatted version of printed advertisements to evaluate the relative size of type used and other visual effects.

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- When advertisements are to be taped for broadcast, the IRB will, at a minimum, review and approve the wording of the advertisement prior to taping, and, if made available review the final audio or videotape.

Approval Criteria
The following criteria must be met in order to gain IRB approval:

- Advertisements must contain the word “Research.”
- Advertisements cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the protocol and consent document.
- Advertisements cannot state or imply that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation.
- Advertisements cannot state or imply that the test article or other research intervention is known to be superior or equivalent to any other drug, biologic, device or intervention.
- Advertisements for recruitment into a research study involving an investigational drug, biologic, or device should not use terms such as "new treatment", "new medication", or "new drug" without explaining that the test article is investigational.
- Advertisements cannot promise “free medical treatment” when the intent is only to state that 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. Advertisements aimed at recruitment of children cannot contain the dollar amount of the compensation.
- Advertisements cannot include exculpatory language through which the participant or their legally authorized representative waive legal rights or releases the investigator, the sponsor or institution from liability for negligence.
- Advertisements cannot include 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.

The advertisement should generally be limited to the information that potential subjects need to determine their eligibility and interest in the research. When appropriately worded, the following items may be included in advertisements, but are not required:

- The name and address of the clinical investigator and / or research facility;
- The condition under study and/or the purpose of the research;
- In summary form, the criteria that will be used to determine eligibility for study participation;
- A brief list of participation benefits, if any;
- The time or other commitment required of the subjects;
- The location of the research and the person or office to contact for further information.

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Investigator Notifications
Investigators will be notified in writing of IRB approval of advertisements directed at potential research subjects. The written notification of IRB approval of the research will include a statement that the advertisement was approved by the IRB. In addition, the correspondence will specify that any substantive modification of the advertisement requires re-approval by the IRB prior to dissemination.

Incentives for Participation in Research Studies

General Policies
Subjects may be paid or otherwise rewarded (e.g., gift card) for participating in a research study. Note, however, that remuneration is a recruitment incentive; it is not a benefit of study participation. Incentives are frequently used when the benefit of study participation is otherwise remote or non-existent.

- The amount of payment, if any, should be reasonable, based on the complexities and inconveniences of the study. The amount of payment should NOT be based on the risk of study participation.
- The magnitude of the incentive and the proposed method and timing of its disbursement must not be coercive or present undue influence for initial or continued participation in the study.

Payment disbursement guidelines
Any payment or reward should accrue as the study progresses and not be contingent upon the human research subject completing the entire study. Disbursement of a proportion of the total payment or reward contingent upon study completion is acceptable, provided that the amount of this incentive is not so large as to unduly induce subjects to remain in the study when they might otherwise withdraw voluntarily.

IRB Review and Approval of Incentives for Participation in Research Studies
Information concerning the remuneration of human research subjects, including its amount or nature and the schedule of its disbursement, is subject to initial and continuing review by the IRB. This information must appear in the informed consent document(s). It cannot be included as a benefit of study participation.