

Research Scope of Practice (SOP): MANDATORY Requirement for ALL Research Personnel

Background:

- Per VHA Directive 1200, the VA's Office of Research and Development (ORD) requires that all research personnel have a Research Scope of Practice (SOP) that outlines their research duties and responsibilities.
- This includes **all** human, animal, and laboratory research personnel.
 - Note: "personnel" includes paid VA employees and those designated as without compensation (WOC) employees, and Intergovernmental Personnel Act (IPA) employees.
 - **This includes MDs, PhDs, and Principal Investigators.**
- The Durham VAMC has created **one** SOP template for all research personnel.
 - Please complete the sections that pertain to you: human, animal, or laboratory research. **You may complete more than one section of the SOP template.**

Requirements:

All personnel who work in research must have a valid SOP. All new research employees, WOCs, etc., must complete a SOP prior to beginning any research work.

- SOPs must be done using the current template.
- SOPs are valid for one year. The date the individual signs his or her SOP will be the basis for annual renewals.
- The following signatures are required before the SOP can be submitted to the Research Office: the individual, the individual's supervisor, and any Principal Investigator(s) who the individual may work with on a per-protocol basis.
- While individuals are accountable for their SOP, each PI is responsible for ensuring that individuals working on their study/studies have current and accurate SOPs.
- SOPs are not tied to continuing reviews and will not require that individuals list each protocol in which they have any study-related duties.
- Individuals are responsible for keeping their SOP with their signature, their supervisor's signature, and all applicable PI signatures.
- Submit SOPs to Kimberly Clark in the Research Office (Building 8, Room 116); the SOP will then be routed for ACOS/R&D review and signature.

Updates/Revisions

- If an employee has a current Research SOP but is assigned to work with a PI that is not listed on the current Research SOP, the individual must complete a SOP PI Update Form and submit the form to the Research Office.
 - The new PI(s) must review the employee's current Research SOP and sign and date the SOP PI Update Form to indicate that s/he agrees that the employee is capable to perform the assigned duties for those protocols in which s/he acts as the PI.
- It is not necessary to remove an obsolete PI from a current Research SOP; instead the individual would remove that PI at the next annual SOP submission.
- If research duties or responsibilities change during the course of a year, the individual must submit a new SOP with the individual's signature, the supervisor's signature, and all applicable PI signatures for ACOS/R&D signature.

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Processing and Tracking:

- All SOPs will be routed to Kimberly Clark for review, processing, and tracking.
- Once all signatures are present, SOPs will be scanned and an electronic version will be saved at S:\Research Forms\Scope of Practice.
- Original hard copies will be kept in the Research Office.
- Once signed by the ACOS/R&D, SOPs will NOT be routed back to the individual; instead the fully executed version will reside in the Research Office.
- A scanned SOP will be available at S:\Research Forms\Scope of Practice.

Questions:

- Questions regarding Human research should be directed to Kimberly Clark:
 - Kimberly.Clark5@va.gov, extension 5671
- Questions regarding Laboratory research should be directed to Kenan Christian:
 - Kenan.Christian@va.gov, extension 7341
- Questions regarding Animal research should be directed to Kathi Jones:
 - Katherine.Jones3@va.gov, extension 6548
- WOCs with questions should contact Nancy Dixon:
 - Nancy.Dixon5@va.gov, extension 6926
- HSR&D personnel with questions should contact Dana Tucker:
 - Dana.Tucker@va.gov, extension 5741