

May 19, 2008

HUMAN SUBJECTS CLINICAL RESEARCH RECRUITMENT AND ADVERTISEMENT

1. **PURPOSE:** The purpose of this policy memorandum is to describe the policies and procedures for recruitment of human subjects for clinical research conducted at the South Texas Veterans Health Care System (STVHCS).

2. **POLICY:** The STVHCS will maintain a policy and standard operating procedure for the recruitment of human subjects for clinical research. Appropriate recruitment will ensure protection of human subjects and maintenance of a high quality research program.

a. Definitions:

(1) **Human Research Protection Program (HRPP)**—The systematic and comprehensive approach by an organization to ensure human subject protection in all research.

(2) **Investigator.** An investigator is an individual under the direction of the Principal Investigator (PI) who is involved in some or all aspects of the research project, including the: design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts. An investigator must be either compensated by VA, be appointed to work without compensation (WOC), or may be an employee assigned to VA through the Intergovernmental Personnel Act (IPA) of 1970. The FDA considers an investigator and a PI to be synonymous.

(3) **Investigator Records.** Investigator records include all IRB records as well as case histories or any data gathered for research purposes. IRB records include but are not limited to: copy of all proposals reviewed including amendments, investigator brochures, any supplemental information including recruitment and informational materials, consent forms, information submitted for continuing review, and all correspondence. A case history is a record of all observations and other data pertinent to the investigation on each research subject. Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but not limited to: progress notes of the physician, study coordinator notes, and any other study related information contained in the computerized patient record system (CPRS).

(4) **Principle Investigator (PI).** Within VA, a PI is an individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The PI is accountable for the proposal and the execution of the research protocol, as designed, by overseeing the performance of research staff to ensure the completion of all research activities.

(5) **VA-approved Research.** VA-approved research is research that has been approved by the VA R&D Committee.

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b. Accountability:

(1) The PI and associated research staff are responsible for assuring all recruitment and advertisements are in accordance with all FDA, IRB, and STVHCS policies and guidelines. The PI and associated research staff are responsible for forwarding all advertisements for the appropriate approvals. PI is responsible for ensuring all key study personnel comply with the Research Service Memorandum Human Subjects Research Recruitment and Advertising Standard Operating Procedure No. 39.

(2) The IRB Office is responsible for approving all research advertisements and providing guidance to investigators regarding appropriate recruitment mechanisms for human subjects' research.

(3) R&D Office is responsible for assuring only advertisements for VA- approved research is posted within the STVHCS.

(4) The STVHCS Office of Public Affairs is responsible for approving all advertisements for VA-approved research which are posted within the STVHCS.

3. **ACTIONS:**

a. Veteran patients can be enrolled in studies that

(1) Have been approved by the UTHSCSA IRB and VA R & D committee

(2) Are performed by research investigators (VA salaried or WOC) who have completed VA credentialing and training

(3) Will be performed on-site at the VA (GCRC or other clinic)

b. Veteran patients cannot be enrolled in studies performed off-site at a non-VA institution through formal referral from VA staff or through formal recruitment at the STVHCS. Active recruitment of VA patients into non-VA studies through posting of fliers at the VA is not allowed.

(1) Veteran patients have a right to seek care from and enroll in a research study outside the VA. When treatment options or relevant research studies are only available through non-VA institutions, a VA physician may inform the veteran about options outside the VA.

(2) Informing the veteran patient of the availability of an outside research study, (i.e. at the UTHSCSA) is not considered a referral, if the referring physician will not have an ongoing participation in the care of the patient.

(a) In informing the veteran patient about an off-site study, it should be made clear to the veteran that the VA will not be responsible for any costs related to their care at the off-site institution or their participation in the off-site research study.

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(b) Enrollment of a veteran in a non-VA study should occur through the veteran's own initiative in contacting the study personnel at the outside institution.

(c) If a veteran enrolls in a research study at a non-VA site on their own initiative the research subject should sign the consent form appropriate for that institution.

(d) The provision of information to a VA patient regarding potential research study options outside the VA and the patient's responsibility for any costs related to the study, should be documented by the VA physician in a progress note in the patient's electronic medical record (CPRS).

