

March 14, 2022

**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.
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 should include:
        1. The name and address of investigator and/or research facility
        2. The condition under study and/or purpose of the study
        3. A summary of the criteria used to determine eligibility
        4. A brief list of participation benefits, if any
        5. The amount of time or other commitment required of subjects
        6. The location of the research
        7. A person or office to contact for further information
      - (b) Advertisements should not include:
        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 the IRB-approved advertisement to the R&D Office. The R&D Office staff will stamp and date the advertisement after verifying R&D approval of the research protocol.

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- d. The R&D Office staff will forward a copy of all IRB and R&D approved advertisements to the STVHCS OPA 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 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 requests must go through STVHCS R&D Administration Office for review and include a copy of the advertisement and the IRB approval letter from the respective institution.
- b. Flyers, recruiting documents, and advertisements for research should include a clear disclaimer that it is not VA research, VA is not responsible for any costs incurred by a Veteran as a research subject, is not endorsed by VA, and that the announcement is being provided for information purposes only.
- c. Research service will review the request for the posting of recruiting documents, flyers, and advertisements as per [ORD Guidance on Advertisement of Non-VA Research Activity in VA Facilities](#). After review, request for advertising will be forwarded for approval to OPA by Research service.
- c. After OPA and Research Service approval, distribution of advertisements is allowed, but face-to-face recruitments are not allowed by any research study team member.
- d. A VA clinician can provide the flyer or advertisement about the non-VA study and inform interested patients or patients who may benefit from this study to contact the study team using the information on the flyer. The VA clinician cannot take any other actions that suggest they are acting as an agent of the study or involved in any aspect of the study (eg. screening medical records for the study, making a determination of eligibility, contacting the study team on behalf of the patient).

- 5. **REFERENCES:** VHA Directive 1200.05(2); FDA guidance documents [www.fda.gov/oc/ohrt/irbs/toc4.html](http://www.fda.gov/oc/ohrt/irbs/toc4.html); [ORD Guidance on Advertisement of Non-VA Research Activity in VA Facilities](#)
- 6. **RESPONSIBILITY:** ACOS for Research and Development (151)
- 7. **RECESSION:** Research Service SOP 18-39, dated April 10, 2018
- 8. **RECERTIFICATION:** March 14, 2027

[Signature on File]

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ACOS for Research and Development