BENAROYA RESEARCH INSTITUTE Virginia Mason

IRB RESEARCH RECRUITMENT & ADVERTISING GUIDANCE

Overview

The Benaroya Research Institutional Review Board (BRI/IRB) must review and approve all recruitment and advertising materials to been seen by human subjects in research prior to the use of those materials. This is an institutional and regulatory requirement for research. The Food and Drug Administration (FDA) considers advertising the first step in the informed consent process per 21 CFR 50.20, 21 CFR 50.25, and 21 CFR 56.111(a)(3) and require IRB's to review and approve all materials soliciting participation in research. See: *http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm*

BRI IRB is required to review such material for informational content as well as the mode of its communication (i.e. TV, radio, newspaper, web-site and bulletin board). Generally, the FDA believes any advertisement to recruit participants should be limited to the information the prospective subjects need to determine their eligibility and interest.

When can advertisements be submitted?

Ads can be submitted with initial approval documents, Continuing Review, or at any time following initial IRB study approval. When submitting materials separately, they should be accompanied by an IRB Study Modification form.

What is an advertisement for subject recruitment?

An advertisement to recruit subjects is any material whose purpose is to inform and/or invite potential subjects to participate in a study. These materials may include:

- Bulletin boards.
- Flyers and handouts.
- Journal articles *(if they contain recruitment information)*.
- Letters and e-mails to subjects.
- Newspapers *(paid and free classified ad and formal display ad)*.
- Posters.
- Presentations to the public with focus being subject recruitment.
- Press releases.
- Radio *(paid and public service announcement (PSA)*.
- TV and cable *(paid and PSA)*.
- Web-site postings *(unless limited to what would be cited on www.clinicaltrials.gov (i.e. title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and contact info)*.
- Telephone contact with potential subject.

What is NOT an advertisement for subject recruitment?

- Communications focused toward health professionals, such as "Dear 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.
- Publicity intended for audiences other than potential subjects, such as financial-page advertisements directed toward prospective investors.
- Patient Education Materials publicly available to be distributed after the consent is signed or general information about the study when the focus is to inform, but not to recruit.
- Information submitted to www.clinicaltrials.gov. The FDA believes IRB review and approval of listings of clinical trials online provides no additional safeguards and is not required when citing basic trial information, such as: title; purpose; protocol summary, basic eligibility criteria, study site location(s), and how to contact the site for further information. *[Examples include: National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS)].*

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

Recruitment materials should contain the following

- Name of facility – "Virginia Mason Medical Center" or "Benaroya Research Institute at Virginia Mason" are the preferred locations of reference. Department should be included whenever possible.
- Name of condition/disease under study.
- Purpose of the research. Use lay language and aim for a 6th to 8th grade reading level. Write in short, complete sentences. Make sure you are clear you are recruiting for research as opposed to providing treatment.
- Major inclusion/exclusion criteria such as age/gender requirements. Do not copy this list from the protocol because this is too much information and too soon in the process.
- Brief list of procedures required *(e.g. blood tests, X-rays, MRI, etc.)* as part of the study.
- Time commitment for participation.
- Compensation should be mentioned, but not emphasized. Make clear if the amount mentioned is per visit or total amount.
- Primary contact name and info.
- Name of Principal Investigator (PI). This is only necessary if it is not the primary contact.
- All images and graphics should be included. Material needs to be in final format.
- If materials will be used in multiple mediums *(e.g. flyer, poster, newspaper, etc.).*

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

Recruitment materials should not include the following

- Do not promise treatment, cures, or benefits.
- Do not use "catchy" words like "free" and "exciting." Avoid all appearance of coerciveness.
- Do not use words that could be insulting to potential subjects. (e.g. "overweight" instead of "fat," or "lean" instead of "skinny", etc.)
- Do not use terms such as "new drug" or "new medication" when describing the study drug.
- Do not claim a favorable outcome or benefit of enrolling in the study.
- Do not make claims inconsistent with FDA labeling of the study drug.
- Do not offer "free care" or "free treatment". However, the statement "Study-related medications, exams, tests, etc. are provided without charge" is acceptable.

- Do not use phrases such as “Help needed…” or “Subjects wanted…” The recommended wording is “You are invited…” or “Participants invited…”
- Do not use exculpatory language *(language in the advertising whereby prospective subjects waive or appear to waive any of their legal rights)*.
- Do not use bold or enlarged print or other means to emphasize payment or the amount to be paid.

Audio/Video ad submission

If your advertisement will be taped for broadcast, a draft or final copy should be submitted to the IRB prior to the recording of the item to avoid unnecessary costs and extra work if the IRB suggests revisions. The IRB will review the draft to confirm wording is appropriate and reflects the intent of the research.

Internet Advertising

All materials posted on the internet to recruit subjects must be approved by the IRB prior to use. This would include teaser ads (ads placed on social media sites or sites other than VM or BRI) as well as ads placed on the VM, BRI or “outside” web-sites. The rules cited above, indicating what to include and exclude, would apply to internet ads as well.

For additional guidance please contact the IRB Office at 206-342-6919 or IRB@benaroyaresearch.org.