

Advertisements

Overview:

Investigators may use various forms of advertising to recruit subjects. Brochures, newspaper ads and other print materials such as bus ads, as well as radio scripts, video, websites, and ads posted on social media such as Facebook and Twitter all require IRB review.

Description:

Direct Advertising

Direct advertising includes, but is not limited to, newspaper, radio, TV, Internet ads, audio/video tapes, bulletin boards, posters, and flyers that are intended to be seen by prospective subjects.

The following are not considered to be 'direct advertising' and do not require prospective IRB review:

- Communications intended to be seen or heard by health professions, such as “dear doctor” letters and doctor-to-doctor letters (even when soliciting for study subjects);
- News stories or other ‘general interest’ stories about research programs as long as information is not provided regarding recruitment;
- Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors;
- Directories or listings of clinical trials on the internet limited to the most basic trial information, such as the study title, eligibility criteria, and contact information for additional information. Examples include the National Institutes of Health (NIH) ClinicalTrial.gov website, the NIH National Cancer Institute clinical trials listing (Physician Data Query [PDQ]), FDA Clinical Trials, and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).
- When a clinical trial website includes additional information such as a description of risks and potential benefits, or asks participants to provide identifiable information such as name and contact information, this is considered to be part of the recruitment / informed consent process and requires IRB review and approval.

Submission of Advertisements Directed at Potential Research Subjects

All direct advertisements that will be viewed by a potential research subject must be reviewed and approved by the IRB prior to dissemination.

- When advertisements will be published, the IRB must review a final formatted version of printed advertisements to evaluate the relative size of type used as well as other visual effects. Pictures should be appropriate for the type of study.
- When advertisements are to be taped for broadcast, the IRB must review both the text of the advertisement prior to taping and the final audio or videotaped version. The IRB pays particular attention to the use of inflection in the recorder's voice to ensure that special attention is not called to wording such as payment to subjects.
- When advertisements will be posted on the internet, the IRB must review screen shots of each page to be displayed. It is not appropriate to include links as a substitute for screen shots as the information on the site may change over time.

Approval Criteria

The following criteria must be met in order to gain IRB approval:

- Advertisements must contain the word 'Research.'
- Advertisements cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the protocol and consent document.
- Advertisements cannot state or imply that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation.
- Advertisements cannot state or imply that the test article or other research intervention is known to be superior or equivalent to any other drug, biologic, device or intervention.
- Advertisements for recruitment into a research study involving an investigational drug, biologic, or device should not use terms such as "new treatment", "new medication", or "new drug" without explaining that the test article is investigational.
- Advertisements cannot promise "free medical treatment" when the intent is only to state that subjects will not be charged for taking part in the investigation.
- Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid by such means as larger or bold type.
- Advertisements aimed at recruitment of children cannot contain the dollar amount of the compensation.
- Advertisements cannot include exculpatory language through which the participant or their legally authorized representative waive legal rights or releases the investigator, the sponsor or institution from liability for negligence.
- Advertisements cannot include 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.

The advertisement should generally be limited to the information that potential subjects need to determine their eligibility and interest in the research. When appropriately worded, the following items may be included in advertisements, but are not required:

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

The IRB approval letter will include a statement that the advertisement was approved by the IRB. It is the responsibility of the investigator to submit modifications to either add new advertising material or change the content of the currently approved advertisement.

Considerations:

- It is not necessary to submit a Modification if the only change is to edit contact information.
- It is permissible to use IRB approved wording in a different media outlet as long as that outlet is broadly described in the recruitment section.
- When sharing information with third parties, make sure they are aware of the importance of maintaining the spirit of the IRB approved wording.
 - For example, it would not be appropriate to tweet a truncated version of an IRB approved ad that only includes the payment
- If any advertisements are aimed at non-English speaking subjects, both the foreign language and English version must be submitted.

OSIRIS:

Section 4, Question 4.1: Upload all forms of recruitment materials for review

Section 4, Question 4.2: Provide a detailed description of recruitment methods including the plan for dissemination of recruitment materials

If informational videos will be used for recruitment and are too large to be uploaded into the IRB application, a CD can be delivered to the IRB Office labeled with date of submission, PI name, study title, and IRB number. Include language in Question 4.2 that this process is being done. Once the information has been reviewed and approved, the IRB staff will attach an approval letter using “send comments to study team” as documentation.

Additional Information:

U.S. Food and Drug Administration

[Recruiting Study Subjects - Information Sheet](#)