

Guidance for Advertisements/Recruitment Materials

Introduction:

- The recruitment process and the materials used to conduct the recruitment process are considered the beginning of the consent process for expedited and full review protocols and the informational process for exempt studies.
- Direct advertising or recruitment refers to any activity that solicits research participation directly from potential subjects. Federal regulations (45 CFR 46.111) require that the IRB review all research documents and activities that have a direct impact on the rights and welfare of the human subjects in the proposed research and must ensure that subject selection is fair and equitable. This guidance applies to all mediums.
- The content of recruitment materials and the recruitment process must be clear and accurate, not be coercive or demonstrate undue influence (especially in the case of vulnerable populations), and should not compromise the privacy of the individual or the confidentiality of information about the individual.
- To ensure that the recruitment process and materials meet these requirements, they must be reviewed by the IRB as part of the IRB protocol submission materials.
- Subjects should not be approached or recruited for research until the IRB has approved the research overall, the methods of recruitment, and the recruitment materials.

General:

- The IRB should review the final copy of printed ads to evaluate the relative font size used and other visual effects. When advertisements are to be taped for broadcast, the IRB should review the final audio/video tape. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording.
- Recruitment materials must be written at a language level understandable to the population the researcher is targeting, generally the 6th-8th grade reading level. Depending upon the age, maturity, and expected abilities of the targeted subjects, the reading level may need to be adjusted, such as when recruiting children or persons with diminished capacity.
- Generally, the content of recruitment materials should be limited to the information the prospective subject needs to determine whether they are eligible to be in the research and whether they are interested in participating in the research.
- **Avoid making broad generalizations** – Be careful in using words like all, always, must, never, and every.

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Materials SHOULD INCLUDE

- ✓ The word “research”
- ✓ A brief description of the research purpose and procedures
- ✓ Any important eligibility criteria
- ✓ The time commitments required
- ✓ The location of the research
- ✓ A person to contact for further information and their affiliated institution
- ✓ Appropriate institutional branding (such as a logo)

Materials SHOULD NOT

- ✗ Claim, explicitly or implicitly, that the research is safe and effective treatment or therapy when the safety and efficacy of a treatment or therapy is what is being tested
- ✗ State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
- ✗ Make claims, either explicitly or implicitly, that the research procedures are safe or effective for the purposes under investigation
- ✗ Make claims, either explicitly or implicitly, that the research procedures or study articles are equivalent or superior to other studies, drugs, biologics or devices. Examples of words to avoid: groundbreaking, cutting-edge, revolutionary, pioneering, state-of-the-art, trailblazing (this is not a comprehensive list)
- ✗ Use terms such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational, as this implies to the subject that the intervention is a tested and approved standard of care intervention.
- ✗ Use "catchy" words like "free," "exciting opportunity," or “here’s your chance to help.” Avoid all appearance of undue influence.
- ✗ Promise “free medical treatment” when the intent was only to say participants would not be charged for taking part in the investigation
- ✗ Emphasize the payment or the amount to be paid, by such means as larger or bold type or other methods of emphasizing payment (i.e. dollar signs, pictures of gift cards). Compensation should not be the header or lead sentence in the recruitment item
- ✗ Characterize payment for participation as a benefit of the research (The amount and method of payment can be stated, but should not be included in the benefits section)
- ✗ Include any language that announces the investigator cannot be held liable or at fault for any research related event

***Adapted from guidance documents from the University of Illinois-Chicago, DePaul University, Kennesaw State University, Emory University, University of Pittsburgh, WIRB, and FDA (Information Sheet: Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators)*