

Guidelines for Advertising (Subject Recruitment Materials)

The FDA and DHHS consider advertising (subject recruitment) to be the first component in the informed consent process. Therefore, the Presbyterian Healthcare Services (PHS) Institutional Review Board (IRB) must review and approve recruitment methods and content of the materials to ensure adequate subject protection. The IRB must review the information contained in all advertisements and the mode of their communication. Advertisements cannot be displayed or put to use until the IRB has approved the final copy of printed ads and the final version of audio/video tape-recorded advertisements.

Federal regulations require that the institutional human research protection program and investigators protect potential and current research subjects from coercion or undue influence, and this requirement underpins PHS IRB advertising guidelines. Federal regulations also require investigators to use fair and equitable recruitment practices. The IRB has established the following requirements for advertisements seeking subjects to participate in research studies at PHS.

All advertisements must be written in simple language (6th to 8th grade reading level). Please use the Flesch-Kincaid test or other readability tool to analyze the grade level of your materials before submitting to the PHS IRB.

The following may be included in the advertisement:

- The principal investigator's name.
- The condition under study and/or the purpose of the research, described clearly and concisely. Clearly state that the project is research and includes the use of an investigational drug or device, if applicable.
- The key eligibility criteria.
- A straightforward description of potential benefits to study participation. Do not overstate.
- A brief list of procedures involved.
- The time or other commitment required (number of visits, duration of study, etc.).
- Advertisements may state "You will be compensated for your study participation" but should not state the specific amount to be paid, or use bold or enlarged print or other means to emphasize compensation. Do not refer to compensation or payment in the header of the ad.
- The location where the research will be conducted and the contact (name, phone, and/or email address) for further information.

The following may NOT be included in the advertisement:

- Claims of safety, effectiveness, equivalence or superiority in reference to the drug, device or procedure under investigation.
- Use of the term "new" in reference to a drug or device without explaining that the test article is investigational.
- Use of the term "free" in reference to treatment or procedures.
- Specific dollar amounts for compensation.
- Use of bold or enlarged print or other means to emphasize compensation.
- Use of exculpatory language.
- A statement or an implication of IRB or other PHS institutional endorsement of the study.

- Claims that the subject will receive therapeutic benefit from participation in the study.
- The use of any inappropriate pictures or images that would be inconsistent with PHS IRB policies on equitable subject recruitment.
- 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.
- Exhibition of the ad in inappropriate venues.

Ads should be submitted electronically by the investigator through the IRBNet system as part of new protocol submissions and amendments. An ad must be re-submitted to the PHS IRB for approval, via an amendment in IRBNet, when any revisions are made to the IRB-approved version of the ad.

All ads must have PHS IRB approval before being exhibited.

Distribution of Ads Within PHS, Clinics, and Hospitals

After IRB approval, research ads can be posted via approved venues (PHS.org, print publications, etc). Research posters, flyers and brochures can be placed in designated areas within clinics and clinical departments at PHS with department management approval. **Posters and flyers are prohibited on walls, lobbies, restrooms, stairwells, hallways, elevators and other general public areas.**

Internet Postings

OHRP guidance on internet website advertising, issued September 20, 2005, may be found at: <http://www.hhs.gov/ohrp/policy/clinicaltrials.html>. FDA guidance on advertisements and recruiting study subjects may be found at: <http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting> (FDA Information Sheets, Guidance for IRBs and Clinical Investigators, 1998 Update). This Guidance also addresses the question of internet postings and IRB review:

'IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. Examples of clinical trial listing services that do not require prospective IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). However, when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.'

In keeping with DHHS and FDA Guidance, the PHS IRB has determined that IRB review/approval for brief internet postings is not necessary provided that the information is limited to:

- Study title;
- Purpose of the study;
- Protocol summary;
- Basic eligibility criteria;
- Study site location(s); and
- How to contact the study site for further information.

When information posted on a clinical trial website goes beyond directory listings with the basic descriptive information given above, such information is considered part of the informed consent process and therefore requires IRB review and approval. Information exceeding such basic listing information includes descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information from potential research subjects.

OHRP guidance states that IRBs, in their review of all advertising/recruitment materials, should pay particular attention to risk and potential benefit information to ensure it is presented in a balanced and fair manner. The information presented should not mislead, for example, by promising benefits or implying a benefit beyond that potentially provided by the research.

The PHS IRB, when reviewing clinical trial websites, also will assess the types of incentives, if any, that are being offered to prospective subjects. Monetary and non-monetary incentives (e.g., access to services or programs) can create undue influence on a potential subject's decision about research participation. The PHS IRB will ensure that the clinical trial website makes clear that participation in a trial is voluntary, and that incentives for participation are not so great that they compromise a prospective subject's assessment of the risks or affect the voluntariness of his or her choices.

Some clinical trial websites ask viewers to answer questions regarding eligibility for a specific clinical trial. If identifiable private information is collected via the clinical trial website, the IRB will review plans for protecting the confidentiality of that information. The IRB will assess whether the website clearly explains how identifiable private information might be used.

Informed consent must be obtained for the collection of any identifiable private information about the respondent unless the IRB has determined that the informed consent requirement can be waived. Respondent authorization must also be obtained if protected health information is collected unless the IRB has determined that the authorization requirement can be waived.

Additional examples of clinical trial listing services that do not require prospective IRB approval include amfAR clinical trial directory listings and the National Institutes of Health (NIH) ClinicalTrials.gov website, providing that the clinical trial information posted is of the limited nature described above.

REFERENCES

45 CFR 46.111(a)(3)
21 CFR 56.111(a)(3)