VA Puget Sound Health Care System
Research and Development
Scope of Work for Research Activity

v.5/21/13

Name of Employee (please print or type)_____

A Scope of Work must be established for every individual appointed at VA Puget Sound who is involved in Research & Development activity, regardless of the type of appointment (e.g. VA employee, WOC, IPA, Contractor) or the Service Line to which they are appointed. The Scope of Work is specific to the duties and responsibilities of this individual related to their participation in the research and development program. The employee, their supervisor and the ACOS, R&D must complete, sign and date this Scope of Work.

This scope of work should describe the full breadth of the research related activities this individual is engaged in, or is likely to be engaged in, within the authority of their appointment. It is not study specific, but encompasses all the projects and activities to which this individual is assigned on a regular and ongoing basis. Changes in the scope of the individual's activities must be documented at the time of the change; this scope of work will be reviewed for accuracy by all parties on an annual basis.

A. Human Research

	Yes	No
0. Principal Investigator who develops and directs human subjects research studies. Responsible for obtaining all relevant institutional approvals for study activities, meeting all relevant initial and annual training requirements, and supervising research staff engaged in the execution of approved research protocols; this includes responsibility for providing job-specific training, performance and competency evaluations, and management of resources.	☐	☑
1. Initiates submission of regulatory documents to the IRB, VA R&D Committee, other relevant subcommittees and sponsors.	☐	☑
2. Prepares study initiation activities on site (e.g. service approvals.)	☐	☑
3. Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.	☐	☑
4. Is knowledgeable about the informed consent process and is authorized to obtain informed consent from research subject	☐	☑
5. Develops recruitment methods to be utilized in the study.	☐	☑
6. Interacts with subjects by performing physical examinations or clinical procedures. If yes, describe the exam to be performed and list all procedures in section G Other below.	☐	☑
7. Provides education and instruction to subjects, relatives, caregivers or VAPSHCS staff regarding details of the study.	☑	☐
8. Provides education and instruction to subjects, relatives, caregivers or VAPSHCS staff regarding study medication (including use, administration, storage, side effects and reporting adverse drug reactions) as necessary per protocol.	☐	☑
9. Administers questionnaires or conducts mental status or psychosocial exams.	☐	☑
10. Prescribes and renews study medication (must be an authorized individual).	☐	☑
11. Has final responsibility for reviewing laboratory data and other entries in the medical record for the purpose of identifying adverse events.	☐	☑
12. Initiates and/or expedites requests for consultation, special tests or studies following the Investigator's approval.	☐	☑
13. Performs venipuncture (if yes, describe training and steps taken by PI to ensure competency in section G Other below).	☐	☑

	Yes	No
14. Places intravenous (IV) lines and administers IV treatment (if yes, describe training and steps taken by PI to ensure competency in section F Other below).	☐	☑
15. Uses CPRS for entering progress notes, extracting patient medical information specified by the IRB-approved protocol, or scheduling subjects' visits.	☐	☑
16. Handles or analyzes biological specimens labeled with any of the 18 HIPAA identifiers or a code number for which the employee has access to the code key/crosswalk.	☐	☑
17. Accesses patient medical information while maintaining confidentiality	☐	☑
18. Limited to analysis of de-identified samples or data; does not access protected health information and has no direct patient contact.	☑	☐
19. Requires VETPRO screening. May have the *potential* by virtue of education, licensure or certification to provide patient care, or oversee the quality or safety of patient care delivered. If yes, *even if their appointment and duties at VAPSHCS do not involve such activity or even if not currently licensed*, this individual must be credentialed through VetPro (unless a trainee, in which case work must be performed under the direct supervision of a mentor who is fully credentialed and privileged) and may not begin work until the VetPro process is completed.	☐	☑
20. Requires Clinical Privileges. Duties in Research involve activities as a Licensed Independent Practitioner (LIP).	☐	☑

B. Animal Research

1. Supervises staff, facilities and resources of the Animal Research Facility. Responsible for ensuring the program meets national VA and AAALAC standards. Provides training to animal caretakers, Principal Investigators, technicians, fellows and students in the appropriate, ethical and safe use of animals in research. Responsible for operation of the animal research facility, equipment, supplies and environment, and for providing performance and competency evaluations of ARF staff. Provides veterinary care	☐	☑
2. Provides animal care and husbandry for animal subjects as an animal caretaker/technician of the Animal Research Facility. Must be qualified by virtue of education, training and experience, must meet all initial and annual training requirements and participate in the respiratory protection program and occupational health program.	☐	☑
3. Principal Investigator who develops and directs research studies using animals. Responsible for obtaining IACUC and R&D Committee approvals for study protocols, meeting all relevant initial and annual training (including species-specific) requirements, and supervising research staff engaged in animal research work.	☐	☑
4. Technician who performs approved animal procedures. Must be listed on the IACUC-approved ACORP, be qualified by virtue of education and training, meet all relevant initial and annual training (including species-specific) requirements, and participate in the occupational health program. May optionally participate in the respiratory protection program.	☐	☑

