Guidelines for Advertisements

Advertisements used to recruit human research participants are reviewed by the IRB as to be part of the recruitment and consent process. Anything that is seen or heard by potential research participants is considered an advertisement. This includes, but is not limited to, flyers, letters, newspaper ads, TV / radio announcements, posters, and bulletins. Review of advertisements is necessary to ensure that the information is not misleading to the subjects.

Therefore, the USC IRB requires that all means of advertising, recruiting and notifying individuals of a study for enrollment be submitted for review and approval. Recruitment materials should be included as part of the initial request for protocol approval or submitted as an amendment (change/revision) to the protocol. It is recommended that the Principal Investigator obtain IRB approval of the advertisement text prior to production / recording in order to avoid rerecording because of unacceptable language or wording.

Advertisements must include:

1. The title of the study.

2.The purpose of the research or the condition in lay terms.

3. Summary of the criteria that will be used to determine eligibility for the study.

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

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

6. The following statement: "A research study at the University of South Carolina."

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".

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.

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.