

St. Louis VA Medical Center  
**SCOPE OF PRACTICE**  
 Clinical and Health Services Research Investigators and Study Staff

NAME
STUDY ROLE
SUPERVISORS (Responsible or Principal Investigators)
ALTERNATIVE SUPERVISOR (If Applicable)
EXPIRATION DATE (Annually, From Date of ACOS for Research Signature)

The Scope of Practice Form is specific to the duties and responsibilities of each research study team member. Each person who works on a study must review, sign, and date their Scope of Practice Form annually, updating as necessary. A Scope of Practice form must be completed/reviewed annually for all research personnel, including Principal & Responsible Investigators

ROUTINE DUTIES	YES	NO
1. Prepare and coordinate study activities including: initiation, study activities, conferences, and data exchange between sites		
2. Submit regulatory documents to St. Louis VA IRB, VA R&D Committee, Sponsor, and other approved regulatory agencies		
3. Develop and implement recruitment and adherence methods to be utilized in the study		
4. Perform the informed consent process		
5. Screen patients to determine study eligibility criteria by review of a patient's medical information or by subject interviews		
6. Access patient medical information while maintaining confidentiality		
7. Utilize VISTA/CPRS computer systems to schedule subjects' research visits, document progress notes, initiate orders, consults, etc.		
8. Provide education regarding study activities to patient, relatives and medical center staff as necessary per protocol		
9. Dispense study medications		
10. Provide subject education and instruction of study medication use, storage, possible side effects and procedure to notify the study site of any adverse reactions		
11. Initiate and administer medication therapies.		
12. Collect various types of human specimens as described in study protocol		
13. Handle, package and ship human specimens to study labs		
14. Initiate and/or expedite request for consultation, special tests or studies		
15. Maintain complete and accurate data collection in case report forms and source documents		
16. Performs or supervises data collection and management for the study		
17. Obtain and organize data, such as study databases, tests results, diaries/cards or other necessary information for the study		
18. Conduct/assist with statistical analysis of de-identified and aggregate level data		
19. Conceptualize, design, and implement data analyses		
20. Interpret results and prepare manuscripts		
<b>Additional duties not included in categories above:</b>		
21.		
22.		

PRINCIPAL INVESTIGATOR STATEMENT:

2/22/2011

