

**TUSCALOOSA VAMC
SCOPE OF PRACTICE FOR RESEARCH PERSONNEL**

Name	Service Line		
Principal Investigator/Primary Supervisor	Alternate Supervisor (if applicable)		
<p>The Scope of Practice is specific to the duties and responsibilities of a research employee as an agent of the listed Principal Investigator and/or alternate supervisor. As such, the employee is specifically authorized to conduct research involving human subjects with the responsibilities outlined below. The supervisor must complete, sign and date this Scope of Practice.</p> <p>PROCEDURES: A research employee may be authorized to perform the following duties/procedures on a regular and ongoing basis. They may be performed without specific prior discussion and/or instructions from the Principal Investigator.</p> <p>The employee should <i>initial</i> the duties that he/she is requesting, and the Principal Investigator should <i>initial</i> what is granted or not granted.</p>			
Routine Duties	Requested	Granted (PI Must Initial)	Not Granted (PI Must Initial)
1. Screens patients to determine if study eligibility criteria are met by reviewing patient medical information or interviewing subjects.			
2. Develops recruitment methods to be used in the study.			
3. Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competency).			
4. Initiates submission of regulatory documents to IRB, R&D Committee and Sponsor(s).			
5. Provides education and instruction about study medication use, administration, storage, and side effects, and notifies study site of adverse drug reactions.			
6. Provides education regarding study activities to patient, relatives and Medical Center staff as necessary per protocol.			

Routine Duties	Requested	Granted (PI Must Initial)	Not Granted (PI Must Initial)
7. Maintains complete and accurate data collection in case report forms and source documents.			
8. Initiates and/or expedites requests for consultation, special tests, or studies following the investigator's approval.			
9. Obtains and organizes data such as test results, diaries/cards or other necessary information for the study.			
10. Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent process.			
11. Uses CPRS to document informed consent, research participation and progress notes, and flags records of research participants.			
12. Accesses patient medical information while maintaining patient confidentiality.			
13. Collects and handles various types of human specimens.			
<p>MISCELLANEOUS DUTIES (if applicable):</p> <p>Mr./Ms/Dr. _____ is authorized to perform the following miscellaneous duties not otherwise specified in this scope of practice:</p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>			
<p>_____ Signature of Employee</p> <p>_____ Date</p>			

PRINCIPAL INVESTIGATOR STATEMENT:

Mr./Ms/Dr. _____'s Scope of Practice was reviewed and discussed with him/her on the date of _____. After reviewing his/her education, clinical competencies, qualifications, training, research practice involving human subjects, peer reviews (where applicable) and individual skills, I certify that he/she possesses the skills safely to perform the aforementioned duties/procedures. Both the research employee and I are familiar with all duties/procedures granted or not granted in this Scope of Practice. We agree to abide by the parameters of this Scope of Practice, all-applicable medical center policies and regulations.

The Scope of Practice will be reviewed every two years and amended as necessary to reflect changes in the research employee's duties/responsibilities, training/experience, utilization guidelines and/or medical center policies.

Principal Investigator / Supervisor (signature) Printed name (PI / Supervisor) Date

Alternate Supervisor (if applicable) Printed name (Alternate / Supervisor) Date

I understand and agree to perform only the duties granted to me in this document:

Employee (signature) Printed name (Employee) Date

OFFICE USE ONLY:

Chief, Research and Development Printed name (C / R&D) Date

ANNUAL REVIEWS: This Scope of Practice has been reviewed with the employee to whom it pertains. No changes are needed at the time of the review (Add continuation pages as needed).

Chief, Research and Development Printed name (C / R&D) Date

Chief, Research and Development Printed name (C / R&D) Date

Chief, Research and Development Printed name (C / R&D) Date

Chief, Research and Development Printed name (C / R&D) Date