

PARTNERS HUMAN RESEARCH COMMITTEE GUIDELINES FOR ADVERTISEMENTS FOR RECRUITING SUBJECTS

Under Federal regulations, the Human Research Committee must review and approve methods used to recruit subjects, one of which is the use of advertisements in various media. The Human Research Committee has prepared the following guidelines to assist investigators in the preparation of advertisements.

Recruitment of Subjects through Advertising

Direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects, must be reviewed and approved by the PHRC prior to distribution, posting, publication, or broadcasting. Direct advertising includes, but is not limited to, notices aimed at recruiting research subjects that investigators intend to place in newspaper, radio, TV, bulletin boards and the internet/world wide web. Advertisements developed by coordinating centers for multicenter study recruitment also require PHRC approval if the MGH or BWH sites intend to enroll from among the pool of prospective subjects responding to these ads. In addition, notices directed to clinical colleagues seeking study referrals require PHRC approval. These include, but are not limited to, letters, electronic and other postings, or notices in professional publications.

Requests for approval of advertisements should specify the mode of advertisement and where the advertisement is going to be placed/posted, e.g., newspapers, internet sites, T-stops, etc. The PHRC must review and approve the final copy of text of print advertisements as the ad will appear in print in the newspaper or other print media so the reviewer can assess the visual impact, emphasis and graphic message. Similarly, the PHRC must review and approve the final copy of the script of the audio/video tape that will be broadcast on radio or television. **Note: Audio/video taped ads (for radio/television broadcast) cannot be uploaded in Insight/eIRB. Contact your protocol administrator for assistance.**

Advertisements should include:

- Name of research facility;
- Purpose of the research
- Eligibility criteria (briefly stated);
- Benefits of participation; e.g., no-cost health examination (briefly stated)
- Duration of study and number of visits;
- Payment, if any, for participation;
- Contact person for more information;
- The word "research" somewhere prominent in the advertisement.

Advertisements should not include: (1) Claims, explicit or implicit, that the drug, biologic or device is safe or effective for the purposes under investigation or that the test article (drug, biologic, device) is known to be equivalent or superior to any other drug, biologic or device; (2) References to "new treatment", "new medication" or "new drug" without explaining that the drug, biologic or device is investigational; and (3) offers of compensation from a sponsor that would involve a coupon good for a discount on the purchase price of the product once it had been approved for marketing. All advertisements should be tastefully composed and not inappropriately emphasize monetary remuneration. If you wish to use BWH/MGH/Partners logos, contact Public Affairs for relevant guidelines.

Do:

USE THE WORD "RESEARCH" in your advertisement, the terms "Study" or "Treatment Study" do not convey the same message

- Provide information prospective subjects need to determine interest, such as eligibility, significant study procedures, and time commitment
 - males, females, adults, children, age range, taking no medications, etc.
 - x-rays, MRIs, exercise testing, overnight stays, frequent blood sampling, etc.
 - duration of study, number of visits and/or length of visits, if only one or two visits
- Use "healthy volunteers" instead of "normal volunteers"
- Use simple lay language without acronyms or abbreviations unless these are well known to the public or to the special patient group you are targeting, e.g., patients with ALS or women with PMS will understand these abbreviations
- Provide simple symptom complexes if you are looking for subjects who do not already carry the diagnosis
- Provide basic exclusion criteria whenever possible to reduce unnecessary calls
- Use the word "investigational" rather than "experimental"
- Name drugs used if approved and/or known to the public, e.g., Aspirin, St. John's Wort
- Use the words "at no cost" rather than "free" where relevant
- Specify amount of monetary compensation (if you wish)
- Use the words "up to" if compensation is pro-rated
- Specify hospital affiliation (e.g. Cardiovascular Division, BWH)

Don't:

- Feature monetary compensation as a lead in before the description of study purpose and procedures
- Bold, italicize, underline or enlarge fonts on type describing monetary compensation
- Imply treatment benefit if the primary focus of the study is safety and tolerability, drug kinetics, or basic physiological processes rather than efficacy
- Imply treatment benefit for chronic problems if the study involves only short-term interventions
- Emphasize no cost treatment if a placebo is involved (you don't need to explicitly state that placebos are used in ads) and/or the protocol involves drugs, biologics, or devices not FDA approved for the condition under study
- Provide detailed lists of risks and benefits (this should be done in person)
- "Hype" the study with overly optimistic or effusive language implying benefit (commercially designed radio ads occasionally do this)
- Use words describing broader affiliations (e.g., "Harvard researchers" or "Harvard Medical School Study") which tend to mistakenly convey endorsement and/or direct oversight of study treatments and procedures by the university or medical school

Notices or letters sent to other health care providers

When seeking assistance of colleagues in referring patients to you, include additional information about study design, placebo, risks, and benefits. Provide enough information for colleagues to reasonably present a study to their patients.