

Investigator Guidance Series

University of Utah Institutional Review Board

RECRUITMENT METHODS AND ADVERTISEMENTS

Description

The IRB reviews recruitment methods, including advertisements to ensure that it does not affect the equitable selection of participants. Additionally, the IRB considers recruitment to represent part of the consent process. The IRB reviews proposed recruitment processes and advertisements to ensure that they do not violate the regulatory requirements of consent.

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.

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.
- 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 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).

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

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- 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

Protocol Summary:	1. Administrative Responsibilities, Recruitment: Please describe methods of participant recruitment (e.g. flyers, advertisements, etc.).
Other Documents:	1. Recruitment Materials: Please attach all recruitment materials for review. 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

Protocol Summary

Template

FDA Information Sheet:

Recruiting Study

Subjects

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

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

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