VA Pittsburgh Healthcare System
Research Scope of Practice Statement

Instructions: This Research Scope of Practice is specific to the duties and responsibilities of the Research Staff member named below as an agent of the listed Supervisor. Only one Research Scope of Practice is required for each research staff member and should include all research duties on all research projects. The Staff Member and his/her Immediate Supervisor must review the Scope of Practice together and the **Supervisor must designate each assigned responsibility by checking the appropriate box and initialing on the appropriate line.**. All Principal Investigators for whom the Staff Member will be working (who are not the Immediate 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.

Please remember:

- The Research Scope of Practice must be reviewed by the listed supervisor(s) and/or Principal Investigator(s) (if different than the supervisor) and the research staff member at least once per year.
- A revised Research Scope of Practice must be submitted to the Research Office if there are any changes in staff duties.
- New Human Subjects Coordinators (hired or transferring into the coordinator position on or after 7/1/2015) on a greater than minimal risk clinical trial or greater than minimal risk comparative effectiveness trial must follow the procedures outlined in policy H-016 before the scope can be submitted for approval.
- All staff must be current with the following training before submitting this form:
    - VA Privacy and Information Security Awareness and Rules of Behavior (annual)
    - VHA Privacy and HIPAA Focused Training (annual)

Research Staff Member Name	Service Line
List all degrees held by the research staff member	Does the staff member hold a U.S. license to practice any healthcare profession?
	☐ YES, List all applicable licenses: ☐ NO
Immediate Supervisor Name	

Please indicate whether this Research Scope of Practice is :

☐ New (a Research Scope of Practice has not been completed for this staff person previously)
☐ Revised (a Research Scope of Practice exists for this person, but there are changes in staff duties)

Please indicate the type(s) of research the staff member will be involved with at VAPHS provide a brief written description of the day-to-day activities this individual will be responsible for, and complete the section(s) noted. Note: You must check all that are applicable and at least one category must be selected.

☐ Human Subjects Research[1] **COMPLETE SECTION A**	Description of responsibilities:
☐ Animal Research[2] **COMPLETE SECTIONS B & C**	Description of responsibilities:
Laboratory/Bench/Other Research[3] **COMPLETE SECTION C**	Description of responsibilities:

[1] The research involves obtaining either (a) data through intervention or interaction with a living individual or (b) identifiable private information about living individuals.

[2] The research involves the use of laboratory animals in research, testing, or training

[3] The research involves chemicals, biological hazards and/or radioactive materials OR research does not involve human or animal subjects.

Section A: HUMAN SUBJECTS RESEARCH DUTIES/RESPONSIBILITIES

Items marked with ▲ require specific training/competencies. Please see Section A.8 for details.

1. Routine Duties (check all that apply)

	Check (x) if duty is assigned to this individual	Supervisor must initial for each duty assigned
a. Initiate submission of regulatory documents to the IRB, VA R&D committee and sponsor	☐	_____
b. Prepare study initiation documents and activities	☐	_____
c. Develop recruitment methods to be utilized for the study	☐	_____
d. Screen patients to determine study eligibility by reviewing patient medical information or interviewing subjects	☐	_____
e. Access or use private medical information while maintaining patient confidentiality	☐	_____
f. Participate in the informed consent process and obtain informed consent from research subjects	☐	_____
g. Maintain completed case reports and source documents including progress notes, test results, diaries, cards or other necessary information for the study.	☐	_____
h. Provide education to patients, relatives, and Medical Center staff on study activities as necessary as per protocol	☐	_____
i. Provide education and instruction on study medication use, administration, storage, and side effects, report adverse drug effects.	☐	_____
j. Initiate and/or expedite requests for consultation, special tests, or studies following the investigator's approval.	☐	_____
k. Use radioactive materials in the conduct of the research ▲	☐	_____

