SCOPE OF PRACTICE FOR MEDVAMC RESEARCH STAFF

Research Service Line (151)

The scope of practice is specific to the duties and responsibilities of the individual as an agent of the listed principal investigator and/or alternate supervisor. As such he/she is specifically authorized to conduct research involving human subjects, animal subjects, laboratory specimens, and or data with the responsibilities outlined below. The supervisor must complete Sections I-III, sign and date this scope of practice.

SECTION I: GENERAL INFORMATION	
Employee's Name	Employee's Title
Principal Investigator (PI)/ Primary Supervisor	Alternate/Secondary Supervisor (if applicable)
VA Credentialing and Privileging	Licensure Type
Are you currently credentialed and privileged at MEDVAMC to perform patient care activities? ☐ YES ☐ NO If yes, do you have a clinical scope of practice or functional statement that include those activities? ☐ YES ☐ NO If no, you must obtain clinical credentials before applying for these activities as part of your Research Scope of Practice	Are you a licensed professional? ☐ YES ☐ NO If yes, indicate type of license: ☐ MD; ☐ PhD; ☐ DNP; ☐ NP/PA; ☐ RN; ☐ LPN; ☐ Other (specify):_____
Certification Eligibility	Type of Research: Clinical (Human Subjects), Animal, Laboratory, or Other
Are you eligible for certification that would be required for clinical practice in your health care profession (i.e., degree)? ☐ YES ☐ NO	☐ Clinical (Human Subjects) ☐ Animal ☐ Laboratory ☐ Data only research ☐ Other:_____

Indicate the employee's interaction with research Participants	
☐ PERSONNEL WITH DIRECT CONTACT: Research employees who perform procedures, interviews, telephone calls to research subjects, clinical interventions with patients during the conduct of a research project. Proceed to Section II	☐ PERSONNEL WITH INDIRECT CONTACT: Research employees who do not interact directly with research subjects, but only manage study data, only have access to medical records, or handle human specimens, for research purposes. Proceed to Section III

SECTION II: DELEGATION OF DUTIES

The above individual may be authorized to perform the following duties/procedures on a regular and ongoing basis under protocols approved by the IRB and R&D Committee. The Principal Investigator should review and discuss the duties that he/she is assigning to the employee.

Please indicate whether this Research Scope of Practice is:
☐ NEW *(A Research Scope of Practice has not been completed for this individual previously)*
☐ REVISED *(A Research Scope of Practice exists for this individual, but there are changes in duties)*

The Principal Investigator must *****initial***** each item assigned.

Routine Duties: Clinical (Human Subjects)	Assigned
1) Screens subjects to determine study eligibility criteria by reviewing subject medical information or interviewing subjects.	
2) Develops and/or implements recruitment methods to be utilized in the study.	
3) Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competencies below)	
4) Initiates submission of regulatory documents to the IRB, MEDVAMC R&D Committee, and the study sponsor.	
5) Prepares study initiation activities.	
6) Provides education and instruction of study medication use, administration, storage, and side effects and notify adverse drug reactions to study site.	
7) Provides education regarding study activities to patient, relative and Medical Center staff as necessary per protocol.	
8) Maintains complete and accurate data collection in case report forms and source documents.	
9) Initiates and/or expedites requests for consultation, special tests or studies following the Investigator's approval.	
10) Obtains and organizes data such as test results, diaries/card or other necessary information for the study.	
11) Uses CPRS computer system.	
12) Monitor patients' clinical condition and report findings.	
13) Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent "process".	
14) Administers questionnaires or conducts mental status or psychosocial exams	
15) Initiates intravenous (IV) therapy and Administers IV solutions. (Must be an RN)	
16) Administers medication (not involving IV). (Must be an RN, LVN)	
17) Collects and handles various types of human specimens	
18) Packaging, transporting, and shipping of human blood, blood components, tissues, or other body fluids. *(Additional training required: "Transportation of Dangerous Goods" Contact: Dr. Torsten Hopp, Biological Safety Office at 713-798-6616 or thopp@bcm.edu)*	
19) Ensures that adverse events are reported to Cooperative Studies Program (CSP), sponsors, VA research department and the IRB according to protocol.	
20) Input data into BRAIN	
21) Input data into Study Manager	
22) *Other duties not listed above but included in the IRB/RDC approved protocol (for example: invasive procedures)*	
a)	
b)	
c)	

