

DEPARTMENT OF VETERANS AFFAIRS  
South Texas Veterans Health Care System  
7400 Merton Minter Boulevard  
San Antonio, Texas 78229-4404

RESEARCH SERVICE  
MEMORANDUM 07-33

February 7, 2007

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.

2. POLICY:

a. All individuals involved in human subjects research at the STVHCS must receive approval for their participation through the Research Office. One of the requirements for approval 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 and specific license.

c. Non-licensed research personnel, including individuals who have an M.D., without licensure, are not allowed to perform procedures that, according to the STVHCS bylaws, would require consent of the patient in a standard (non-research) patient care setting. These procedures are listed in the Bylaws and Rules of the Medical Staff of the STVHCS, Section R3.

d. Research personnel participation in a research protocol may not start until all requirements are met, including an approved Scope of Practice.

3. RESPONSIBILITY:

a. Research Office. The 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, maintain a copy in the employee file, and advise the investigator when the two-year review is required.

b. Research Employee and Principal Investigator. Employee and investigator will complete the 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.

c. Associate Chief of Staff for Research and Chief of Staff. The Scope of Practice must be reviewed and approved by the Associate Chief of Staff for Research and the Chief of Staff.

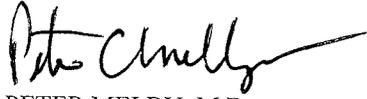
4. PROCEDURES:

a. Investigators must complete and submit the Scope of Practice to the Research Office when the individual is first added to their research protocol(s), whenever the duties must be modified, and when notified that the two-year review is required.

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

c. 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 employee file and tracked for two-year review.

5. RECISSION: None.

A handwritten signature in black ink, appearing to read "Peter Melby", with a long, sweeping horizontal stroke extending to the right.

PETER MELBY, M.D.  
ACOS for Research and Development