
Yale University Institutional Review Boards Procedure

Procedure 410 PR.3 Advertisements, Notices and Scripts Used for Recruitment

Overview	1
Developing Advertisements:	1
Submitting Advertisements to the IRB	2
IRB Responsibilities in the Approval of Advertisements	2

Overview

This procedure provides information for researchers and IRB members in the development of appropriate materials including advertisements, internet advertisements and telephone, video and audio scripts used to recruit volunteers into research studies.

Developing Advertisements:

Ethical Considerations:

Advertising for research enrollment is considered the start of the subject selection process. It is also considered the prelude to the informed consent process. Therefore advertisements, like consent documents, must not unduly coerce or imply a guarantee of benefits beyond what is outlined in the protocol and consent form.

Advertisements should be limited to the information needed by prospective subjects to determine their eligibility and interest. Advertisements should be designed with the following in mind:

- No claims should be made, either explicitly or implicitly that the drug or device is safe or effective for the purposes under investigation, or that the test article is known to be comparable or superior to any other drug or device.
- Advertisements for studies using investigational drugs or devices must also not use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational.
- Advertisements should not promise “free medical treatment” when the intent is only to say subjects will not be charged for taking part in the study.
- Advertisements may state that subjects will be paid but should not be coercive by emphasizing the payment or the amount to be paid by such means as larger or in bold font.

Considerations for Advertisement Content:

- The purpose of the study including a clear statement that it is research
- A summary of the eligibility criteria
- A brief description of benefits
- The time or other commitment required
- The location of the study
- The name and contact information of the person responsible for explaining the study to the subjects
- The IRB protocol number

See: Guidance:410 GD.1: Guidelines on Posting for Recruitment

Submitting Advertisements to the IRB

Advertisements should be submitted to the IRB at the time the investigator is submitting the initial protocol. However, should an investigator decide at a later date to advertise for subjects, the advertising may be submitted to the IRB as an amendment to the protocol. Changes to previously approved advertisement methods must be formally submitted to the IRB as an amendment.

Investigators should remember the following when submitting an advertisement for review and approval to the IRB:

- Print advertisements, web pages, newspaper advertisements, poster and flyers should be in final format, including any graphics or photographs to be used.
- For advertisements that will be used in the media, such as radio or television, submit all text, graphics and other substantive materials. A copy of video clips should be provided to the IRB. Alternatively, the wording for advertisements that will be taped should be reviewed and approved by the IRB prior to the taping to avoid having to re-tape the advertisement. However, if the IRB requires revisions, the investigators may tape the advertisement with the appropriate revisions prior to re-submitting the advertisement script to the IRB. The version used for the final taping must be submitted to the IRB for approval.
- All advertisements should conform to commonly accepted standards of “good taste,” meaning the use of standards, graphics and verbiage that the general public finds non-offensive..

IRB Responsibilities in the Approval of Advertisements

The IRB must review the mode and content of recruitment methods and activities for each research study and consider whether or not the recruitment is equitable, free from coercion, bias and undue influence. The IRB may also consider the inconvenience to the potential subject, such as, time required for participation, restrictions on diet or other activities, discomfort, and whether or not they need be mentioned in the advertisement to ensure a fair representation of the research project.

The IRB will notify the investigator of its approval of recruitment methods and activities.

The official version of this information will only be maintained in an on-line web format. Any and all printed copies of this material are dated as of the print date. Please make certain to review the material on-line prior to placing reliance on a dated printed version.
