

SOP 410: Research Project Recruitment

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") are prohibited.

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

Private Medical Information: Common resources for identifying potential research participants include 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 approve all methods of obtaining private health information for study recruitment 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 for patients to learn more about the project and whether they might be eligible. The IRB shall review in advance all materials sent to referring physicians about the research project

Advertisements: The IRB and the FDA consider advertising for research project participants to be the start of the informed consent and participant selection process. Advertising that is intended to be seen or heard by prospective participants to solicit their participation in a research project is not, in and of itself, an objectionable practice. Investigators are required to submit to the IRB the final form of any advertising materials that will be used to recruit potential participants. At a minimum, advertising materials must include the title of the research project and the name and contact information of the investigator. In addition, investigators should include in their advertising materials a brief description of the research protocol, the length of time required to participate, the research project location and the University IRB assigned research project number.

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

- Newspaper
- Radio
- TV
- Bulletin boards

- Posters
- Flyers
- Postings to group listserves, the University or PI's website, Internet and/or Social Media
- Emails to participants not affiliated with the University
- Mass Mail (OUMM) to groups of participants affiliated with OU. Investigators must review the OU Information Technology Target Emailing policy if they wish to use this form of advertising.

(Note on the Norman campus, Investigators are required to include this language on their OUMM advertising submission: "The OU IRB has approved the content of this research recruitment message but the investigator is responsible for securing authorization to distribute this research recruitment message by mass email.")

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 research participants); news stories; or publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

Specific Policies

1.1 IRB Review of Research project Recruitment Methods and Advertisements

- 1.1.1 The IRB shall review research project recruitment methods and advertisements prior to their use by the Investigator, usually as part of the approval of the research project. The Investigator shall include recruitment methods in the IRB submission and upload 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 informed consent documents and the research protocol. This review is especially critical when a research project 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 regarding participation.
- 1.1.3 If direct advertisements are not included in the initial project plan and are not submitted to the IRB at the time of initial submission, but the Investigator later decides to advertise for participants, the Investigator shall submit the documents to the IRB as a modification 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 or electronic 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 articles is investigational. The IRB shall review advertisements to make certain exculpatory language is not included in advertisements.

1.2 Advertisements to Recruit Participants May Include Only the Following:

- 1.2.1 The individual name or specific office or department and the accurate address and telephone number of the 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 research project; and
- 1.2.3 A straightforward and truthful description of the benefits (payments or free treatment shall not be overstated or be the main focus) to the participant from participation in the research project, the duration of the research project, 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 research project;
 - 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 to say that 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). [Exceptions to this prohibition may be considered by the IRB on a case-by-case basis.](#)

1.4 Payment to Participants

- 1.4.1 The IRB requires payment to participants to accrue as the research project progresses and be prorated based on the number of research project visits completed by the participant. It should not be contingent upon the participant completing the entire research project. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to remain in the research project when they would otherwise withdraw.
- 1.4.2 Compensation for participation in a research project offered by the sponsor must NOT be in the form of a coupon, good for a discount on the purchase price of the research 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 documents.

1.5 Equal Opportunity Statement

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

1.6 VA Research Projects

For additional requirements for VA research projects, see SOP 603A: Veterans Affairs Medical Center.

2. SCOPE

This SOP applies 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

FDA Information Sheets-Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update

5. REFERENCES TO OTHER APPLICABLE SOPS

301: Research Submission Requirements

6. ATTACHMENTS

203-A HSC Reviewer Checklist

203-A-1 NC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 Review of Advertisements by the IRB

- 7.1.1 The IRB reviewer shall review advertisements received with the submission.
- 7.1.2 The IRB reviewer shall review the information contained in the advertisement, the mode of its communication, the final copy of printed or electronic advertisements, and the final audio/video taped advertisements.
- 7.1.3 The IRB reviewer shall review advertisements to make certain that advertisements do not include language, as described in Section 1.3 of this policy.
- 7.1.4 The IRB reviewer shall review advertisements to make certain that advertisements do not include exculpatory language.
- 7.1.5 After the IRB reviewer completes the review, the IRB Administrator shall process the submission following the procedures outlined in SOP 301: Research Submission Requirements.
- 7.1.6 On the HSC campus, for approved email advertisements, the IRB Administrator shall forward an electronic copy of the email advertisement to the appropriate email distributor in accordance with current policy.

APPROVED BY: _____ **DATE:** 09/09/2016

NEXT ESTABLISHED REVIEW DATE: AUGUST 2018