Policy Statement: The Institutional Review Board (IRB) is responsible for ensuring the equitable selection of research subjects and must therefore review the methods that investigators use to recruit subjects, including advertisements. Advertising for research subjects is not in and of itself an objectionable practice. However, when advertising is to be used, the IRB shall review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects is not coercive, affords adequate protection and does not distract from equitable subject participation.

Procedure:

I. Requirements

Advertisements, study brochures, posters, scripts or similar documents used to recruit subjects are an extension of the informed consent and subject selection processes. Saint Alphonsus Regional Medical Center (SARMC), therefore, requires IRB review of such documentation. IRB review is necessary to ensure that the information is not misleading to subjects and that subject selection is equitable, especially if a study will involve persons with acute or severe physical or mental illnesses, or persons who are economically or educationally disadvantaged.

A. Advertisements, brochures, and/or other information used to recruit and screen potential subjects must be submitted to the IRB and address the following:

1. The name and address of the principal investigator, the research facility and the title of the study;
2. The purpose of the research and the condition being studied;
3. A summary of the criteria that will be used to determine eligibility for the study (a complete list of eligibility criteria is not required);
4. A straightforward and truthful description of the potential benefits and potential burdens (e.g., as applicable: payments, no-cost treatment, the percentage of subjects who will receive a placebo, etc.) to the subject for participating in the study;
5. The amount of time or other commitment required of the subjects;
6. The location of the research and the person or office to contact for further information.

These requirements apply regardless of whether the recruitment documentation is in print, broadcast on the radio or television, or posted on the Internet. It is not required that the complete title be read aloud for radio and television advertisements.
II. **Initial submission**

A. A new project application must be completed for all new research projects. The application requires the following information to be addressed in regards to subject recruitment and screening:

1. Explain in detail the methods and process that will be used for recruitment.
2. Indicate the timing of the recruiting methods.
3. State who will be recruiting participants.
4. State where will recruitment take place.
5. State the methods for screening participants.
6. State who will be responsible for screening participants.

III. **Further cautions**

A. For advertisements, brochures, pamphlets, posters, scripts, commercials, newspaper articles and informed consent/assent:

1. Do not use the phrase "Free medical treatment".
2. Do not call the intervention a new treatment, medication, drug, device, etc.
3. If the study is a blinded multi-armed investigational drug study, describe the study arms in the following manner. "You will receive a pill (or patch, injection, etc.). This pill (or patch, injection, etc.) may contain the study drug, an inactive substance called a placebo, or...(continue listing any other possible interventions). You have a 1 in "X" chance of receiving the study drug."
4. Indicate the proposed media to be used and whether any subsequent advertisements in different media are planned.
5. No claims should be made, either explicitly or implicitly, that the drug or device is safe or effective for the purpose under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would be a violation of FDA's regulations concerning the promotion of investigational drugs [21 CFR 312.7 (a)] and of investigational devices [21 CFR 812.7 (d)].
6. Monetary compensation should not be emphasized.
7. Documents should be clear that research participation is what is being solicited.
8. If posters, flyers, etc are being used, assure that permission has been given for placement of these materials in hospital waiting rooms, emergency rooms or offices/clinics, etc.

**Related Policies:** None

**Related Forms:** None
References:

Code of Federal Regulations. (Last revised April 1, 2010). Title 21 – Department of Health and Human Services; Part 56.111 (a) (3) – Criteria for IRB approval of research – selection of subjects.