Policy Name: **Advertisements for Research Participants Policy and Procedures**			
Approved			**Date: 11/01/08**
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I. POLICY

A. Introduction

Advertisements designed to solicit participants for entry into human research must be fair and equitable.

B. Requirements

The MUSC IRB considers advertising to be part of the recruitment and consent process. Therefore, the MUSC IRB requires that all means of advertising, soliciting and notifying individuals of a study for enrollment be submitted for review and approval.

II. PROCEDURES

A. Generally, advertisements should be submitted with the initial proposal review but can be submitted at any time for review. The review of advertisements is generally considered a minor change to approved research and may be reviewed under the expedited review procedure.

B. When reviewing advertisements and recruitment the MUSC IRB will consider:

1. The information contained in the advertisement.
2. The mode of its communication.
3. The final copy of printed advertisements.
4. The final audio/video taped advertisements.

C. Advertisements may not:

1. State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
2. Include exculpatory language.
3. Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

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

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

6. 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.

7. Place emphasis on the payment or the amount to be paid using large or bold type.

D. Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such a:

1. The name of the investigator or research facility.

2. The purpose of the research or the condition under study.

3. In summary form, the criteria that will be used to determine eligibility for the study.

4. A brief list of participation benefits, if any.

5. The time or other commitment required of the participants.

6. The location of the research and the person or office to contact for further information.

E. IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as:

1. the title;

2. purpose of the study;

3. protocol summary;

4. basic eligibility criteria;

5. study site location(s); and

6. how to contact the site for further information.

Examples of clinical trial listing services that do not require prospective IRB approval include:

1. The National Cancer Institute's cancer clinical trial listing (PDQ) and

2. The government-sponsored AIDS Clinical Trials Information Service (ACTIS).

However, when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

III. REFERENCES

A. NIH Clinical Trials