

Scope of Practice for Research Personnel

NAME OF RESEARCH PERSONNEL	EMAIL ADDRESS
PRIMARY SUPERVISOR <i>(conducts the employee's annual evaluation and initiates this form)</i>	ROLE IN RESEARCH <i>(Investigator, Research Staff, Statistician, Consultant, Etc...)</i>
<p>Please indicate type of Employee: Study Team Member – VA Employee Study Team Member – IPA or WOC Employee</p>	

1. RESEARCH TEAM MEMBERS: The Scope of Practice is specific to the duties and responsibilities of Research Personnel (Employee or WOC) as an agent of the listed Supervisor. As such he/she is specifically authorized to conduct research with the responsibilities outlined below. Only one Research Scope of Practice is required for each Research Staff Member. When Research personnel are involved in multiple studies, this scope of practice should encompass all of the duties that the individual is authorized to perform. All Principal Investigators for whom the staff member will be working (who are not the supervisor), should also review the Scope of Practice Statement to ensure that the duties authorized match those that will be performed as part of the research. Local training may be required to perform some of the duties authorized to conduct a study.

2. PRINCIPAL INVESTIGATORS: A Scope of Practice must be completed for Principal Investigators to delineate their Research duties outside of the Credentialing and Clinical Privileges granted by the Medical Center. This includes all duties performed in addition to the PI oversight responsibility.

3. PROCEDURES: The supervisor(s) must complete this Scope of Practice granting duties/procedures the personnel may be authorized to perform on a regular and ongoing basis. Please check and complete the applicable Sections I and II. Section III is required for all Scopes of Practice.

SECTION I is completed for Human Subject research activities.

SECTION II is completed for Bench and/or Animal research activities.

SECTION III requires signatures of the Research Personnel and PI/VA Supervisor and date. If the individual works for more than one PI, that PI should also review this document.

SECTION IV Documentation of Annual Review will be required annually at the time of Continuation Review.

SECTION I HUMAN SUBJECT RESEARCH

Routine Duties	YES	NO
1. Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.		
2. Develops recruitment methods to be utilized in the study.		
3. Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competencies).		
4. Initiates submission of regulatory documents to VAAHHS VA IRB, VA R&D committee, sponsor and other regulatory agencies.		
5. Involved in study medication use, administration, storage, side effects and notification of adverse drug reactions to study site.		
6. Provides education to patient, relatives and Medical Center staff regarding study activities.		
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. Demonstrates proficiency with VISTA/CPRS computer system by scheduling subjects research visits, documenting progress notes, initiating orders, consults, etc.		
10. Accesses patient medical information while maintaining patient confidentiality.		
11. Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent "process".		
12. Collects and handles various types of human specimens (serum, sputum, urine, tissue, etc.)		
13. Process and ship specimens, chemicals, reagents, etc. (<i>Requires Shipping of Hazardous Materials training, U.S. Department of Transportation, available through the Safety Office – Joe Jurasek</i>)		
14. Enters data into databases.		
15. Initiates intravenous (IV) therapy and administers IV solutions and medications.		
Principal Investigator Duties	YES	NO
Serves as the Principal Investigator/Co-Principal Investigator on human subjects Research; thereby, providing oversight of the study and all study staff.		

MISCELLANEOUS DUTIES (if applicable):

The above individual is authorized to perform in the following miscellaneous duties not otherwise specified in this Scope of Practice.

1. _____
2. _____
3. _____

If Section II Bench and/or Animal research is not applicable, skip to the Signature page (Section III).

SECTION II BENCH and/or ANIMAL SUBJECT RESEARCH

Bench Routine Duties	YES	NO
1. Use and store chemicals (e.g., toxic, carcinogenic, flammable, teratogenic)		
2. Operate routine laboratory equipment including centrifuges, safety cabinets, exhaust hoods, etc.		
3. Use containment equipment (e.g., protective clothing, safety cabinets, etc.)		
4. Use biomaterials, microbial or viral agents, pathogens and/or toxins.		
5. Use molecular biology techniques (e.g., cloning, etc.) and vectors.		
6. Use radioactive materials and/or radiation generating equipment. <i>(Radiation Safety approval required to order/use radioactive materials.)</i>		
7. Collects, records, or analyzes animal/laboratory research data.		
8. Process and ship specimens, chemicals, reagents, etc. <i>(Requires Shipping of Hazardous Materials training, U.S. Department of Transportation, available through the Safety Office – Joe Jurasek)</i>		
Principal Investigator Duties	YES	NO
Serves as the Principal Investigator/Co-Principal Investigator on bench science research; thereby, providing oversight of the study and all study staff.		

Animal Subject Routine Duties	YES	NO
1. Is knowledgeable about the ethical and safe handling of animals and performs procedures involving animals (e.g. tailing, surgery, and/or behavioral interventions). <i>Requires completion of the CITI Species Specific training.</i>		
a. Performs special husbandry and/or practices as required.		
b. Performs surgical procedures on small animals.		
c. Performs surgical procedures on large animals.		
d. Administers euthanasia for animals in approved ACORPs.		
e. Obtains blood specimens from animals.		
f. Administers parenteral injections (IP-intraperitoneal, SQ-subcutaneous, IM-intramuscular, IV-intravenous) I		
g. Administers substances PO (orally).		
h. Works with breeding colony protocols		
2. Uses safe procedures involving animals and uses protective equipment appropriately (e.g. gloves, mask, eye protection, protective clothing).		
3. Orders laboratory animals.		
Principal Investigator Duties	YES	NO
Serves as the Principal Investigator/Co-Principal Investigator on animal subject research; thereby, providing oversight of the study and all study staff.		

MISCELLANEOUS DUTIES (if applicable):

The above individual is authorized to perform in the following miscellaneous duties not otherwise specified in this Scope of Practice.

1. _____
2. _____
3. _____

Complete the Signature Page in Section III.

SECTION III SIGNATURE PAGE (Submit along with the Section(s) applicable to the individual's Scope of Practice)

Principal Investigator/Supervisor's Statement:

The Scope of Practice was reviewed and discussed with the personnel on the date shown below. After reviewing his/her education, competency, qualifications, peer reviews, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties/procedures.

Both the personnel and I are familiar with all duties/procedures granted in this Scope of Practice. We agree to abide by the parameters of this Scope of Practice, all applicable facility policies and regulations.

This Scope of Practice will be reviewed annually and amended as necessary to reflect changes in the individual's duties/ responsibilities. A new Scope of Practice will be completed if the employee is assigned a new supervisor.

Research Personnel

Date

Supervisor

Date

The original signed Scope of Practice will be maintained in the Research Business Office. The Supervisor and Research Personnel should maintain a copy of the Scope of Practice in preparation of any change in duties and required annual review. The PI must keep a copy of all SOPs in each study's Regulatory Binder.

OFFICE USE ONLY:

ACOS/Research & Development Service

Date