

 <b>JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH</b>	<b>Human Research Protection Program Policies &amp; Procedures</b>	
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<b>Title: Recruiting Research Subjects: Direct Advertisements</b>	Date Effective: 10/15/04	Supersedes P&P Dated: 5/25/04

## Background

The use of direct advertisements to recruit potential research subjects is the beginning of the process of subject selection and informed consent. Direct advertisements include, but are not limited to:

- written scripts,
- mailings,
- printed flyers,
- posters,
- newspaper advertisements,
- press releases,
- television and radio spots,
- videotapes,
- web pages and
- electronic mailings

that are intended to be seen or heard by prospective subjects in order to solicit their participation in a study.

## JHSPH POLICY AND PROCEDURES

Research proposals submitted for review by CHR must describe in detail the content of all advertisements and when, where and how they will be communicated to potential research subjects. The advertisement should accurately describe the purpose of the study, study procedures, or both. For example, if the study will compare an investigational drug and a placebo, the advertisement should state that some subjects will receive the drug and others a placebo.

*All advertisements must be approved by CHR before being used to recruit research subjects.* They should either be provided with the application or, if not yet developed, submitted later for review by CHR as an amendment. The CHR will review the information contained in the advertisement as well as the mode of communication. Special attention is paid when the study will involve persons with acute or severe physical or mental illness, minors, persons who are economically or educationally disadvantaged, or members of other vulnerable populations. The goal of the CHR review is to ensure that recruitment procedures are informative, but not coercive or misleading, and do not imply an outcome or benefit for participants unless it is also described in the study protocol and informed

consent document. Additionally, the advertisement should not falsely imply or suggest that research is treatment. Overall, the advertisement should be limited to the information that prospective subjects need in order to determine their eligibility and whether they are interested. Some guidelines on the development of acceptable advertisements are as follows:

The content of advertisements should be limited to:

- the name and address of the Principal Investigator,
- a statement that the study is being conducted by JHSPH,
- a statement that the study is research,
- where the research will take place,
- the purpose of the study,
- a brief description of the eligibility criteria,
- a straightforward, truthful description of any incentives or benefits to participants; the amount of payment may be stated but should not be stressed; alternatively, the advertisement may simply state: “A payment will be provided”,,
- the time commitment required of participants, and
- the person to contact for further information and how to contact him or her.

The advertisement should avoid:

- implying that the safety or effectiveness of an investigational drug, biological or device has been determined or is equivalent, or in any way superior, to any other drug or device,
- statements that may be considered coercive,
- promising “free medical treatment”, when the intent is to say that subjects will not be charged for taking part in the investigation,
- misleading statements about the benefits arising from participation in the study,
- using the name of the commercial sponsor or product manufacturer,
- stating or implying certainty of a favorable outcome or other benefit beyond what is outlined in the consent document or protocol, and
- overemphasis on payment as an enticement to enroll, e.g. indicating the amount of payment in a larger font than other text or in bold type.

The wording of all advertisements must be exactly as approved by CHR.

The PI is required to maintain the approved copy, which will have the CHR stamp, study number and “valid through” dates. Once approved, each advertisement must contain the statement “Approved by CHR on <date>” and include the study number assigned by CHR.

Approval of advertisements by CHR is only valid for the period for which the study is approved by CHR and does not exceed one year. Review and re-approval of advertisements is required with each continuing review of the study.

## **DEFINITIONS**

Direct advertising - Advertising (written scripts, mailings, printed flyers, posters, newspaper advertisements, press releases, television and radio spots, videotapes, web pages and electronic mailings) that is intended to be seen or heard by prospective subjects to solicit their participation in a study. The following are not within the FDA definition of direct advertising: (1) communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters, (2) news stories, and (3) publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.