2. Duties which may result in exposure to human blood, body fluid, or tissues (check all that apply)

	Check (x) if duty is assigned to this individual	Supervisor must initial for each duty assigned
a. Transport human blood, body fluid, or tissues within the Medical Center ▲	☐	_____
b. Ship or transport specimens outside the medical center ▲	☐	_____
c. Handle or process human specimens ▲	☐	_____
d. Draw blood ▲	☐	_____
e. Initiate intravenous (IV) therapy and administer IV solutions and medications (Note: Individuals requesting this function must attach their current clinical scope of practice). ▲	☐	_____
f. Use of formaldehyde/formalin/paraformaldehyde for perfusions or other tissue fixation ▲	☐	_____

	Check (x) if duty is assigned to this individual	Supervisor must initial for each duty assigned
3. Access the VISTA/CPRS computer systems for scheduling subjects' research visits, documenting progress notes, initiating orders, consults, etc. (Note: If requesting scheduling privileges you must contact the Research Office (412-360-2390) for additional information).	☐	_____
4. Serve as the Study Coordinator on a greater than minimal risk clinical trial (i.e., a study involving the controlled clinical testing in humans of investigational drugs or devices). An investigational drug is defined as either (a) a new chemical compound which has not been released by the Food and Drug Administration (FDA) for general use, or (b) an approved drug that is being studied for an approved or unapproved use, dose, dosage form, administration schedule, or under an Investigational New Drug (IND) application, in a controlled, randomized or blinded clinical trial. An investigational device is defined as a device permitted by the FDA to be tested in humans, which is not yet regarded as safe and effective for a particular use in the general population and not yet licensed for marketing.	☐	_____
5. Serve as the Study Coordinator on a greater than minimal risk comparative effectiveness study (i.e**.,** the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels	☐	_____
6. Serve as the Principal Investigator/Co-Principal Investigator on one or more human subject projects thereby providing overall oversight of the project and all study staff.	☐	_____

7. Miscellaneous Human Subject Duties (Provide details regarding the additional duties this individual is authorized to perform that have not otherwise been specified in this Research Scope of Practice):

	Supervisor must initial for each duty assigned
a.	_____
b.	_____
c.	_____

8. **Training, Competencies and Supporting Documentation:**

Please complete and attach verification of completion of the following trainings and/or competencies as applicable.

Check if Complete	Training	Required for:	**FOR RESEARCH OFFICE USE ONLY**
☐	VA Human Subjects Training	All Human Research Staff	☐ Verified ☐ Not Applicable
☐	Bloodborne Pathogens Training	Research Staff working directly with human blood, body fluids, tissues, or cells. Practicing Physicians and Clinical Nurses may fulfill this requirement by providing the Research Office with verification of completed related clinical trainings such as JCAHO biological training.	☐ Verified ☐ Not Applicable
☐	SAF-T-PAK (Attach certificate)	Research Staff shipping biological hazards	☐ Verified ☐ Not Applicable
☐	Phlebotomy Competency (Attach certificate)	Research Staff for whom phlebotomy is not part of their clinical responsibilities	☐ Verified ☐ Not Applicable
☐	CPR/ Basic Life Saving (Attach a copy of BLS card)	Any physician, dentist, podiatrist, optometrist, social worker, psychologist, psychiatrist, audiologist, speech pathologist, physician assistant, nurse practitioner, clinical nurse specialist, nurse anesthetist, registered nurse, or respiratory therapist interacting with human subjects.	☐ Verified ☐ Not Applicable
☐	VAPHS Research Radiation Safety Training	Research Staff working with radioactive materials	☐ Verified ☐ Not Applicable
☐	Copy of the signed Mentoring Plan or written assurance that a mentoring plan is not required (Must be attached)	Individuals who will be serving as the study coordinator on a greater than minimal risk clinical trial or a greater than minimal risk comparative effectiveness study.[4]	☐ Verified ☐ Not Applicable
☐	Global Harmonization System (GHS) training	Research staff working with chemicals in a laboratory	☐ Verified ☐ Not Applicable
☐	Safe Use of Formaldehyde	Research Staff working with formaldehyde/formalin/paraformaldehyde	☐ Verified ☐ Not Applicable

[4] Requirement applies only to those hired or transferring into the position on or after July 1, 2015.

