IRB Guidance on Recruitment Materials and Advertising

The FDA “considers direct advertising to subjects to be the start of the informed consent and subject selection process.”¹ This brings plans for recruitment and advertising under the purview of the IRB as part of the review of a research study. The IRB is expected to review both the content of advertisements as well as the mode of communication. The FDA Guidance explains the IRB must find that the procedure for recruiting is not coercive and that the information provided “does not imply a favorable outcome beyond what is outlined in the consent document and the protocol.” For studies involving investigational products, advertisements should not include claims that a study product is safe or effective or that it is known to be equivalent or superior to other products.

Furthermore, FDA Guidance advises that advertisements should be limited to the information the prospective subjects need to determine their eligibility and interest.

IRB Responsibilities

The IRB is expected to review the final copy of printed and online advertisements to evaluate the size of type used and other visual effects. Any audio or video must also be approved by the IRB in final format before it is used.

Submissions of website content to the IRB may require additional documentation or explanation. For example, screenshots of the planned web-page or an explanation of how and when an advertisement may appear could be submitted to assist the IRB in their review of the advertising.² It is important to keep in mind that the IRB should be reviewing the relative size of type used and other visual effects.

The FDA does not require the IRB to review:

- Communications intended to be seen or heard by health professionals (doctor to doctor letters)
- News stories
- Publicity intended for other audiences (e.g. financial page advertisements directed toward prospective investors)
- Listings of clinical trials on the internet if the system format limits the information to basic trial information, such as: 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 include: the National Institutes of Health (NIH) ClinicalTrials.gov website, the NIH National Cancer Institute’s cancer clinical trials listing (Physician Data Query [PDQ]), and the government sponsored AIDS Clinical Trials Information Service (ACTIS).

With respect to payment, the FDA allows advertisements to indicate subjects will be paid, but warns that they should not over-emphasize payment.

Given the FDA’s interpretation that advertisements are the beginning of the informed consent process, the IRB reviews recruitment materials to ensure that participant selection is equitable and that advertising materials abide by important informed consent principles. Advertisements must not contain exculpatory language, unduly coercive or misleading content, or promises of a certainty of a cure beyond what is outlined in the consent.

Quorum Review's Approach

Quorum Review IRB's primary goal when reviewing advertisements is to ensure the appropriate safeguards exist to protect the rights and welfare of research participants.

Board Considerations
When reviewing advertisements, Quorum Review IRB will ask the following questions regarding any ad material submitted with a protocol:

- Is this direct advertising or a clinical trial listing that allows additional descriptive information about the trial?
- Is the proposed plan for recruiting or advertising (including the information provided and mode of communication) coercive, or does it represent a risk to privacy or confidentiality of participants?
- Does the information provided imply a favorable outcome beyond what should be expected of the research?
- If the study involves investigational products, does the advertisement claim that a study product is safe, effective, equivalent, or superior to other products?
- If payment is mentioned, is the payment or the amount of payment over-emphasized?
- Does the advertisement use phrases, such as “free medical treatment” when intending to describe study procedures or receiving the study product?

Submitting with Initial Protocol
Submitting recruitment or participant study material along with the initial protocol or site submission materials is the most efficient method for IRB Review. Submitting materials this way ensures an inclusive review of all materials at one time. If recruitment materials are approved through the initial submission process, Quorum Review will prepare all site approval documents at no additional charge.

Guidelines for Submitting Recruitment Materials to the IRB

When preparing materials to submit to the IRB, use the following checklist to stay within both Quorum's recruitment materials policies and the FDA regulations.

Do...
- Do make plain that the solicitation is for the purpose of participation in research and not for the provision of medical care.
- Do use the term “research” (or a synonym) when describing the study.
- Do use the term “investigational” (or a synonym) if a test article or treatment is referenced in the advertisement.
- Do indicate that the research involves the “investigational use” of an approved drug if applicable to the study.
- Do make sure that the material complies with applicable state and local laws and institutional or IRB policies.
- Do submit the material in final format, including site-specific information as appropriate and graphics that will be used.
- Do submit radio and television scripts for IRB review before production of the recording is started.
- Do submit final recordings for IRB review and approval prior to broadcast.
- Do read radio scripts for live broadcast exactly as approved by the IRB.

Do Not...
- Do not use language or graphics that may be coercive or misleading.
- Do not state or imply a guarantee of benefits, cures, or favorable outcomes.
- Do not emphasize “free” treatment or study products.
- Do not claim the study product or treatment is safe, effective, equivalent, or superior to other options when it is investigational.
- Do not place emphasis on payment, including bolding or highlighting the compensation language.
- Do not use the terms “safe,” “effective,” “new,” “best,” “cure,” “treatment,” “therapy,” or “free.”