DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio, Texas 78229-4404

Research Service Policy Memorandum 16- 39

January 7, 2016

RESEARCH STANDARD OPERATING PROCEDURES
Human Subjects Research Recruitment and Advertising

1. **PURPOSE**: To describe the policies and procedures for research subject recruitment and advertising for human subjects research protocols approved at the South Texas Veterans Health Care System (STVHCS).

2. **POLICY:** Advertisements may be used to assist in the recruitment of prospective human subjects for an approved protocol. No materials can be provided to subjects without Institutional Review Board (IRB) approval. Any recruitment advertisements to be posted at the STVHCS must have prior University of Texas Health Science Center at San Antonio (UTHSCSA) IRB, STVHCS R&D, and STVHCS Office of Public Affairs (OPA) approval. These documents will be stamped "IRB Approved" "R&D Approved" and "Public Affairs Approved" and cannot be posted at the STVHCS without these stamps.

3. **ACTIONS:**

a. The clinical investigators and study team will discuss research study recruiting needs and determine the type of advertisement to be used (print/audio/video).

(1) The study team members will review the FDA/IRB accepted guidelines for advertisements prior to developing proposed advertisements.

(a) Any and all advertisements <u>should include</u>:
The name and address of investigator and/or research facility
1. The condition under study and/or purpose of the study
2. A summary of the criteria used to determine eligibility
3. A brief list of participation benefits, if any
4. The amount of time or other commitment required of subjects
5. The location of the research
6. A person or office to contact for further information

(b) Advertisements <u>should not include</u>:
1. Claims that the test article is safe or effective for the purpose of the investigation
2. Claims that the test article is known to be equivalent or superior to any other drug
3. Terms which imply the receipt of newly improved products of proven worth such as "new treatment", "new medication", or "new drug". The advertisement must explain that the drug or device is investigational.
4. Promises of free medical treatment when intent is only to state that subjects will not be charged for taking part in the investigation
5. Emphasis of payment for participation

b. The clinical investigator or study team member will submit the proposed advertisement to the UTHSCSA IRB for review and approval. No advertisement will be implemented without approval from the IRB.

c. The clinical investigator or study team member will submit a copy of all IRB approved advertisements to the R&D Office to verify R&D approval of the research protocol. The R&D Office staff will stamp and date the advertisement after verifying R&D approval.

d. The R&D Office staff will forward a copy of all IRB and R&D approved advertisements to the STVHCS Public Affairs Office for approval to post the advertisement within the STVHCS.

(1) For expedited posting the clinical investigator or study team member may walk the IRB and R&D approved advertisements to the STVHCS OPA (located within the STVHCS Directors suite) for approval to post the advertisement within the STVHCS.

e. A copy of the approved advertisement should be maintained by the clinical investigator in the Essential Regulatory Binder in the appropriate section.

4. Advertising for research related to veterans not taking place at the VA

a. All such request must go through STVHCS R&D Administration Office for review and include a copy of the advertisements and the IRB approval letter from the respective institution.
b. After Research Service approval will be forwarded for approval by public affairs.
c. Posting of advertisements are allowed, but no face-to-face recruitments are allowed.

5. **REFERENCES**: VHA Handbook 1200.05; FDA CRF 21 www.fda.gov/oc/ohrt/irbs/toc4.html)

6. **RESPONSIBILITY**: ACOS for Research and Development (151)

7. **RECESSION:** Research Service SOP 08-39, dated October 3, 2011

8. **RECERTIFICATION:** January 2021

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