The IRB defines **advertising** as "any outreach effort designed to encourage potential subjects to contact the investigator requesting information." Advertisements are an extension of the consent process and subject selection process. Therefore, the IRB must review all means of recruiting subjects to participate in a research study, including advertisements **prior to publication**.

Advertisements will be reviewed and approved by the IRB as part of the package for initial review. If the investigator decides at a later date to advertise for subjects, this will be considered a revision to the ongoing study and a request for modification of an approved protocol must be submitted. If the investigator wishes to change message content, message audience, or advertising strategies (e.g., add television ads) after IRB approval, this also requires a request for modification of an approved protocol. When such advertisements are easily compared to the approved consent document, the IRB chair or Research Compliance Officer may review and approve by expedited means. When the IRB reviewer or Research Compliance Officer has doubts about the materials submitted or complicating issues are involved, the advertising will be reviewed at a convened board meeting of the IRB.

Note that raffles or lotteries are illegal under Alabama law (Article IV Section 65, Alabama Constitution of 1901) and may not be included in advertising.

**What requires review and approval?**

The IRB review policy includes, but is not limited to:

- The final copy of printed advertisements including: newspaper ads, bulletin board tear-offs, and posters.
- The final audio or video taped advertisements, such as radio or television announcements
- Health fair materials about the study
- Computer bulletin boards or internet advertising (includes student research pool)
- 800 number ads
• Disease databases (PDQ) - if the original researcher has any control over the content
• Talk show appearance media kits
• Press releases designed to promote a study and encourage participation

**What should advertisements include?**

Advertisements to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. It should be noted that the IRB office does not require inclusion of all of the listed items.

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

**What does the IRB consider when reviewing advertisements?**

1. The IRB considers the information contained within the advertisement and the mode of its communication.
2. The advertisement cannot be misleading. It can not make promises of safety or efficacy. Benefits, incentives, or remuneration must be reasonably stated. Outsized fonts or boldface emphasizing money and free services are discouraged.
3. No claims should be made, explicitly or implicitly, that the research is superior to any current practice.
4. It must be clear that the opportunity is for research or is an investigation.
5. It should give the name of a primary contact and a method of making contact.

6. It may give some brief eligibility criteria such as disease, condition, or age limits.

7. It may give brief procedural information such as the location of the research, duration of participation, mode of administration and name of the test article.

8. For e-mail or internet advertising, how secure (private, confidential) is the prospect’s response?

9. It should not include exculpatory language (language in the advertising whereby prospective subjects waive or appear to waive any of their legal rights).

10. It should not promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

The IRB will also consider placement of any advertising. For each advertisement, please provide:

1. The name or type of the media (e.g., the *Birmingham News*)

2. The targeted audience of the selected media

3. Whether the medium selected is primarily designed to target a specific group. (e.g., a specific ethnic or cultural group, gay or lesbian persons, adolescents, persons with HIV/AIDS, etc.)

The IRB reviews will ensure that advertisements do not:

1. Make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.

2. Use terms, such as “new treatment,” “new medication,” or “new drug, without explaining that the test article is investigational.

3. Allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
Investigators are invited to call the Office of Research Compliance at (205)-348-8461 to discuss their planned advertising in advance of submission to IRB if they wish.