# Recruitment and Media Advertising

## PURPOSE
This policy provides information regarding IRB oversight of and allowable practices in recruitment of subjects into a research study.

## SCOPE
All BCOM agents and students involved in human subjects research

## RESPONSIBLE OFFICIAL(S)
Authorized Institutional Official for Research, Director of Research, Assistant Dean for Multicultural Affairs, Marketing and Communications

## POLICY
### Recruitment and Media Advertising
When direct advertising is to be used in the recruitment of research subjects, the IRB should review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. The IRB should review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the IRB should review the final audio/video tape. The IRB may review and approve the wording (script) of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures. The IRB should caution investigator(s) to obtain IRB approval of message text prior to taping, in order to avoid excess expense necessitated by a requirement to re-tape an ad because of inappropriate wording.

No claims should be made, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic, or device. Such representation would not only be misleading to subjects but would also be a violation of regulations concerning the promotion of investigational drugs and of investigational devices.

Advertising for recruitment into investigational drug, biologic, or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" may leads study subjects to believe they will be receiving a new FDS-approved product, or a newly improved product of substantiated worth.

Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be paid, but should not emphasize the payment, nor the amount to be paid, by such means as larger or bold type. To do so could be understood by the IRB to represent coercive advertising.

Generally, any advertisement 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, however, that FDA does not require inclusion of all of the listed items.

1. the name and address of the clinical investigator and/or research facility;
2. the condition under study and/or the purpose of the research;
3. a summary of the criteria used to determine eligibility for the study;
4. a brief list of participation benefits, if any (e.g., a no-cost health examination);
5. the time or other commitment required of the subjects; and
6. the location of the research and the name of contact to obtain information.

**Use of Receptionist Scripts for Office Staff:**

The first contact prospective study subjects make is often with a receptionist who follows a script to determine basic eligibility for the specific study. The IRB should assure that the procedures followed adequately protect the rights and welfare of the prospective subjects. In some cases personal and sensitive information is gathered about the individual. The IRB should have assurance that the information will be appropriately handled, by describing the specific protocol for securing this information. A simple statement such as "confidentiality will be maintained" does not adequately inform the IRB of the procedures that will be used.

Examples of issues that are appropriate for IRB review: What happens to personal information if the caller ends the interview or simply hangs up? Are the data gathered by a marketing company? If so, are names, etc. sold to others? Are names of non-eligibles maintained in case they would qualify for another study? Are paper copies of records shredded or are readable copies put out as trash? The acceptability of the procedures would depend on the sensitivity of the data gathered, including; personal, medical and financial.

# APPROVAL PAGE

**Approved by:** _____
Robert J. Ketchum, Ph.D.
Associate Dean, Academic & Pre-Clinical Affairs
Authorized Institutional Official for Research
Burrell College of Osteopathic Medicine

APPROVED
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