



VA Maryland Health Care System (VAMHCS) Research Scope of Practice for Research Staff/Personnel

INSTRUCTIONS / GUIDANCE

PRINCIPAL INVESTIGATOR'S (PI) RESPONSIBILITIES

- Complete a Scope of Practice for VA Research Staff for research team members who work on the “VA portions” of a VAMHCS R&D Committee approved research project. “VA portion” is that part of the research project that is conducted in VA space, uses VA-paid staff or uses other VA resources. (See DEFINITION section: VA Research, Research Scope of Practice, especially with regard to “collaborative studies”).
- **Be knowledgeable about the relevant issues and definitions needed to accurately complete this form.**
- **Ensure that the individual has the appropriate training, education, licensure/credentials and privileges for the tasks listed in the Scope of Practice document.**
- **Ensure that research activities are not performed without an approved Research Scope of Practice.** By submitting a Scope of Practice for VA Research Staff to the Research Service, your team member is applying for ACOS/R&D approval of the Research Scope of Practice. The Research Scope of Practice is not active until the ACOS/R&D has signed the document.
- Maintain or ensure that a copy of the Scope of Practice for VA Research Staff and associated documents are maintained for all team members. Research Scopes of Practice must be readily accessible for audits, study monitoring, etc. See Procedures section, #7.
- **Complete a new Scope of Practice for VA Research Staff whenever a team member's research duties change.**
- PI's should periodically review the Scope of Practice for VA Research Staff with their staff/team members, for example at the time of Annual Performance Appraisals. If there is a change in the staff/team member's duties, a new Scope of Practice for VA Research Staff must be submitted to the R&D Service.
- It is recommended that you document your periodic review of team members' scopes of practice in some way in order to provide confirmation of “current” scopes of practice, if asked for audit purposes.
- Provide local training to staff as necessary for research activities. It is the individual's responsibility to complete all required trainings and any additional trainings needed to conduct the research activities; it is the PI's responsibility to ensure that all members of the research team are appropriately trained.
- PI's attest to their own Research Scope of Practice through a different form. (Scope of Practice for Principal Investigator)

PROCEDURES:

1. There are three sections of the Scope of Practice for VA Research Staff:
 - Applicant information (Section I),
 - Human Research (Section IIA),
 - Animal Research (Section IIB),
 - Laboratory/Bench procedures (Section IIC), and
 - Certifications (Section III).

Complete Section I, all applicable parts of Section II, and Section III. Be aware that if you handle human or animal specimens, you must also complete Section IIC as well as Sections IIA and/or IIB.

2. Staff member puts a checkmark in the boxes in the left columns of the tables in Section II requesting approval for research-related tasks.
3. The Principal Investigator (PI) places his/her initials in the appropriate column on the right, indicating what is granted or not granted based on the individual's education, training and experience.
4. Both the team member and the PI sign in Section III (page 4).
5. Send or deliver the completed Scope of Practice for VA Research Staff to the R&D Service for review and signature of the ACOS for Research.
6. Pick up the signed copy of the Scope of Practice for VA Research Staff from the R&D Service when you receive a notice from the R&D Service that the form is available.
7. Place the signed copy of the Scope of Practice for VA Research Staff into your Service's (and/or the team member's) personnel files. The Scope of Practice for VA Research Staff must also be accessible when needed for regulatory audits or other reasons.

DEFINITIONS

- A **Research Scope of Practice** is required for all VA research personnel (VA paid, WOC or VA IPA) involved in VA research. *(If this is a collaborative project with the University of Maryland or other institution, this Research Scope of Practice requirement only applies to staff who work on the VA portion of the project and only when they work on the VA portion of the project. The VA-UM delineation needs to be stated in the protocol through specific discussion in the protocol and associated documents, and through the "Collaborative Studies Tool").*
- **VA research** is defined as research involving VA space (including VA-leased space), VA funding (including funding administered through the BREF), VA data or other VA resources (i.e. personnel, VA-paid time, supplies, equipment, etc.). Such research must be approved by the VAMHCS R&D committee and all applicable subcommittees (IRB, IACUC, and SRS).
- VA requires that if an activity/procedure needs **clinical privileges**, a **functional statement**, or a **position description** in order to be done in the clinical setting, then the same standard

applies if the activity is to be done in a research setting. *Do not confuse “clinical privileges”, “functional statement”, “position description”, “credentialing”, “scope of practice”, or a “research scope of practice”. None are the same as or equivalent to the others.*

