

SOP: 410
STUDY RECRUITMENT AND ADVERTISEMENTS

1. POLICY

Generally, the IRB discourages investigators from recruiting or enrolling themselves, their students, or their employees 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 personnel to accept bonus payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”).

Payments for referrals of potential participants (“finder’s fees”) is not acceptable.

Potential research participants may be identified through any of the following methods:

Private Medical Information: Common resources for identifying potential research participants include the medical records, clinical databases, patient registries, and psychosocial screening databases. These resources allow the investigator to review records and identify eligible participants. The IRB/Privacy Board shall review and approve all methods of obtaining private health information before the investigator may use them.

Referring Physicians: Referrals from treating physicians can be useful in identifying potential research participants. Referring physicians who have been provided with general information about a research project may inform their patients that a research project is available and provide the patients with contact information to learn more about the project and whether they might be eligible. The IRB shall review all materials sent to referring physicians about the study.

Advertisements: 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. The investigator shall submit all advertisements to the IRB for review and approval as part of the package for initial review or as a protocol modification at a later time. The investigator may not use direct advertisements without IRB approval.

Direct advertisements that are intended for prospective participants include, but are not limited to the following:

- Newspaper
- Radio
- TV
- Bulletin boards
- Posters
- Flyers

- Emails

Direct advertisements do not include participant or Investigator 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 for study participants), news stories, or publicity intended for other audiences such as financial page advertisements directed toward prospective investors.

Direct advertisements may be reviewed and approved by the IRB as part of the package for initial review, or as a protocol modification at a later time.

Specific Policies

1.1 IRB Review of Study Recruitment Methods and Advertisements

- 1.1.1 The IRB shall review study recruitment methods and advertisements prior to their use by the researcher, usually as part of the initial review and approval of the research project. The Investigator shall include recruitment methods in the IRB application and submit the proposed advertisements at the time of the initial submission or as a modification of an approved protocol. The Investigator shall not use the methods or advertisements in the recruiting process without IRB approval.
- 1.1.2 The IRB shall review direct advertising to assure that it is not unduly coercive and does not overstate the potential benefits of the research beyond what is outlined in the consent and the protocol. This review is especially critical when a study may involve participants who are likely to be vulnerable to undue influence. Advertisements shall be limited to the information necessary for potential participants to make an informed decision.
- 1.1.3 When direct advertisements are not included in the initial project plan and are not submitted to the IRB at the time of initial submission, if the Investigator later decides to advertise for participants, the Investigator shall submit the documents to the IRB as an amendment to the ongoing research project.
- 1.1.4 The IRB shall review the information contained in the advertisement, the mode of its communication, the final copy of printed advertisements, and/or the final audio/video taped advertisements.
- 1.1.5 The IRB shall review advertisements to make certain advertisements do not use terms, such as "new treatment," "new medication," or "new drug" without explaining that the test article is investigational. The IRB shall review advertisements to make certain exculpatory language is not included in advertisements.

1.2 Advertisements to Recruit Participants Include Only the Following:

- 1.2.1 The individual name or specific office or department and the accurate address and telephone number of the Principal Investigator, as well as the location of the research and the person to contact for further information;
- 1.2.2 Wording that effectively communicates the purpose of the research and, in summary form, the eligibility criteria that will be used to admit participants into the study; and
- 1.2.3 A straight-forward and truthful description of the benefits (payments or free treatment shall not be overstated or the main focus) to the participant from participation in the study, the duration of the study, and the treatment.
- 1.2.4 When appropriately worded, the Investigator **may** include the following in advertisements.
 - a. The name and address of the investigator and/or research facility;
 - b. The condition being studied and/or the purpose of the research;
 - c. In summary form, the criteria that will be used to determine eligibility for the study;
 - d. A brief list of participation benefits, if any;
 - e. The time or other commitment required of the participants; and
 - f. The location of the research and the person or office to contact for further information.

1.3 Advertisements to Recruit Participants SHALL NOT:

- 1.3.1 Mislead participants;
- 1.3.2 Claim, either explicitly or implicitly, that the drug or device is safe or effective for the purpose under investigation or that the drug or device is in any way equivalent or superior to any other drug or device;
- 1.3.3 Use terms such as “new treatment,” “new medication,” or “new drug” without an explanation that the test article is investigational;
- 1.3.4 Include exculpatory language;
- 1.3.5 Imply the research or investigator has a unique or special skill, remedy, or treatment;
- 1.3.6 Promise “free medical treatment,” when the intent is only to say participants will not be charged for taking part in the investigation. Advertisements may state that participants will be paid but shall not emphasize the payment or the amount to be paid by such means as larger or bold type.
- 1.3.7 Include monetary amounts as rewards or inducements to participate (they may, however, mention there will be compensation for the participant’s time or travel).

1.4 Payment to Participants

- 1.4.1 The IRB requires payment to participants to accrue as the study progresses and be prorated based on the number of study visits completed by the participant. It should not be contingent upon the participant completing the entire study. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to remain in the study when they would otherwise withdraw.

- 1.4.2 Compensation for participation in a study offered by the sponsor should NOT be in the form of a coupon, good for a discount on the purchase price of the product once it has been approved for marketing.
- 1.4.3 The IRB requires all information regarding payment, including the amount and schedule of payments, to be set forth in the informed consent document.

1.4.4 For VA Research:

Payment to participants for research is prohibited when the research is integrated with a patient's medical care and when it makes no special demands on the patient beyond those of usual medical care.

1.4.5 Payment to participants is permitted under the following circumstances:

- The research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the participant is being treated, and when the standard of practice in affiliated non-VA institutions is to pay participants in this situation.
- The research is a multi-institutional study and participants at collaborating non-VA institutions are paid for the same participation in the same study at the same rate proposed.
- The IRB has determined that payment of participants is appropriate in other comparable situations.
- The participant will incur transportation expenses that will not be incurred in the normal course of receiving treatment and are not reimbursed by another mechanism.

1.5 Equal Opportunity Statement

All advertisements shall contain the following statement: "The University of Oklahoma is an equal opportunity institution."

2. SCOPE

These policies and procedures apply to all advertisements that pertain to human participant research.

3. RESPONSIBILITY

The IRB is responsible for reviewing recruitment methods and all direct advertisements submitted by the Investigator that pertain to research projects involving human participants.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 56

5. REFERENCES TO OTHER APPLICABLE SOPS

None.

6. ATTACHMENTS

305-C New Study Approval Checklist

7. PROCESS OVERVIEW

7.1 Review of Advertisements by the IRB

- 7.1.1 The convened IRB shall review advertisements received with the initial submission of convened Board studies.
- 7.1.2 The IRB Chair shall review advertisements received with the initial submission that meet the criteria for expedited review.
- 7.1.3 The IRB Chair shall review advertisements received as an amendment to an ongoing research project.
- 7.1.4 The IRB shall review the information contained in the advertisement, the mode of its communication, the final copy of printed advertisements, and the final audio/video taped advertisements.
- 7.1.5 The IRB shall review advertisements to make certain that advertisements do not include language as described in 1.3 of this policy.
- 7.1.6 The IRB shall review advertisements to make certain that advertisements do not include exculpatory language.
- 7.1.7 The IRB Administrator generates an IRB letter communicating the action of the IRB/IRB Chair with regard to the advertisement and presents to the IRB Chair for signature.
- 7.1.8 For approved email advertisements, the IRB Administrator forwards an electronic copy of the email advertisement to the appropriate email distributor.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012