

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." Advertisements are an extension of the consent process and subject selection process. Therefore, the CU-Boulder IRB must review and approve recruitment methods and content of the materials to ensure adequate subject protection. The IRB must review the information contained in all advertisements and the mode of their communication. Advertisements cannot be displayed or put to use until the IRB has approved the final copy of printed 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.

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.
- Be conservative with the use of pictures, graphics, fonts and symbols.

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, 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 an IRB.
- Do **not** include statements of implied safety and/or efficacy.
- Do **not** include inappropriate promises of benefit.
- Do **not** include misleading content.
- Do **not** use potentially coercive or reassuring graphics, pictures, fonts or symbols.

What type of advertisements require review and approval?

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

- Newspaper ads
- Radio or television announcements
- Bulletin board tear-offs

- Posters
- Health fair materials about the study
- Computer bulletin boards or internet advertising (includes student research pool)
- 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. (Oversized 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).

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 advertisement, must be reviewed and approved before it can be used. The Amendment submission should include a copy of all new or revised advertisements.

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 should be avoided and will usually be disapproved by the IRB. In this setting, there are confidentiality problems and issues of coercion or obligation (either real or perceived) which are best avoided entirely. It is acceptable to advertise for subjects in approved areas in the investigator's department and allow individuals in the department who are not directly supervised by the investigator(s) to participate in research studies.

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://humanresearch.colorado.edu/submit-era/era-submission-instructions> . See the Initial Application training manual or Amendment training manual.
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. 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.