- **Clinical Privileges** are granted by the Facility (VAMHCS), to allow a VAMHCS “licensed independent practitioner” (LIP) (whether an employee, contractor or WOC) to perform specific duties or types of duties on/with humans, whether for clinical or research purposes.

Clinical privileges are granted only to “**licensed independent practitioners**” (LIP). LIPs MUST apply to the VAMHCS Professional Standards Board (PSB) through a specific process. VAMHCS grants or denies clinical privileges based on the determination of the PSB. *This applies to the following LIPs: MDs, DOs, DDS’, DPMs, ODs, PAs, CRNPs, CRNAs, CNS’, LCSWs, Licensed Psychologists, Licensed Pharmacists. No other occupation/profession can be granted clinical privileges in VA. See VAMHCS Policy Memorandum 512-11/COS-102 in addition to the additional information below.*

- VAMHCS allows other occupations and “**dependent practitioners**” to perform specific duties or types of duties on/with humans for clinical or research purposes. Those occupations and “dependent practitioners” must have “**functional Statements**” (FS) or “**position descriptions**” (PD) (or, in some instances, both a PD and a FS), based on the “occupational code” and the scope of work for a position.

The following dependent practitioners MUST have a FS if they are to work within one of the following occupations: *unlicensed Psychologist, Social Worker, Nuclear Medicine Technologist, Registered Nurse, Practical Nurse, Dietitian, Occupational Therapist, Physical Therapist, Diagnostic Radiologic Technologist, Therapeutic Radiologic Technologist, Respiratory Therapist, Pharmacist, Pharmacy Technician (General Schedule (GS) 6 and above), Optometrist, Audiologist, Podiatrist, Dental Assistant, Dental Hygiene, Chiropractor, Corrective Therapist, Recreation and/or Creative Arts Therapist, Medical Technologist, Medical Technician, Pharmacy Technician, Speech Pathologist, Orthotist and Prosthetist.*

- **Functional Statement (FS)** Description of duties for employees hired under Title 38
- **Position Description (PD)** Description of duties for employees hired under Title 5
- Some research positions only need PDs. Some need only FS’. Some need both. It depends on your occupation and the title of the position for which you are hired or appointed to the VA.

- If the team member is a student or trainee the PI must check with the student's/trainee's affiliated academic office to ensure that the research activities are within the student's/trainee's competencies and/or the parameters for supervision
- **PERSONNEL WITH DIRECT CONTACT**: Research employees who perform procedures, interviews, telephone calls to research subjects, clinical interventions with patients, etc. during the conduct of a research project.
- **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.
- **Engaged/Engagement in research**: An individual is “engaged” in human subject research whenever they intervene or interact with living individuals for research purposes, or they obtain, release, or access individually-identifiable private information (or individually-identifiable specimens) for research purposes. [38 CFR 16.102(f)]
- **Human Subject research activities**: The research involves observation, manipulation, or sampling of human subjects or their biological samples or identifiable data for research purposes. A **human research subject** is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains either: (a) Data through intervention or interaction with the individual; interaction includes communication or interpersonal contact between the researchers and the subject; or (b) Identifiable private information (38 CFR 16.102 (f)). For FDA-regulated research, a **human research subject** is involved as a recipient of a test article or as a control, or as an individual on whom or on whose specimen an investigational device is used or as a control.
- **Animal research activities**: The animal research involves physical contact with living or dead animals or their unfixed tissues or urine or feces regardless of the funding source of that research.
- **Lab/Bench research activities**: The research involves laboratory procedures or analysis conducted in laboratories at the VAMHCS or in VAMHCS leased space regardless of the funding source of the research.