(e) Veterans who seek care from, or elect to enroll in a research study, at an institution outside of the VA will have access to general care (unrelated to the research study) at the VA as determined by their eligibility status.

(f) In accordance with VHA privacy laws, VA records may not be accessed to obtain information for research purposes for a veteran research subject enrolled in a non-VA study.

c. Non-veterans may be entered into VA-approved research studies when there are insufficient veterans available to complete the study in accordance with 38 CFR 17.45 and 38 CFR 17.92.

(1) All regulations pertaining to the participation of veterans as research subjects including requirements for indemnification in case of research-related injury pertain to non-veteran subjects enrolled in VA-approved research.

(2) Recruitment may be accomplished through IRB-approved mechanisms such as physician referral or posting of IRB-approved advertisements. For additional guidance on IRB-approved recruitment mechanisms refer to the IRB policy titled "Privacy and Confidentiality During Identification and Recruitment of Research Subjects."

(3) Recruitment advertisements posted at the STVHCS must be:

(a) Approved and stamped by the UTHSCSA IRB

(b) Verified and stamped by the STVHCS R&D office.

(c) Approved by STVHCS Public Affairs Office prior to posting the advertisement within the STVHCS.

d. Reviews Preparatory to Research

(1) A review of individually-identifiable information by a VA investigator to prepare a research protocol (i.e. to generate a hypothesis, determine the feasibility to conduct a study, determine the number of eligible patients) does not require R&D Committee approval.

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(2) Neither written authorization from the research subject nor an UTHSCA IRB waiver of authorization is required for an investigator to conduct a review of individually-identifiable information in preparation of a research protocol. [45 CFR 164.512(i)(1)]

(3) Contacting of potential research subjects or conducting pilot studies are not Preparatory to Research.

(a) Use of individually-identifiable information to contact potential research subjects would require an IRB approved waiver of HIPAA authorization.

(b) Pilot studies require both UTHSCSA IRB and R&D Committee approval prior to initiation.

e. Payment for Subjects

(1) Subjects are prohibited from receiving payment if the research is integrated with a patient's medical care and when it makes no special demands on the patient beyond those of usual medical care.

(2) Payments to subjects may be permitted, with IRB approval, in the following circumstances:

(a) No direct subject benefit. The study is not directly intended to enhance the diagnosis or treatment of the medical condition for which the subject is being treated, and when the standard of practice in affiliated non-VA institutions is to pay subjects in this situation.

(b) Others being paid. In multi-site studies, when subjects at a collaborating non-VA institution are being paid for the same participation in the same study at the same rate proposed.

(c) Comparable situations. In other comparable situations in which, in the opinion of the IRB, payment of subjects is appropriate.

(d) Transportation expenses. When transportation expenses are incurred by the subject that would not be incurred in the normal course of receiving treatment and which are not reimbursed by any other mechanism.

(3) The IRB must be able to verify the following in order to approve payment of subjects for a specific protocol:

(a) Proposed payments are reasonable and commensurate with the expected contributions of the subject.

(b) Terms of the subject participation and the amount of payment are listed in the informed consent document.

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(c) Subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the prospective research subjects to volunteer for, or to continue to participate in, the research study; and that the payments do not constitute (or appear to constitute) coercion to participate in, or continue to participate in, the research study

(3) All patient compensations must be approved by the UTHSCSA IRB and the R&D Committee.

4. REFERENCES: UTHSCSA IRB Privacy and Confidentiality During Identification and Recruitment of Research Subjects Policy and Procedure; Research Service Memorandum Human Subjects Research Recruitment and Advertising Standard Operating Procedure No. 39; VHA Handbook 1200.5; 38 CFR 17.45 and 38 CFR 17.92; 45 CFR 164.512(i)(1)]

5. RESPONSIBILITY: ACOS for Research and Development (151)

6. RESCSSION: STVHCS Policy Memorandum 151-07-03 dated April 17, 2007

7. RECERTIFICATION: May 2011

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RICHARD J. BALTZ, FACHE
Director

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