University of Colorado Boulder

Office of Research Integrity
Institutional Review Board
3100 Marine Street | ARC Room A15
Boulder, CO 80309
irbadmin@colorado.edu | (303) 735 - 3702

Guidance Document: Advertising and Recruitment

Background

The IRB defines advertising as "any outreach effort designed to encourage potential subjects to contact the investigator requesting information." Because advertisements involve providing information to potential subjects in an effort to solicit their participation in research, this is considered to be an extension of the Consent and subject selection processes. Therefore, the CU-Boulder IRB must review and approve the information contained in all advertisements and the mode of their communication to ensure appropriate subject protection. Advertisements cannot be displayed or put to use until the IRB has approved the final copy of ads and the final version of audio/video tape recorded advertisements.

The following guidelines should be used for advertisements seeking subjects to participate in research studies at CU-Boulder.

General Information and Requirements

Do:

- Comply with the guidance in the FDA Information Sheet, "Recruiting Study Subjects".
- Include a clear statement that the information concerns a research study.
- Include general information about who is eligible to participate.
- Provide information about how to find out more about the study
- Be conservative with the use of pictures, graphics, fonts and symbols.
- Include the IRB Protocol Number

Don't:

- Do **not** state or imply that the FDA or IRB has approved the research.
- Do **not** refer to investigational drugs, devices, or procedures as *"new," "safe," "effective," "a cure," "treatment" or "therapy."*
- Do **not** call the investigational medication simply *"medication"* or *"drug"*; qualify each use appropriately with *"investigational" or "study"* as in *"investigational medication"* or *"study medication."*
- Do **not** emphasize payment to subjects or the word "free" (e.g., bold, large font, conspicuous coloring, dollar signs).
- Do **not** include payment amounts for studies involving underage subjects.
- Do **not** use the terms *"confidential"* or *"completely private."*
- Do **not** include exaggerated statements about the potential benefits of participating in the research, receiving treatment from the investigator, or receiving treatment from the organization
- Do **not** use the phrases *"Enrollment Limited," "Study ends soon,"* or *"Call today!"*
- Do **not** include the statements *"You deserve to feel better," "Join this study and take charge of your life,"* or similar phrases or logos.
- Do **not** include references to website recruitment content that has not been reviewed and approved by the IRB.

What type of advertisements require review and approval?

The IRB review policy includes, but is not limited to:

- Newspaper ads

Office of Research Integrity
Institutional Review Board
3100 Marine Street | ARC Room A15
Boulder, CO 80309
irbadmin@colorado.edu | (303) 735 - 3702

- Radio or television announcements
- Bulletin board tear-offs
- Posters
- Health fair materials about the study
- Online advertising or computer bulletin boards
    - Lab websites or pages that are designed expressly for informing potential subjects about research studies and soliciting participation must be reviewed before being posted/going live. The URL to the proposed website should be included in the Protocol, Recruitment Methods section.
- Research Subject Pools (for payment or course credit)
- Press releases designed to promote a study and encourage participation
- Presentations given to groups to solicit participants (scripts and/or PowerPoints).
- "Snowball" recruiting materials
- Mailings

What should advertisements include?

Advertisements to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. It should be noted that the IRB office does not require inclusion of all of the listed items:

- The name and address of the 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 the study
- A brief list of participation benefits, if any (e.g., a no-cost health examination)
- The time or other commitment required of the subjects
- The location of the research and the person or office to contact for further information

What does the IRB consider when reviewing advertisements?

- The advertisement cannot be misleading. It cannot make promises of safety or efficacy. Benefits or payments must be reasonably stated. (Outsized fonts emphasizing money and free services are not allowed.)
- No claims should be made, explicitly or implicitly, that the research is superior to any current practice.
- It must be clear that the opportunity is for research or an investigation.
- It should give the name of a primary contact and a method of making contact.
- It may give some brief eligibility criteria such as disease, condition, or age limits.
- It may give brief procedural information such as the location of the research, duration of participation, mode of administration and name of the test article.
- For e-mail or internet advertising, how secure (private, confidential) is the prospect's response?
- **The IRB will also consider placement of any advertising**. For each advertisement, please provide the following information in your protocol document:
    - The name or type of the media
    - The targeted audience of the selected media
    - Whether the medium selected is primarily designed to target a specific group (e.g., a specific ethnic or cultural group, gay or lesbian persons, adolescents, persons with HIV/AIDS, etc).

Office of Research Integrity
Institutional Review Board
3100 Marine Street | ARC Room A15
Boulder, CO 80309
irbadmin@colorado.edu | (303) 735 - 3702

What if I change my advertisement after it's been approved?

If you wish to change message content, message audience, or advertising strategies (e.g., add television ads) after IRB approval, this requires an Amendment submission. The Amendment, with the revised Protocol and any new or revised advertisements, must be reviewed and approved by the IRB before it can be used.

Can I recruit employees I supervise or students I teach?

Studies of subjects who are directly supervised by the investigator(s) or who are the investigator's students entail confidentiality problems and issues of coercion or obligation (either real or perceived) which are best avoided whenever possible. If potential subjects must be drawn from in investigator's classroom or employees, specific provisions must be included to minimize the possibility of undue influence to participate in the study to the greatest extent possible. For example, a non-supervisory co-investigator should directly recruit subjects rather than the supervising investigator or course instructor. Subject participation must in no way influence grading, course outcome or employment and subjects should be expressly informed of this. An exception is provided for small amounts of course credit where alternatives are available for obtaining credit that are of equivalent effort to research participation. Students are to be explicitly informed of this alternative to research participation to obtain credit.

How do I request approval of my advertisements?

1. Follow the basic instructions for an Initial Application or Amendment submission (for changes to existing advertisements/recruiting procedures) that are on our website at http://www.colorado.edu/innovate/irb/submit-irb-review/submission-guides. See the Initial Application or Amendment Submission Guide.
2. Be sure you have identified and clearly described the method(s) of advertisement for research subjects in your protocol document.
3. Attach a copy of the text or a printed copy of any website, newspaper, or other media advertisements you plan to use to your Initial Application or Amendment submission. Include a link to advertisements wherever possible. You will need to include any other forms of advertisement (e.g., electronic mail, letters to private practitioners, letters to potential subjects, etc.) for IRB approval as well.
4. Don't forget! The IRB must approve any and all advertisements prior to posting and/or distribution.