Section B: ANIMAL RESEARCH DUTIES/RESPONSIBILITIES

Items marked with ▲ require specific training. Please see Section B.4 for additional details.

1. Routine Duties (check all that apply)

	Check (x) if duty is assigned to this individual	Supervisor must initial for each duty assigned
a. Administer euthanasia for rats and/or mice	☐	_____
b. Administer analgesics	☐	_____
c. Administer injections	☐	_____
d. Administer test substance	☐	_____
e. Identify humane endpoints (i.e, identify when protocol endpoints are reached, as described in the protocol)	☐	_____
f. Identifying research animals and performing ear clips, tail clips, tags or tattooing	☐	_____
g. Use of anesthesia (specify type below). ☐ Injectable ☐ Gas ▲	☐	_____
h. Use of infectious, toxic, hazardous agents in animals as described in the protocol ▲	☐	_____
i. Perform surgical procedures as described in the protocol.	☐	_____
j. Antemortem Blood/Tissue Collection.	☐	_____
k. Use radioactive materials in the research ▲	☐	_____
l. Ship or transport specimens outside of the medical center ▲	☐	_____
m. Use of formaldehyde/formalin/paraformaldehyde for perfusions or other tissue fixation ▲	☐	_____

	Check (x) if duty is assigned to this individual	Supervisor must initial for each duty assigned
2. Serve as the Principal Investigator/Co-Principal Investigator on one or more animal research projects thereby providing overall oversight of the project and all study staff.	☐	_____

3. Miscellaneous Duties (Provide details regarding the additional duties this individual is authorized to perform that have not otherwise been specified in this Research Scope of Practice):

	Supervisor must initial for each duty assigned
a.	_____
b.	_____
c.	_____

4. Training, Competencies and Supporting Documentation:

Please complete and attach verification of completion of the following trainings and/or competencies as applicable.

Check if Complete	Training	Required for:	FOR RESEARCH OFFICE USE ONLY
☐	Working with the VA IACUC	Research Staff who conduct or supervise use of animals 1) on VA property, 2) purchased with VA funds, or 3) while on a VA tour of duty but not on VA property.	☐ Verified ☐ Not Applicable
☐	Working with Mice in Research Settings/Post-Procedural Care of Rodents	Research Staff working with mice	☐ Verified ☐ Not Applicable
☐	Working with Rats in Research Settings/Post-Procedural Care of Rodents	Research Staff working with rats	☐ Verified ☐ Not Applicable
☐	Working with Nonhuman Primates in Research Settings	Research Staff working with nonhuman primates	☐ Verified ☐ Not Applicable
☐	Other Training for other animal populations (contact the Research Office)	Research Staff working with animals other than mice, rats, or nonhuman primates	☐ Verified ☐ Not Applicable
☐	Bloodborne Pathogens Training	Research Staff working with biological hazards	☐ Verified ☐ Not Applicable
☐	VAPHS Research Radiation Safety Training	Research Staff working with radioactive materials	☐ Verified ☐ Not Applicable
☐	Safe Use of Anesthetic Gases	Research Staff working with Anesthetic Gases	☐ Verified ☐ Not Applicable
☐	Safe Use of Formaldehyde	Research Staff working with formaldehyde/formalin/paraformaldehyde	☐ Verified ☐ Not Applicable
☐	Global Harmonization System (GHS) training	Research staff working with chemicals in a laboratory	☐ Verified ☐ Not Applicable

Section C: LABORATORY/BENCH/OTHER RESEARCH DUTIES/RESPONSIBILITIES

Items marked with ▲ require specific training. Please see Section C.4 for additional details.

