Ann Arbor VA Healthcare System IRB

**Procedures for the implementation of the revised Scope of Practice for Research Staff**

1. **In accordance with VA Directive 1200, *Veterans Health Administration Research and Development Program*, the Ann Arbor VA Healthcare System Research Service has developed and introduced at new Research Scope of Practice form and process.**
2. The new SOP defines all the duties an employee is allowed to perform for research purposes. Thus, it is person-specific, not study-specific and each employee should have only one SOP.  Any employee engaged in research must have one.
3. The SOP requires the signature of the employee and the employee’s direct supervisor, defined for these purposes as whoever conducts and signs the annual evaluation. This person may or may not be the PI of a study(ies) for which the employee is working. The signature of the ACOS/R&D is also required. The PDF form allows for the use of electronic signatures with a PIV card.
4. If research personnel are involved in more than one study, the SOP should be written to cover all of them.
5. When the employee is working on multiple research protocols, the PI for each protocol must also agree that the SOP includes all activities required of the employee. In some cases, the SOP may need to be modified by the supervisor, the PI and the employee to accommodate new responsibilities.
6. **The following procedures describe in detail the usage of the form.**
7. Employees should complete the SOP with their supervisor.
8. Investigators must also complete an SOP to be signed by their supervisor that includes their Research duties outside of the Credentialing and Clinical Privileges granted by the Medical Center.
9. Once the SOP has been signed by the employee and supervisor, it should be sent to the Research Office the next time a study the employee is part of submits a new application or continuing review
10. The Research Service will obtain the signature of the ACOS/R&D and forward a copy of the ACOS signed version to the supervisor and the employee.
11. Employees will forward a copy of their new SOP to the PI/Project Manager of each study they work on to be included in its regulatory binder.
12. Employees should retain a copy of their SOP for reference and to share with other PIs as the need arises.
13. When an employee changes supervisors, a new SOP must be completed.
14. SOPs are to be reviewed annually by the employee, their supervisor and the PIs for whom they work for accuracy and comprehensiveness.