Mass General Brigham

HUMAN RESEARCH AFFAIRS

GUIDELINES FOR ADVERTISEMENTS FOR RECRUITING SUBJECTS

Under Federal regulations, the Mass General Brigham IRB must review and approve methods used to recruit subjects, one of which is the use of advertisements in various media. The Mass General Brigham IRB 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 Mass General Brigham IRB 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. Advertisements developed by coordinating centers for multicenter study recruitment, study sponsors or Contract Research Organization (CRO), also require Mass General Brigham IRB approval if the Mass General Brigham 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 Mass General Brigham IRB 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, public transportation. The Mass General Brigham IRB must review and approve the final copy of advertisements as the ad will appear in the newspaper or other print/multimedia form so the reviewer can assess the visual impact, emphasis, and graphic message. Similarly, the Mass General Brigham IRB must review and approve the final copy of the script of the audio/video tape that will be broadcast on radio, television, or the internet. **Note: Audio/video taped ads (for radio/television broadcast) cannot be uploaded in Insight. Contact the IRB office for assistance.**

Advertisements should include:

- Name of research facility and/or location;
- 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.

When a study includes minors, the advertisement must indicate that parental or guardian permission is required to recruit and/or enroll this population unless the IRB has granted a waiver of parental or guardian permission for screening and/or enrollment.

Advertisements should not:

- Claim, explicitly or implicitly, 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;
- Include references to "new treatment", "new medication" or "new drug" without explaining that the drug, biologic or device is investigational;
- 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;
- Feature monetary compensation as a lead in before the description of study purpose and procedures;
- Emphasize monetary compensation by using bolded italicized, underlined, or enlarged fonts;
- Include 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.

The use of logos (e.g., Mass General Brigham, Harvard Medical School) must comply with institutional policies. Posting advertisements in hospital facilities may require additional approval from the specific department, clinic or facility.

For Single IRB studies where the Mass General Brigham IRB is the reviewing IRB for multiple sites, advertisements intended for use at multiple sites should be submitted in a template format with generic placeholders for the site name and study contact information. This allows for submission and IRB approval of the advertisement once rather than per site.

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.