

Wayne State University Human Investigation Committee	
Subject:	Advertising for Research Participants
Section:	
Form Date:	September 22, 2006
Approvals	3/18/98 Steering Committee, 4/25/98 Administrative Approval, 11/03/06, Revised Steering Committee, 11/08/06 Administrative Approval

Background:

Federal regulations require that an Institutional Review Board (IRB) review and have the authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [45 CFR 46.109(a), 38CFR16.109(a), 21 CFR 56.109(a)]. The IRB reviews, as part of this process, the methods that investigators propose to use to recruit participants.

One method of recruiting participants is through advertisements. Direct advertising for research participants is not in and of itself an objectionable recruitment practice but is seen as part of the informed consent and participant selection process. IRB review is necessary to ensure that information is not misleading to participants. This is especially critical when a study may involve vulnerable participants such as those with acute or severe physical or mental illness or persons who are educationally or economically disadvantaged.

Direct advertising includes, but is not necessarily limited to: newspaper, radio, TV, bulletin boards, posters, email and flyers that are intended for prospective subjects. **Not included** are: (1) communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects), (2) news stories and (3) publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title, purpose of the study, protocol summary, 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 listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). However, when the opportunity to add additional descriptive information is not prohibited by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

IRB approval is not needed for non-study-specific advertising because these materials do not specifically relate to an IRB-approved study/protocol/program. These materials are typically general in nature. They serve to facilitate subject recruitment by raising awareness, delivering information about being a research

subject, and providing links to information about specific research participation opportunities. Examples include:

1. Non-study-specific recruitment that does not match subjects to specific studies and registries
2. Generic information for prospective subjects
3. Research announcements that promote research in general to community and are intended to inspire interest of prospective subjects

HIC Policy/Procedure:

All advertisements for a research protocol must be submitted to the IRB for review and approval *prior* to their use.

The WSU IRB will review the final copy of printed advertisements to evaluate the content, relative size of type used and graphics. When advertisements are to be taped for broadcast, the IRB will review the final audio or videotape. The IRB is willing to review the wording of the advertisement prior to taping to preclude re-taping because of inappropriate content. The review and approval of a taped message prepared from IRB approved text may be accomplished through expedited procedures. If a clinical investigator decides to begin advertising for participants after a study has received IRB approval or makes changes to the currently approved advertisement, an amendment should be submitted for review and may receive expedited approval.

Criteria for advertisement review includes the following:

- Advertisements may not imply a certainty of favorable outcome or benefits beyond what is outlined in the informed consent.
- No claims should be made 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.
- The terms "new treatment", "new medication" or "new drug" should not be used without explaining that the test article is investigational.
- Advertisements should not promise "free medical treatment", when the intent is only to say that participants will not be charged for taking part in the investigation.
- Advertisements may state that the participants will be paid, but should not emphasize the payment or the amount to be paid. See HIC policy on "Compensation for Research Participants" for guidelines on compensation.
- Advertisements may not be coercive or imply undue pressure.
- Advertisements may be limited to the information the prospective participants need to determine their eligibility and interest.
- Advertisements may not include exculpatory language

Advertisements should include the following items.

1. The name and address of the clinical investigator and the identity of the research facility.
2. The condition under study and/or the purpose of the research.
3. The criteria, in summary form, that will be used to determine eligibility for the study.
4. A brief list of the benefits or incentives of participation, if any.

5. The time or other commitment required of the participants.
6. The name of the person or office to contact for further information.

Researchers can employ web-based or other recruiting mechanisms. If the text on the website is identical to text being used in flyers or newspaper advertisements, then the IRB only needs to receive one ad with appropriate indications of how and where this ad will be displayed. If an advertisement or posting is modified, the researcher must provide the IRB with an Amendment Form and the modified advertisement text for approval before it can be posted on the website.