1. PURPOSE

To outline the procedure for advertising to recruit Study Participants (SP) and/or patients to participate in clinical trials/research studies requiring human subjects.

2. SCOPE

Applies to all clinical site research personnel involved in the implementation and coordination of clinical investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for all aspects of the study in question, including delegating personnel responsible for obtaining Institutional Review Board (IRB) approval of advertisements aimed at recruiting persons in the community to become SPs in a clinical trial.

4. BACKGROUND

Advertising for clinical trial participants often provides a significant number of potential study participants. Recruitment ads for clinical studies must be objective and make no efficacy or comparative claims for the product being investigated. Also, by Food and Drug Administration (FDA) regulation, advertisements for clinical trial subjects must be approved by the IRB that reviews the clinical protocol.

5. PROCEDURE

5.1. Elements that the advertisement should include:

- 5.1.1. Contact person (avoid using last name), phone number and/or email, and may or may not include address
- 5.1.2. Brief description of the type of study or the condition/disorder that the study is about
- 5.1.3. An outline of the criteria that the SP must meet in order to participate
- 5.1.4. Brief description of the procedures being conducted

5.2. Elements that the advertisement shall not include:

- 5.2.1. Claims that the drug, biologic or device is safe or effective for the purpose of the investigation
- 5.2.2. Claims that the test article is known to be equivalent or superior to any other drug, biologic, or device [21 CRF 312.7(a) 812.7(d)]

5.2.3. Promises of free medical treatment when intent is only to state that SPs will not be charged for taking part in the research study

5.2.4. Stipend information may be included: this information must NOT be highlighted or the focal point of the advertisement.

5.3. Prior to IRB Submission

5.3.1. Ads must be approved by the study sponsor, if applicable, and submitted to the IRB.

5.3.2. Prior to submitting ads to the IRB and sponsor, it is necessary to determine whether the money for advertising has been supplied within the study budget.

5.3.3. Creighton University Public Relations is available to assist in developing and disseminating recruitment material.

5.3.4. If the ad is to run on the radio, it should be approved by the sponsor and then the IRB. A contract with the radio station must be arranged prior to submission of the ad to the radio station.

5.3.5. Prior to submitting advertisements, it is necessary to determine what medium would yield the most patients. Advertisements may be in print form or audio or visual format. A final copy of a printed advertisement will be submitted to evaluate the size of type and other visual effects. Advertisements that will eventually be in audio format must be submitted in script form for approval. Visual (TV) ads must be submitted on videotape, CD, or DVD.

5.4. Submission to the IRB

5.4.1. The advertisements (any and all forms) are submitted to the IRB with the protocol, the investigator's binder, and informed consent if available at the time of initial application. Subsequent advertisements are submitted with cover letter to the IRB for approval, The advertisement may either be drafted by the PI or delegated personnel, or the sponsor of the study, but must not make any claims of a beneficial nature.

5.4.2. A copy of all IRB-approved advertisements will be forwarded to the sponsor and a copy will be maintained in the study regulatory binder.

5.4.3. All clinical investigators that are actively enrolling should be posted on the Creighton University Participant Website.

6. TERMS & ABBREVIATIONS

FDA Food and Drug Administration
IRB Institutional Review Board
PI Principal Investigator

PR Public Relations
SC Study Coordinator
SP Study Participant

7. REFERENCES

7.1. 21 CFR 312.7(a)
7.2. 21 CFR 812.7(d)
7.3. 21 CFR 56.109(a)
7.4. Food, Drug, and Cosmetic Act section 502(a)
7.5. 21 CFR 201.6 (a)
7.6. 21 CFR 202.1 (e)(6)(i)
7.7. 21 CFR 202.1 (e)(6)(ii) Title 21 CFR 312.7 - Promotion and Charging for Investigational Drugs
7.8. FDA Information Sheet - Recruiting of Study Subjects
7.9. FDA Information Sheet - A Guide to Informed Consent
7.10. FDA Information Sheet - Payment to Research Subjects

8. ATTACHMENTS

None