C. Biomedical Laboratory Research

1. Principal Investigator who develops and directs laboratory-based research studies. Responsible for obtaining all relevant institutional approvals for study activities, meeting all relevant initial and annual training requirements, and supervising research staff engaged in the execution of approved research protocols; this includes responsibility for providing job-	☐	☑

	Yes	No
specific safety training, performance and competency evaluations, and management of laboratory resources (e.g. funding and equipment) and environment (safety, functionality).		
2. Laboratory Technician, Fellow, Student, or other individual assigned to an investigator's program who executes approved study protocols. Must be qualified by virtue of education and training, meet all relevant initial and annual training requirements and is compliant with all national, VA, and local safety policies, SOPs and guidelines.	☑	☐
3. Initiates requests for laboratory supplies, equipment and service, operates within study budgets.	☐	☑
4. Uses and is knowledgeable about the handling and storage of hazardous materials (chemical, toxic, carcinogenic, flammable, biohazardous, etc.) used in the laboratory's approved protocols.	☐	☑
5. Uses and is knowledgeable regarding the safe operation and maintenance of laboratory equipment (e.g. centrifuges, biological and fume hoods, etc.).	☐	☑
6. Uses and is knowledgeable about personal protective equipment (PPE), e.g. gloves, gowns/lab coats, face masks, respirators, etc.) used in the laboratory's approved protocols.	☐	☑
7. Uses and is knowledgeable about molecular biology techniques and the handling of vectors.	☐	☑
8. Uses and is knowledgeable about the safe handling of radioactive materials and/or radiation-generating equipment used in the laboratory's approved protocols.	☐	☑

D. Data Management, Extraction and Analysis

1. Manages the secure storage of identifiable data or other VA-sensitive data or research materials.	☐	☑
2. Collects, organizes and/or analyzes source documents or identifiable data specified by the IRB-approved protocol.	☐	☑
3. Collects, organizes and/or analyzes only de-identified data used in the research protocol.	☑	☐
4. Uses SAS, SQL and/or other programming languages to extract identifiable and other research data from national data bases warehoused on the Austin Automation Center (AAC) mainframe, VHA Corporate Data Warehouse, VINCI, VISN 20 data warehouse, or other administrative, clinical or research data repositories.	☐	☐
5. Organizes and structures analytic data sets to conduct various statistical analyses.	☐	☑
6. Develops statistical models used for analysis.	☐	☑
7. Using standard statistical software and methods, develops programming scripts to implement various statistical models for analysis.	☐	☑

E. General

1. Is knowledgeable and trained to ship biological or hazardous materials (meets initial and annual local training requirements for this activity).	☐	☑

F. Management and Administrative Support

	Yes	No
1. Provides management of R&D administrative operations, including supervision of administrative support staff, management of resources (human resources, budget, space, equipment, facilities), institutional assurances, compliance and relevant accreditations.	☐	☑
2. Provides administrative and programmatic support to R&D managers, principal investigators, centers of excellence or other units.	☐	☑
3. Provides support requiring a specialized role or expertise , such as R&D Safety Officers, members of institutional review boards (e.g. IRB, IACUC, Safety, BioSafety and rDNA Subcommittees) including non-affiliate community members; R&D Service ADPACs; Information Security Officer (ISO), Privacy Officer (PO), and Research Compliance Officer (RCO).	☐	☑
4. By virtue of their duties and responsibilities the employee has access to sensitive information (e.g. personnel records, documents bearing individual identifiers or other confidential information of research subjects, employees, contractors, etc.) requiring compliance with appropriate security practices when receiving, utilizing, filing and communicating such information.	☐	☑

G. Other

The employee is authorized to perform in the following duties either requiring more detail or not elsewhere specified in this Scope of Work (continue on additional sheets as needed):

SUPERVISOR/PRINCIPAL INVESTIGATOR STATEMENT:

Employee's Scope of Work was reviewed and discussed with him/her. After reviewing the employee's qualifications based on the education, training, and experience as detailed in the employment application and comments of references contacted as part of the recruitment process, supplemented by orientation and training I or others at this institution have provided, I believe that he/she possesses the knowledge, skills and experience to safely perform the specified duties/procedures. Both the employee and I are familiar with all duties/procedures discussed in this Scope of Work. We agree to abide by the parameters of this Scope of Work, and all-applicable Federal, VA and VA Puget Sound policies and regulations. This Scope of Work will be amended in writing as necessary to reflect changes in the employee's duties/ responsibilities, utilization guidelines and/or medical center policies.

_____ _____

Supervisor/Principal Investigator Date

_____ _____

Employee Date

_____ _____

ACOS, Research & Development Date