



UNIVERSITY OF  
SOUTH ALABAMA

**IRB SOP 1201**  
**Advertising and Subject Recruitment Materials**

**Purpose**

This Standard Operating Procedure (SOP) is to document the procedures for review of study advertisements and/or subject recruitment materials submitted to University of South Alabama Institutional Review Board (USA IRB).

**Scope**

This SOP applies to investigators and sponsors whose studies are reviewed and approved by the USA IRB.

**Definitions**

**Advertisement:** Any material **whose purpose** is to inform and invite potential subjects to participate in a research study and provides contact information for the potential subject to initiate study related communication. Typical recruitment materials includes:

**Indirect methods**

- bulletin boards, flyers and handouts, posters
- classified ads (print and online)
- general media (radio, television, online videos)
- journal or magazine articles (print and online) soliciting participation
- listserv emails
- newspaper ads (print and online)
- online ads
- press releases that contain recruitment elements
- social media posts

- websites and website postings
- presentations to the general public with the focus on recruitment may also be included

Examples of the above include Facebook, Google, Vimeo, Youtube, USA Health System Clinical Trials website posts. These lists are not all inclusive, please contact the IRB if you have any questions.

#### **Direct contact**

- letters
- e-mails
- telephone calls
- verbal consent scripts

### **Policy**

Recruiting is part of the informed consent process; therefore the recruitment and advertising methods must be reviewed by the reviewing IRB prior to their use by an investigator. The review is done to ensure that the information is not misleading to subjects. The IRB is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

It is also the responsibility of the reviewing IRB to determine that the procedure for recruitment is not coercive and that it accurately describes the likely risks and benefits of study participation. In addition, Federal Regulation states that selection of subjects must be equitable ([45 CFR 46.111](#)).

### **Procedures**

Every research protocol submitted for review must adequately complete the recruitment section, as applicable to the study, which clearly describes:

- how potential subjects will be identified
- how, where, and by whom subjects will be approached about participation
- when informed consent is obtained in relation to enrollment and the start of the study procedures; and
- if applicable, whether third parties will assist with recruitment of subjects and how.

The following are guidelines intended to offer guidance to researchers in advertising and recruiting participants for their studies.

## **1.0 Recruitment**

1. Advertising and recruiting procedures must protect potential participants' confidentiality.
2. When obtaining the names of potential participants from third parties, the investigator must consider whether any breach of confidentiality or privacy laws has occurred. For example, doctors must contact their patients for written permission before releasing their names to a third party.
3. Investigators are responsible for ensuring that approved procedures are followed by any third parties (e.g., therapists, teachers, or social-service providers) who may be aiding in the recruitment and/or advertising process.
4. There are acceptable means of recruiting USA students or personnel via email (e.g., requesting permission from listserv masters to post a message to a group, obtaining permission from student organizations to send a message to their membership, obtaining permission from a department head or other authority to send a message to use of wide-spread mass mailings to the campus community. All proposed methods of recruitment must be described in the research protocol and approved by the IRB.
5. Researchers may not share names of previous research participants with other researchers without permission from the participants.

## **2.0 Criteria for Advertisement Review**

- 2.1 Advertisements may not imply a certainty of favorable outcome or benefits beyond what is outlined in the informed consent.
- 2.2 Advertisements should state that it is for a research study.
- 2.3 Advertisements may not be coercive or imply undue pressure.
- 2.4 Advertisements may be limited to the information the prospective participants need to determine their eligibility and interest.
- 2.5 Advertisements may not include exculpatory language
- 2.6 Advertisements should not promise "free treatment", when the intent is only to say that participants will not be charged for taking part in the investigation.
- 2.7 Advertisements recruiting children must explicitly state that parental consent is required for participation (unless the IRB has granted approval for a waiver of parental consent).
- 2.8 Typically advertisements should include eligibility criteria.
- 2.9 The IRB requires that a copy of the planned advertisement and the mode of its communication to ensure that advertisements do NOT:
  - 2.9.1 State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the informed consent form and the application/protocol.
  - 2.9.2 Make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation.
  - 2.9.3 Use catchy words like "free" or "exciting."

- 2.9.4 Make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device.
- 2.9.5 Promise "free medical treatment" when the intent is only to say participants will not be charged for taking part in the investigation.
- 2.10 Advertisements may state that participants will be paid, but should not emphasize the payment or the amount to be paid by such means as larger or bold type.
- 2.11 Items that may be included in advertisements (the inclusion of all items is not required)
  - The name and address of the clinical investigator and the identity of the research facility.
  - The condition under study and/or the purpose of the research.
  - The criteria, in summary form, that will be used to determine eligibility for the study.
  - A brief list of the benefits or incentives of participation, if any.
  - The time or other commitment required of the participants.
  - 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.

### **3.0 Promotional materials**

As stated in FDA's Information Sheet Guidance on "Recruiting Study Subjects," FDA requires that an Institutional Review Board (IRB) review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109(a)]. An 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, an IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The protocol, the consent document and (for studies conducted under the Investigational New Drug (IND) regulations) the investigator's brochure are examples of documents that the IRB should review. The IRB should also review the methods and material that investigators propose to use to recruit subjects.

The current IRB procedure is to "acknowledge" these materials (rather than facilitating a formal review and signed approval letter). However, the IRB does review and approve materials used in media advertising to recruit study subjects. If advertising materials used to recruit potential subjects (i.e., newspaper ads, radio script, television) are submitted AFTER initial approval, an amendment request must be completed to facilitate review and approval. Additionally, all

clinical research newspaper ads must be approved for appropriate layout/design through USA Health Marketing, Office of Marketing and Communications.

It is the responsibility of the IRB to provide information based on its written standard operating procedures, and not to deviate to serve specific requests by of study sponsors. It is time intensive to provide study sponsors specific written documentation. The IRB needs to be consistent in following its written procedures for handling this type of request for review of promotional or study guidance materials.

## **Related University Documents**

[SOP 1202: Recruitment of Research Participants](#)

### **History:**

Effective Date:

Revisions: November, 2018

### **Responsible Office:**

Office of Research Compliance and Assurance