1. Routine Duties (check all that apply)

	Check (x) if duty is assigned to this individual	Supervisor must initial for each duty assigned
a. Maintain laboratory equipment, calibration and cleanliness	☐	_____
b. Maintain lab areas. Maintain a safe work environment	☐	_____
c. Keep inventories of laboratory supplies, order supplies	☐	_____
d. Carry out research activities typically performed as outlined in the protocol	☐	_____
e. Use radioactive materials in research ▲	☐	_____
f. Use infectious, toxic, hazardous agents in the lab ▲	☐	_____
g. Use of recombinant or synthetic nucleic acid molecules (e.g., DNA) in a laboratory ▲	☐	_____
h. Ship or transport specimens outside of the medical center ▲	☐	_____
i. Use of chemicals in a laboratory ▲	☐	_____

	Check (x) if duty is assigned to this individual	Supervisor must initial for each duty assigned
2. Serve as the Principal Investigator/Co-Principal Investigator on one or more lab/bench/other projects thereby providing overall oversight of the project and all study staff.	☐	_____

3. Miscellaneous Duties (Provide details regarding the additional duties this individual is authorized to perform that have not otherwise been specified in this Research Scope of Practice):

	Supervisor must initial for each duty assigned
a.	_____
b.	_____
c.	_____

4. Training, Competencies and Supporting Documentation:

Please complete and attach verification of completion of the following trainings and/or competencies as applicable.

Check if Complete	Training	Required for:	**FOR RESEARCH OFFICE USE ONLY**
☐	Introduction to VA Biosecurity Concepts	All **NEW** VA and WOC research laboratory staff	☐ Verified ☐ Not Applicable
☐	VAPHS Research Lab Safety Training	All **NEW** VA and WOC research laboratory staff	☐ Verified ☐ Not Applicable
☐	SAF-T-PAK (Attach certificate)	Research Staff shipping biological hazards	☐ Verified ☐ Not Applicable
☐	Bloodborne Pathogens Training	Research Staff working with biological hazards	☐ Verified ☐ Not Applicable
☐	Global Harmonization System (GHS) Training	Research Staff working with chemicals in a laboratory	☐ Verified ☐ Not Applicable
☐	Overview of NIH Guidelines	Research Staff working with recombinant or synthetic nucleic acid molecules in a laboratory	☐ Verified ☐ Not Applicable
☐	VAPHS Research Radiation Safety Training	Research Staff working with radioactive materials	☐ Verified ☐ Not Applicable

Research Staff Member Statement:

This Research Scope of Practice outlines routine general duties I am permitted to undertake in conjunction with one or more VA approved projects. I understand that all research must be approved by the appropriate subcommittee of the VAPHS Research and Development Committee, as well as the VAPHS Research and Development Committee. I certify that I will perform only the duties listed and approved above while participating in research at VAPHS. I understand that performing any duty beyond that outlined in this Research Scope of Practice without specific authorization may lead to disciplinary action. My supervisor, all Principal Investigators with which I will be working, and I are familiar with all duties and procedures granted in this Research Scope of Practice. I agree to abide by the parameters outlined in this Research Scope of Practice and all-applicable hospital policies and regulations.

I also understand that I may not perform any procedures which constitute the profession for which I may be eligible for, but for which I have not obtain the license, registration or certification for that profession (e.g., unlicensed physician cannot perform any procedures that would be considered the practice of medicine).

_____ _____

Research Staff Member's Signature Date

Supervisor's Statement

This Research Scope of Practice for (name) was reviewed and discussed with him/her on (date) In addition, this Research Scope of Practice has been reviewed by all Principal Investigators for whom the staff member will be working. After reviewing his/her education, clinical competency, qualifications, research practice, peer reviews, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties/ procedures. Both the research

staff member and I are familiar with all duties/procedures granted or in this Research Scope of Practice. We agree to abide by the parameters of this Research Scope of Practice, and all-applicable hospital policies and regulations.

This Research Scope of Practice will be reviewed annually and amended as necessary to reflect changes in the research staff member's duties/ responsibilities and/or VAPHS hospital policies.

_____ _____

Immediate Supervisor's Signature Date

OFFICE USE ONLY:

Functions Approved

_____ _____

Associate Chief of Staff for Research and Development Date