

RESEARCH AND DEVELOPMENT SERVICE

SCOPE OF PRACTICE FORM FOR RESEARCH STAFF

1. PURPOSE: To define the policy and procedures for approval of the designated roles and responsibilities of research staff in research projects that involve human subjects, animals, database studies, health system research and basis laboratory.

2. POLICY:

a. All individuals involved in research activities at the St. Louis VA Medical Center ("SLVAMC") must receive approval for their participation through the SLVAMC Research Office by following the Institutional Review Board ("IRB") and/or Research and Development ("R&D") submission process. A Scope must be developed for all individuals in research that defines the parameters and functions of their duties and responsibilities. Research personnel may **not** participate in a research protocol until all requirements of this policy are met. All personnel working in research are expected at all times to function within the limits of their training, credentialing, privileging, Scope, and appointment at the St. Louis VA Medical Center. An individual's role in research may not exceed or allow them to function in any capacity that they would not be authorized to carry out in routine clinical practice. Research staff must meet all requirements for the job to which they are appointed.

b. Personnel may have only the roles and responsibilities, as defined by their approved Scope, that are appropriate to their level of training, specific license, and clinical credentials. Licensed research personnel may **not** perform or be trained to perform procedures outside of those allowed under their respective license and credentialing. Research staff with credentials, clinical privileges, and a Scope already granted by the medical center as part of their clinical appointment, still may need a separate Scope for research since all activities for research may not be covered by the medical center process.

c. Non-licensed research personnel, including but not limited to individuals who have an MD, DO, BSN, or MSN degree, without licensure (excluding those in an ACGME approved training program), are not allowed to perform duties that would be considered part of their professional practice. Any procedures that, according to the SLVAMC bylaws, would require consent of the patient in a standard (non-research) patient care setting may **not** be performed by non-licensed research personnel. Unlicensed research personnel may not be trained to do procedures that require a professional license.

d. Unlicensed research personnel working as research coordinators or research fellows may obtain informed consent if competency verification has occurred and is documented

on the Research Scope. However, unlicensed research personnel (excluding those in an ACGME approved clinical training program) may not use their educational degree after their signature on IRB approved consent forms or on Research Staff Contact lists. Furthermore, unlicensed research personnel may not display their educational degree (e.g. M.D. or R.N. on a name tag) in any way that would convey to the research participant or staff that he/she is a licensed practicing clinician.

3. ACTION:

a. Accountability:

(1) **Research Office:** will provide required forms and instructions for completing the Scope to all research staff actively engaged in approved SLVAMC research, provide the employee with a copy of the approved Scope or notification if the Scope is not approved, and maintain a copy in the Research Office file. The Research Office will track the completion of Scopes annually from the date of the previously approved Scope.

(2) **Supervisors:** Principal investigators (or if the Scope is for the Principal or Responsible Investigator, then the Principal or Responsible Investigators' Section or Service Chief, Department Chair, etc) must verify the employee's competency to perform the roles and responsibilities identified on the Scope. Principal Investigators (Section or Service Chief, Department Chair, etc) will verify that the approved Scope accurately defines the activities of research personnel at least annually by the anniversary date of the previous approved Scope.

(3) **Research Staff:** Must work within the developed Scope and not take on any duties or perform any procedures that are beyond their allowed practice. Update their supervisor immediately if their credentialing or licensure changes so that the scope may be updated appropriately. An investigator, who holds clinical privileges, may submit them in lieu of a Scope. The investigator's clinical privileges must cover all research duties and responsibilities that are needed to conduct the research project(s). If the clinical privileges do not cover all research duties and responsibilities, then an additional Scope is required in order to conduct research activities.

(4) **Associate Chief of Staff (ACOS) for Research and Chief of Staff or designee** will review and approve the Scope.

b. Procedures:

(1) Principal and Responsible Investigators must complete and submit the Scope to the Research Office as part of either initial submission, when an individual is first added to their IRB and or R&D research approved protocol(s), or whenever the duties of the employee are modified. Principal and Responsible Investigators must annually verify that the approved Scope accurately defines the activities of research personnel. Investigators should retain a fully executed copy of the employee's Scope with the Investigators files, after it is signed by the ACOS for Research or designee.

(2) The ACOS for Research or designee will review the Research Scope annually and approve if the requested roles and responsibilities are appropriate.

(3) The Research Office will provide the employee with a copy of the approved and fully executed Scope or notification of disapproval if the Scope could not be approved as submitted. The new or reviewed Scope will be entered into the R&D Training log and a hard copy kept in the Research Office. The Research Office will request verification from the Research Office will tracking completion of Scope for all Research staff actively engaged in VA approved research.

4. REFERENCES:

Handbook 1200.05
VHA Handbook 1200.7 VHA
VHA Directive 2003-036
Good Clinical Practice: Consolidated Guidance
Medical Center Bylaws, Rules, & Regulations

5. RESPONSIBILITY: Associate Chief of Staff for Research, or designee (151)

6. Rescission: None

7. REVIEW DATE: November 5, 2013

ATTACHMENTS:

Attachment A-Human Study Scope of Practice Form for Research
Attachment B- Animal Study Scope of Practice Form for Research



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