

**THE UNIVERSITY OF ALABAMA
HUMAN RESEARCH PROTECTIONS PROGRAM**

INVESTIGATOR GUIDANCE: IRB ADVERTISING GUIDELINES

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:

- Newspaper ads
- Radio or television announcements
- Bulletin board tear-offs
- Posters
- 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 advertisement can not be misleading. It can not make promises of safety or efficacy. Benefits or payments must be reasonably stated. (Outsized fonts emphasizing money and free services are discouraged.)
2. No claims should be made, explicitly or implicitly, that the research is superior to any current practice.
3. It must be clear that the opportunity is for research or an investigation.
4. It should give the name of a primary contact and a method of making contact.

5. It may give some brief eligibility criteria such as disease, condition, or age limits.
6. 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.
7. For e-mail or internet advertising, how secure (private, confidential) is the prospect's response?

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.)

Investigators are invited to call the Office for Research Compliance at (205)-348-5152 to discuss their planned advertising in advance of submission to IRB if they wish.