

Advertising for Study Subjects

Institutional Review Boards (IRBs) are responsible for ensuring the equitable selection of research subjects [21 CFR 56.111 (a)(3)] and must therefore review the methods that investigators use to recruit subjects, including advertisements. Advertising for research subjects is not in and of itself an objectionable practice. However, when advertising is to be used, the IRB should review the information contained in the advertisement, and the mode of its communication, to determine that the procedure for recruiting subjects affords adequate protection.

FDA requires that an IRB review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109]. FDA expects an IRB to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The protocol, the consent form, and the investigator's brochure have consistently been cited as specific examples of documents that the IRB should review.

Advertisements used to recruit subjects should be seen as an extension of the informed consent and subject selection processes [21 CFR 50.20, 21 CFR 50.25, 21 CFR 56.111 (a)(3)]. Institutions should, therefore, require IRB review of such advertisements. IRB review is necessary to ensure that the information is not misleading to subjects, especially when a study will involve persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged. The IRB is responsible for assuring that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.111(b)].

Based on FDA regulation and OHSU IRB policy, any advertisement used to recruit subjects should be limited to:

1. the name and address of the clinical investigator and/or the research facility and the IRB number of the study;
2. the condition under study and/or the purpose of the research;
3. in summary form, the criteria that will be used to determine eligibility for the study (a complete list of eligibility criteria is not required);
4. a straightforward and truthful description of the benefits or burdens (e.g. as applicable, payments, no cost treatment, the percentage of subjects who will receive a placebo) to the subject for participating in the study;
5. the time or other commitment required of the subjects;
6. the location of the research and the person or office to contact for further information.

These requirements apply regardless of whether the advertisement is in print, on the radio, on television, or on the Internet, with the exception that it is not required that the IRB number be read aloud for radio and TV ads.

In addition:

- Do not use the phrase "Free medical treatment"
- Do not call the intervention a new treatment, medication, drug, device, etc.
- If the study is a blinded multi-armed investigational drug study, describe the study arms in the following manner. "You will receive a pill (or patch, injection, etc.). This pill (or patch, injection, etc.) may contain the study drug, an inactive substance call a placebo...(continue listing any other possible interventions). You have a 1 in "X" chance of receiving the study drug."
- When submitting an advertisement for review, indicate the media used and whether any subsequent advertisements in different media are planned.

No claims should be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would also be a violation of the FDA's regulations concerning the promotion of investigational drugs [21 CFR 312.7 (a)] and of investigational devices [21 CFR 812.7 (d)].

These requirements apply regardless of whether the advertisement is in print, on the radio, on television, or on the Internet.

Investigators who would like to place advertisements that have **ALREADY BEEN APPROVED** by the OHSU IRB in the Oregonian can contact Sharon Fleming at 503-221-8263 for assistance.