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)
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- 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 is are not all inclusive, please contact the IRB if you have any questions.

1.0

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

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
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