

August 28, 2008

SCOPE OF PRACTICE FOR RESEARCH PERSONNEL

1. PURPOSE: To outline the policy and procedures for approval of the designated roles and responsibilities of research personnel involved in human subjects research at the South Texas Veterans Health Care System (STVHCS). This component of the STVHCS Human Research Protection Program is designed to ensure that research personnel are qualified to conduct the research.

2. POLICY:

a. All individuals involved in human subjects research at the STVHCS must receive approval for their participation through the STVHCS Research Office. This includes research staff who interact directly with human subjects and research staff who interact with individually identifiable human subject information. One of the requirements for approval of research personnel, excluding physicians holding a valid medical license, is having an approved Scope of Practice that specifically defines their roles and responsibilities in the research protocol.

b. Personnel may have only the roles and responsibilities, as defined by their approved Scope of Practice, that are appropriate to their level of training, specific license, and clinical credentials. Licensed research personnel may *not* perform or be trained to perform procedures outside of those allowed under their respective license and credentialing. If a licensed clinician wishes to perform a clinical procedure for research purposes outside the scope of their current credentialing, he/she must have the change approved through the Medical Staff Office. Unlicensed research personnel may not be trained to do procedures that require a medical license.

c. Non-licensed research personnel, including individuals who have an MD, DO, BSN, or MSN degree, without licensure (excluding those in an ACGME approved training program), are not allowed to perform duties that would constitute the practice of medicine, including physical examination of subjects; ordering medications or investigational agents; altering or adjusting the dose of medications or investigational agents; evaluating acute medical problems, including adverse events; and ordering, administering, or modifying intravenous solutions or medications. Any procedures that, according to the STVHCS bylaws, would require consent of the patient in a standard (non-research) patient care setting may *not* be performed by non-licensed research personnel. These procedures are listed in the Bylaws and Rules of the Medical Staff of the STVHCS, Section R3.

d. Research personnel may *not* participate in a research protocol until all requirements of this policy are met, including an approved Scope of Practice.

e. Unlicensed research personnel working as research coordinators or research fellows may obtain informed consent if competency verification has occurred and is documented on the Research Scope of Practice form. However, unlicensed research personnel (excluding those in an ACGME approved clinical training program) may not use their educational degree after their signature on Institutional Review Board approved consent forms or on Research Staff Contact

lists. Furthermore, unlicensed research personnel may not display their educational degree (e.g. M.D. or R.N. on a name tag) in any way that would convey to the research participant or staff that he/she is a licensed practicing clinician.

3. ACTION:

a. Accountability:

(1) *Research Office* will provide required forms and instructions for completing the Scope of Practice, provide the employee a copy of the approved Scope of Practice or notification if the Scope is not approved, and maintain a copy in the employee file.

(2) *Research Employee and Principal Investigator* will complete the Research Scope of Practice form. The principal investigator must verify the employee's competency to perform the roles and responsibilities identified on the Scope of Practice. The principal investigator will verify that the approved Scope of Practice accurately defines the activities of research personnel at least annually through the Continuing Review process. Where the Scope of Practice applies to a principal investigator who is not a licensed physician, that principal investigator's supervisor (Section or Service Chief, Department Chair, etc.) must approve the duties requested on the Scope of Practice form.

(3) *Associate Chief of Staff (ACOS) for Research and Chief of Staff* will review and approve the Scope of Practice.

(4) The *Institutional Review Board (IRB)* will require the Principal Investigator to verify that all research staff on a protocol have a current approved Research Scope of Practice form, both at initial approval and the on continuing review progress report for each protocol.

b. Procedures:

(1) Principal Investigators must complete and submit the Research Scope of Practice to the Research Office when an individual is first added to their research protocol(s), whenever the duties of the employee must be modified, and must verify that the approved Scope of Practice accurately defines the activities of research personnel at least annually through the Continuing Review process. Investigators should retain a copy of the employee's Research Scope of Practice. A revised Research Scope of Practice should be submitted if modifications are needed to cover duties on a new protocol.

(2) The ACOS for Research and the Chief of Staff will review the Research Scope of Practice and approve if the requested roles and responsibilities are appropriate.

(3) The Research Office will provide the employee with a copy of the approved Scope of Practice or notification of disapproval if the Scope could not be approved as submitted. The new/revised scope will be entered into the employee file. The Research Office will request verification from the principal investigator that the approved Scope of Practice accurately defines the activities of research personnel at least annually through the Continuing Review process.

c. Education Requirements:

POLICY MEMORANDUM 151-08-07

(1) All individuals involved in human subject research at the STVHCS must complete the Human Subject Protection Education requirement using the Collaborative IRB Training Initiative, CITI course.

b. All individuals involved in direct interactions with human subjects (clinical trials, epidemiologic research, socio-behavioral research) are encouraged to also complete the Conducting Clinical Research course offered by the Office of Clinical Research, UTHSCSA or an alternate course approved by the Office of Clinical Research (SOCRA, ACRP, FDA sponsored GCP) within six (6) months of the Scope of Practice approval.

4. REFERENCES: None

5. RESPONSIBILITY: Associate Chief of Staff for Research (151)

6. RESCISSION: STVHCS Policy Memorandum 151-08-07, dated April 19, 2008

7. RECERTIFICATION: August 2011

(original signature on file)

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Center Director

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