

VAMHCS RESEARCH & DEVELOPMENT SERVICE
R&D Service Process Module

PM-RDS-028

Date: 8/28/14

Research Scope of PracticeApplicable Regulatory Context:

[VHA Directive 1200 §4.c(9)(a)]:

(9) Ensuring that all individuals working within and supporting the research program have been officially appointed as paid employees, without compensation employees (WOC) employees, or either appointed or detailed through the authority of the Intergovernmental Personnel Agreement (IPA).

(a) All individuals must be appropriately credentialed and privileged (if applicable). In any case, a Research Scope of Practice Statement or Functional Statement must be defined for all individuals conducting VA research, including individuals who do not function as health care providers. The Scope of Practice Statement or Functional Statement must be consistent with the position to which the individual is appointed and must define the duties of the individual. The Scope of Practice Statement or Functional Statement must not include any duties or procedures for which the individual is not qualified. If the individual holds clinical privileges at the facility and the research responsibilities and duties match the clinical privileges, the clinical privileges may be used in lieu of a Scope of Practice Statement. If there are additional responsibilities and duties, these should be included in the Scope of Practice Statement along with a copy of the clinical privileges. *NOTE: If applicable because of the position the individual holds, a functional statement may be used in lieu of the Scope of Practice Statement.*

(b) For contractors, the requirement for the appropriate background investigation, credentialing, and privileging must be specifically defined in the contract, which must clearly define their duties.

[VHA Handbook 1200.05 §29]

a. **Qualifications to Conduct Human Subjects Research.** VA investigators must have the appropriate training, education, expertise, and credentials to conduct the research according to the research protocol.

(1) PIs must ensure that all research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, and credentials) to perform procedures assigned to them during the course of the study.

(2) Investigators and their staff conducting human subjects research must be credentialed and privileged as required by current local and VA requirements (see VHA Handbook 1100.19 and VHA Directive 2012-030, Credentialing of Health Care Professionals, or successor policy). Investigators and their research staff may only perform those activities in a research study for which they have the relevant credentials and privileges.

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(3) Investigators and co-investigators must be identified on the IRB application and must provide credentials, conflict of interest statements or other documentation required by VA and local facility policies.

1. Research team members must have a research scope of practice (SoP) form on record with the R&D service (RDS).
 - a. Team members and their PI/Supervisor complete "Scope of Practice for VA Research Staff" form.
 - b. PI's sign a "Scope of Practice for Principal Investigator".
2. Implementation of new form:
 - a. Initiation began on June 13, 2014.
 - b. Initial: GRECC + MERCE + any new studies being submitted to RDC.
 - c. 2nd: MIRECC + new studies.
 - d. 3rd: Ongoing until all active studies have been updated.
 - e. 4th ("Maintenance"): Ongoing as new studies initiate, as new staff are added, or as SoPs of current staff change. This is achieved through routine processing of the R&D Committee transactions. (See PM-RDS-031)
3. PI and team member fills out applicable sections of the SoP form; PI signs.
 - a. If the team member works for more than one PI, one of the PI's can discuss and sign the team member's SoP (It is permissible for one SoP to cover the individual, even if s/he works for more than one PI).
 - b. If the team member performs different activities for different PIs, it may be appropriate for all applicable PIs to sign the form, or the team member can have separate forms, etc. This should be determined on a case-by-case basis. The ACOS/R&D can be involved in this determination.
4. The signed form is delivered to RDS point of contact (POC).
5. RDS POC reviews for completeness. Sends back to PI/team member if additional information is needed.
6. RDS POC sends to ACOS/R&D for his review and signature.
 - a. It is possible that the ACOS/R&D may request additional documentation from the PI or team member.
 - b. ACOS/R&D gives signed SoP to RDS POC,

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7. Signed SoPs are scanned into Research Service network.
 - a. Scanning staff places the signed original into file cabinet for pick-up by team member.
 - b. RDS POC notifies team member/PI that signed form is available for pickup
8. SoPs are logged into an RDS excel spreadsheet for tracking purposes.

Version	1.1	Origin: 1.0	
Author	Jessica Mendoza		
Changes	<ul style="list-style-type: none"> • Revised the “Applicable Regulatory Context” section in response to ORO recommendation for ‘outdated policy’. Removed the reference to the May 2012 version of 1200.05. The content of the PM remains unchanged. 	New Version #	1.1
Approved	Thomas j. Hornyak, ACOS/R&D Date: 7/29/16		
File Name	\\PM-RDS-028 Research Scope of Practice 082814		