



## Advertisement Guidance for Subject Recruitment

Submit all subject recruitment materials with your application to: [irb@umontana.edu](mailto:irb@umontana.edu)

### Introduction to human subject recruitment

The Institutional Review Board must approve all materials for human subject recruitment before your recruitment efforts begin. This is a federal requirement. The Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) consider advertising the first step in the informed consent process. Federal Regulations [21 CFR 50.20, 21 CFR 50.25, and 21 CFR 56.111(a)(3)] require that the IRB review and approve all advertisements seeking participants for enrollment in research. The IRB is required to review such material for informational content as well as the mode of its communication (i.e., TV, radio, video, Internet, or print). Generally, any advertisement to recruit participants should be limited to the information the prospective subjects need to determine their eligibility and interest.

### What is an advertisement for subject recruitment?

An advertisement to recruit subjects is any material whose purpose is to inform and invite potential subjects to participate in research. These materials include:

- Bulletin boards
- Flyers and handouts
- Journal articles (if they contain recruitment information)
- Letters and e-mails
- Newspapers (paid and free classified ad and formal display ad)
- Posters
- Presentations to general public with focus being subject recruitment
- Press releases
- Radio (paid and public service announcement (PSA))
- TV and cable (paid and PSA)
- Website postings
- Telephone contact with potential subject

### What is NOT an advertisement for subject recruitment?

- Communications focused toward academic or health professionals, such as "Dear Professor/Doctor" letters and doctor-to-doctor letters (even when asking the physicians to refer potential subjects)
- News stories and press releases that DO NOT contain recruitment information
- Patient Education Materials to be distributed after the consent is signed or general information about the study when the focus is to inform but not to recruit

### How to develop advertising copy (text) for recruitment of human subjects:

Recruitment materials may contain any of the following elements:

- Name of the university. The department and/or division must also be included whenever possible. For non-display ads where space is an issue, "UM" is an acceptable abbreviation.
- Name of condition/subject/disease under study.
- Purpose of the research. Use lay language and aim for a sixth-grade reading level. Write in short, complete sentences. Make sure you are clear that you are **recruiting for research** as opposed to providing treatment. Make sure you use the word **research** at least once at the beginning.
- Major inclusion/exclusion criteria such as age/gender requirements. If extensive, do not simply copy the list from the protocol because this may be too much information too soon in the process. Just list the major ones.

- BRIEF list of procedures required. For example, blood tests, X-rays, MRI, etc. that will be performed as part of the study.
- Time commitment for participation. For example, number of visits, length of each visit and total length of study participation.
- Compensation. Compensation can be mentioned but not emphasized. It should not constitute the beginning of the ad. The font size should not be larger than other body text. Make it clear if the amount mentioned is per visit or at study completion.
- Contact Information. Primary contact name and info.
- Name of Primary Investigator (PI). This is only necessary if it is not the primary contact.
- Allow space for the IRB stamp (1" x 2.5"). Do not write in text "... approved by..."

**Note:** All elements listed above do not have to be present in every ad.

**Recruitment materials should not include the following:**

- Do not promise or imply treatment, cure or benefits. If the treatment is what is under investigation, then you must term it as such. Do say, "Investigational treatment will be provided." Do not simply state, "Treatment will be provided."
- Do not use "catchy" words like "free" and "exciting." Avoid all appearance of coerciveness.
- Do not use words that could be insulting to a potential subject. For example, use "overweight" instead of "fat," and "lean" instead of "skinny", etc.
- Do not use words that evoke the "YUK response" (such as pus, snot, etc.)
- Do not offer free care. The statement that "Study-related medications, exams, tests, etc. are provided free of charge" is acceptable. **Do not state "Free treatment" or "Free care."**
- Payment is not a benefit, and participation in research does not constitute employment. Do not use words such as "earn" or "make." Subjects can be "compensated," "reimbursed" for their time and/or travel, or may receive an "incentive" for participation.

**Questions?**

Please contact the IRB office at (406) 243-6672 or email [irb@umontana.edu](mailto:irb@umontana.edu).