

ADVERTISEMENTS

Description

The IRB reviews recruitment methods, including advertisements to ensure that it does not interfere with the equitable selection of participants. The IRB reviews proposed advertisements and solicitations for research participation to ensure that they do not violate the regulatory requirements of consent. For more information on the topic of recruitment methods (including in-person recruitment, telephone calls, recruitment through databases containing health information, use of medical records for recruitment, etc.) please see Investigator Guidance Series: Recruitment Methods.

ADVERTISING GUIDELINES

Advertising is a common method used by researchers to contact potential participants. Examples of advertisements include flyers, brochures, television ads, radio ads, etc. When an individual is interested after coming into contact with an advertisement, he/she contacts the research team directly. The Investigator must obtain IRB approval prior to the use of all television, radio, print advertisements, e-mail solicitations, letters, websites, and other recruitment methods and materials intended for the recruitment of prospective research participants. Advertisements must be submitted to the IRB in their final form in order to receive IRB final approval for use.

Internet Advertising

Advertisements posted on the internet must adhere to the guidelines below. All advertisements must be approved by the IRB prior to posting. The researcher may submit the advertisement text to the IRB as a document for approval. The intended internet sites where the advertisements will be posted must be described in the Study Information section of the IRB application.

Researchers may use the Internet as a forum for disseminating study information to participants. The use of websites, blogs, internet forums, and social networking sites for the dissemination of study information must be described in the Study Information section of the IRB application. The IRB requires the following statement to be posted on internet sites used for this purpose:

The information posted on this site is consistent with the research reviewed and approved by the University of Utah Institutional Review Board (IRB). However, the IRB has not reviewed all material posted on this site. Contact the IRB if you have questions regarding your rights as a research participant. Also contact the IRB if you have questions, complaint, or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

What should advertisements include?

Advertisements for recruitment should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. The IRB does not require inclusion of all of the listed items.

- The name and address of the investigator or research facility/building.
- The purpose of the research or the condition under study.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of participation benefits, if any.
- The time or other commitment required of the participants.
- The location of the research and the person or office to contact for further information.

What is not acceptable in advertisements?

The IRB will not allow recruitment methods or advertisements that are misleading, inaccurate, exculpatory, coercive or unduly influential. The IRB will review advertisements to ensure that they **do not**:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and protocol.
- Include exculpatory language.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

Investigator Guidance Series

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- Emphasize the payment or the amount to be paid, by such means as larger or bold type. **Please Note:** The dollar amount to be paid to participants may be included in advertisements. However, the IRB may determine that stating the specific amount is coercive or unduly influential. In these instances, the IRB will only allow the advertisement to state that compensation will be offered without including the dollar amount.
- Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

What are the additional considerations for advertisements for FDA-regulated research?

The IRB advises all investigators conducting research subject to FDA regulation to review the FDA Information Sheet regarding Study Subject Recruitment (see below under References and Links). The IRB will review advertisements for FDA-regulated research to ensure that the advertisements **do not**:

- Make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA labeling (e.g. stating the test article is known to be equivalent or superior to any other drug, biologic or device).
- Use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.
- Allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

Points to Address

IRB Application:

1. Study Information: The following questions are asked:

- How will participants be recruited or identified for inclusion in the study?
- Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):

2. **Documents and Attachments (Recruitment Materials, Advertisements, etc.):** Please attach all recruitment materials for review in the sub-section entitled Recruitment Materials, Advertisements, etc. This includes recruitment letters, advertisements, flyers, scripts, etc. If a recorded advertisement is planned, audio or video files should be attached. Please note that if the final recorded version is not available at the time of review, the IRB must review the final script. Once the final audio or video is prepared from the IRB approved script, it must be submitted via amendment.

References & Links

Investigator Guidance Series:
Recruitment Methods

See “Recruitment Methods”:
http://www.research.utah.edu/irb/guidelines/investigator_guidance.html

FDA Information Sheet:
Recruiting Study Subjects

<http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting>

Recruitment Letter Template

See the IRB HIPAA Forms Menu: <http://www.research.utah.edu/irb/forms/healthScienceForms.html>

Simple Referral Template

See the IRB HIPAA Forms Menu: <http://www.research.utah.edu/irb/forms/healthScienceForms.html>

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