• If any item from 1-22 listed above has been checked, CITI Human Subjects Training and Privacy and HIPAA Traini (*TMS# 10203*) is required. *NOTE: This area must be initialed and completed by the Training Coordinator:* ➢ CITI Human Subjects Training and Privacy and HIPAA Training (*TMS# 10203*) is required ☐YES ☐ NO	

Routine Duties: Animal Research	Assigned
1) Conducts research involving live or dead animals or their unfixed tissues (organs, skin, blood, cultures, etc.) or products (urine, feces, other body fluids, cell lines, etc.).	
Species: ☐ Mice ☐ Pigs ☐ Rats ☐ Rabbits ☐ Dogs ☐ Other-*specify*	
2) Performs surgical procedures	
3) Handles or administers controlled substances.	
4) Trains or supervises others in carrying out research activities	
5) Performs statistical analysis	
6) Develops articles or presentations of research results	
7) *Other duties not listed above but included in IACUC/RDC approved protocol*	
a)	
b)	
c)	
• **If any item from 1-6 listed above has been checked, CITI Working with the VA IACUC Training and Animal Specific Training (i.e., mouse, rat, pig), is required.** ***NOTE: This area must be initialed and completed by the Training Coordinator:*** ➢ **CITI Working with the VA IACUC and Animal Specific Training (i.e., mouse, rat, pig) is required** ☐**YES** ☐ **NO**	

Routine Duties: Laboratory Research	Assigned
1) Uses and stores chemicals.	
2) Orders biological materials or chemicals	
3) Operates laboratory equipment	
4) Uses and stores biomaterials (for example: tissues, secretions, cell lines, microbiological or viral agents, pathogens or toxins, recombinant or synthetic DNA, etc.	
5) Use radioactive materials and/or radiation generating equipment.	
6) Uses controlled substances	
7) Trains or supervises others in carrying out research activities	
8) Collects, records, or analyzes research data.	
9) Processes and/or ships infectious and or biological reagents and materials.	
10) Performs statistical analysis	
11) Develops articles or presentations of research results	
12) *Other duties not listed above but included in SRS/RDC approved protocol*	
a)	
b)	
c)	
• **If any item from 1-12 listed above has been checked, CITI VA ORD Biosecurity Training is required.** • **If item 9 is checked, CITI Packaging and Shipping of Class 6.2 Hazardous Agents (*or BCM equivalent*) is required.** ***NOTE: This area must be initialed and completed by the Training Coordinator*** ➢ **VA ORD Biosecurity Training or Biosafety training is required** ☐**YES** ☐ **NO** ➢ **CITI Packaging and Shipping of Class 6.2 Hazardous Agents (*or BCM equivalent*) is required** ☐**YES** ☐ **NO.**	

MISCELLANEOUS DUTIES (IF APPLICABLE):

_____ (*WOC/MEDVAMC employee)* is authorized to perform in the following miscellaneous duties not otherwise specified in this scope of practice.

1. _____
2. _____
3. _____

VERIFICATION OF SPECIMEN COLLECTION (IF APPLICABLE):

I _____ have observed _____
Principal Investigator *WOC/MEDVAMC employee*
using proper aseptic technique when performing venipuncture on research subjects. She/he uses universal precautions when executing blood drawing skills and proper disposal of biological waste used. _____ (*WOC/MEDVAMC employee)* follows all policy and procedure guidelines when performing this skill.

SECTION III: CERTIFICATIONS

NOTICE TO LICENSED PROFESSIONALS:
Licensed professionals should be credentialed by VA Human Resources – Credentialing Office. Individuals found to be working outside their privileges as granted by the MEDVAMC may be subject to disciplinary action.

PRINCIPAL INVESTIGATOR STATEMENT:

_____ (*WOC/MEDVAMC employee*) Scope of Practice was reviewed and discussed with him/her on the date signed below. After reviewing his/her education, clinical competency, qualifications, research practice involving human subjects, animal subjects, laboratory skills, peer reviews, and individual skills. I certify that he/she possesses the skills to safely perform the aforementioned duties/ procedures. The above named individual 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 hospital policies and regulations.

This scope of practice will be reviewed and amended as needed to reflect changes in the nurse, study coordinator, and research assistant duties/responsibilities, utilization guidelines and/or hospital policies.

_____ _____
Principal Investigator Signature Date

_____ _____
Employee Signature Date

_____ _____
ACOS/R&D Signature Date

NOTE: Internal Office Use Only
All initial required training has been verified as completed.

_____ _____
Training Coordinator Signature Date