Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 410: Recruiting Study Participants

POLICY

The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. In fulfilling these responsibilities, the IRB will review all research documents and activities that bear directly on the rights and welfare of the participants of the proposed research, including all recruitment materials.

Generally, the IRB discourages investigators from recruiting or enrolling themselves, their interns, or their staff in their own studies, but the IRB will review such situations on a case-by-case basis. The IRB shall consider the degree of risk and likelihood of benefit to the participants and the protections for participants from coercion or undue influence.

The IRB does not allow investigators or key study personnel to accept bonus payments as incentives for participant recruitment.

PROCEDURES

1. Direct Advertising

1.1 The IRB and the FDA consider direct advertising for study participants to be the start of the informed consent and participant selection process. Direct advertising for research participants (i.e. advertising that is intended to be seen or heard by prospective participants to solicit their participation in a study) is not, in and of itself, an objectionable practice. Direct advertising includes, but is not necessarily limited to: Newspaper, radio, TV, bulletin boards, posters, flyers, and e-mails that are intended for prospective research participants.

1.2 Direct advertisements do not include interviews, communications intended to be seen or heard by health professionals, such as 'Dear Doctor' letters (or communication with other types of practitioners for the purpose of soliciting assistance in identifying research participants) or doctor-to-doctor letters (even when soliciting assistance for study participants), news stories, or publicity intended for other audiences such as financial page advertisements directed toward prospective investors.

2. IRB Review of Advertisements for Research

2.1 The IRB shall review advertisements for research prior to their use by the researcher, usually as part of the initial review and approval of the research project. The Investigator shall submit the proposed advertisements at the time of the initial review or as an amendment to the approved protocol. When submitted as an amendment to the protocol, if the advertisement is easily compared to the approved consent form, the IRB Co-Chair may review and approve the advertisement by expedited means, as provided by 21 CFR 56.111(b)(2).

3. Format of Study Advertisements

3.1 Any advertisement to recruit participants should be limited to the information the prospective participants would need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. It should be noted, however, that FDA does not require inclusion of all of the items listed.

3.1.1 Name and address of the Investigator and/or research facility/institution

3.1.2 Condition under study and/or purpose of the research

3.1.3 Inclusion/exclusion criteria in summary form

3.1.4 A brief list of procedures involved

3.1.5 Time or other commitment required (number of visits, total duration including follow-up visits, etc.)

3.1.6 Compensation/reimbursement (DMH requires the amount not be specified)

3.1.7 Location of research and the contact person for further information

3.2 Additional guidelines include the following:

3.2.1 Advertisements cannot emphasize monetary compensation.

3.2.2 Advertisements cannot use catchy words like “free” or “exciting”.

3.2.3 Advertisements must be very clear that research participation is what is being solicited.

3.2.4 Advertisements cannot be misleading about the purpose of the research.

3.2.5 Advertisements cannot contain exculpatory language.

3.2.6 Advertisements cannot overstate the benefits.

3.3 DMH Requirement

3.3.1 Any “home grown” hand-out to be given to a patient must include the name of the Investigator and a contact number.

SCOPE

This SOP applies to all IRB members, the IRB administrator, and members of the research community.