

Why does the IRB care about Advertising?

In general, IRBs care about advertising that is specific to an approved protocol because it is considered to be the beginning of the informed consent process. Advertisements are visible tools of recruitment, and they must present information that is adequate, accurate, and balanced so that potential subjects can make an informed decision about possible participation. Providing misinformation (even unintentionally) at the beginning of the informed consent process is not consistent with the principle of [Respect for Persons](#). Additionally, some content, as listed at the end of this guidance, is [required](#) for all advertisements. Other content, including statements like “free” treatment or statements that emphasize subject compensation, are considered [not acceptable for study materials](#). Without IRB review of these materials, researchers may inadvertently include unacceptable content or omit required content.

At CMU, reported concerns related to altered recruitment and consent documents are common. These are usually a result of study personnel, often someone other than the Principal Investigator (PI), creating documents that were not included in the IRB protocol and that inaccurately described things like inclusion or exclusion criteria (who can participate); performance dates of the study; performance locations; compensation; and the degree of anonymity or confidentiality of participation. Inclusion of some of these topics with descriptions that were either different from the approved protocol or incomplete when compared to the approved protocol have led to a number of findings of non-compliance. Often those differences found in the advertisement were also accompanied by the [conduct](#) of something different from what was described in the approved protocol, which can be more serious.

The IRB at CMU has generally not made a distinction between advertisement (raising awareness) and recruitment materials, because they often overlap significantly and are usually specific to a single study. That said, if a PI were interviewed for radio or TV and had the opportunity to discuss their research and just happened to mention a specific study, the IRB would confirm that:

1. The PI has an approved protocol or is in the process of obtaining one and;
2. What was said in the interview matched what was in the protocol (it was not potentially misleading to participants).

The same standard described above can be applied to other forms of advertising and recruitment. The expectation of the CMU IRB has been consistent in requiring that all advertising and recruiting materials be described in the protocol to avoid not matching what was approved and misleading potential participants.

For more on this subject, please contact the IRB Office or consult the [IRB SOPs](#) (section 3.7.7). Investigators may also wish to consult one of the many helpful guidance documents and webpages available. A few are listed here for convenience:

- Schulman IRB Recruitment and Study Related Materials [Guidance](#)
http://www.sairb.com/IRBForms/Guidance_for_Recruitment_and_Study-Related_Materials.pdf
- Quorum Review IRB [Guidance](#) on Recruitment Materials and Advertising
https://www.quorumreview.com/wp-content/uploads/2013/03/Recruitment-Materials-Info-Sheet.pdf?utm_source=Quorum%252BRewiew&utm_medium=Email&utm_term=Quorum%252BIRB&utm_campaign=Info%252BSheet
- WIRB Copernicus Group OHRP and FDA [Guidance](#)
<https://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>

Generally, advertisements need only the following information:

- The name and address of the investigator and/or research facility
- The condition under study and/or purpose of the research
- In summary form, the criteria that will be used to determine eligibility
- A brief list of benefits (e.g. no-cost health examination)
- The time or other commitment required of subjects
- The location of the research and the person or office to contact for further information

When submitting recruitment or advertising documents to the IRB:

Do....

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

Do Not....

- Use language or graphics that may be coercive or misleading.
- State or imply a guarantee of benefits, cures, or favorable outcomes.
- Emphasize “free” treatment or study products.
- Claim the study product or treatment is safe, effective, equivalent, or superior to other options when it is investigational.
- Place emphasis on payment, including bolding or highlighting the compensation language.
- Use the terms “safe,” “effective,” “new,” “best,” “cure,” “treatment,” “therapy,” or “free.”