

Dayton VA Medical Center
Scope of Practice for Research Personnel

Please Print

Research Staff Member Name & Job Title	Dayton VAMC Credentialing (Internal Use Only)
	From: _____ To: _____
Licensed or Eligible for License YES NO	WOC Period (Internal Use Only)
<input type="checkbox"/> MD <input type="checkbox"/> NP <input type="checkbox"/> RN <input type="checkbox"/> None <input type="checkbox"/> Other, List below <input type="checkbox"/> WSU Resident <hr/>	From: _____ To: _____
Principal Investigator (PI)	Immediate Supervisor
Salary Source	CPRS Access Requested
<input type="checkbox"/> VA <input type="checkbox"/> WSU <input type="checkbox"/> CFBRE <input type="checkbox"/> Other, List below <hr/>	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, please attach Computer Access Request form.

The Scope of Practice is specific to the duties and responsibilities of the Research Staff member named above as an agent of the listed Principal Investigator(s), and/or alternate supervisor for one year. As such he/she is specifically authorized to conduct research with the responsibilities outlined below in conjunction with approved research protocols. This document does not waive the responsibility to secure Dayton VA clinical privileges for any licensed independent provider under VHA Directive 1100.19 Credentialing & Privileging or nursing credentialing and boarding process. The Principal Investigator remains responsible at all times for the conduct of the employee and must complete, sign and date this Scope of Practice.

PROCEDURES:

A research employee may be authorized to perform the following duties and procedures on a regular and ongoing basis. They may be performed without specific prior discussion/instructions from the Principal Investigator. The Principal Investigator **must initial** whether or not the research employee is granted each duty listed below. A signed/dated copy of this document will be maintained in the Research Office.

Section I. HUMAN RESEARCH DUTIES <input type="checkbox"/> N/A, Proceed to Section II	Granted	Not Granted
Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.	<input type="checkbox"/>	<input type="checkbox"/>
Develops recruitment methods to be utilized in the study.	<input type="checkbox"/>	<input type="checkbox"/>
Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competencies).	<input type="checkbox"/>	<input type="checkbox"/>
Initiates submission of regulatory documents to IRB, VA R&D committee and sponsor.	<input type="checkbox"/>	<input type="checkbox"/>
Prepares study initiation activities.	<input type="checkbox"/>	<input type="checkbox"/>
Provides education and instruction of study medication use, administration, storage, side effects and notifies adverse drug reactions to study site.	<input type="checkbox"/>	<input type="checkbox"/>
Provides education regarding study activities to patient, relatives and Medical Center staff as necessary per protocol.	<input type="checkbox"/>	<input type="checkbox"/>
Maintains complete and accurate data collection in case report forms and source documents.	<input type="checkbox"/>	<input type="checkbox"/>
Initiates and/or expedites requests for consultation, special tests or studies following the Investigator's approval.	<input type="checkbox"/>	<input type="checkbox"/>
Obtains and organizes data such as tests results, diaries/cards or other necessary information for the study.	<input type="checkbox"/>	<input type="checkbox"/>
Demonstrates proficiency with VISTA/CPRS computer system by scheduling subjects research visits, documenting progress notes, initiating orders, consults, etc.	<input type="checkbox"/>	<input type="checkbox"/>
Accesses patient medical information while maintaining patient confidentiality.	<input type="checkbox"/>	<input type="checkbox"/>
Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent "process".	<input type="checkbox"/>	<input type="checkbox"/>
Initiates intravenous (IV) therapy and Administers IV solutions and medications.	<input type="checkbox"/>	<input type="checkbox"/>
Drug Accountability: Obtains study drugs from research pharmacy after order by licensed provider. Delivers/administers study drug to research participant.	<input type="checkbox"/>	<input type="checkbox"/>

Section II.	Granted	Not Granted
HUMAN DATA DUTIES <input type="checkbox"/> N/A, Proceed to Section III		
Organizing, filing and analyzing human subject data.	<input type="checkbox"/>	<input type="checkbox"/>
Section III.	Granted	Not Granted
Specific Duties not specified above <input type="checkbox"/> N/A, Proceed to Section VII		
	<input type="checkbox"/>	<input type="checkbox"/>

Section IV.**Education Requirements:**

1. VA Research Certification in Human Subject Protection and Good Clinical Practice
 - a. CITI Program – www.citiprogram.org FOR ALL EMPLOYEES. THIS MUST BE COMPLETED ANNUALLY.
2. VA HIPAA/Privacy Training: THIS MUST BE COMPLETED ANNUALLY.
 - a. <https://www.lms.va.gov/plateau/user/login.jsp> VA paid employees only.
 - b. <https://www.ees-learning.net> for all non-VA paid employees.
3. VA Information Security Awareness Training: THIS MUST BE COMPLETED ANNUALLY.
 - a. <https://www.lms.va.gov/plateau/user/login.jsp> for all VA paid employees only.
 - b. <https://www.ees-learning.net> for all non-VA paid employees.

NOTICE TO LICENSED PROFESSIONALS:

Individuals found to be working outside their privileges as granted by the DVAMC will be subject to disciplinary action and possible reporting to the National Practitioner Data Bank.

RESEARCH EMPLOYEE’S STATEMENT:

This Scope of Practice outlines routine general duties I am permitted to undertake in conjunction with a VA approved protocol. I understand that all research must be approved by the WSU IRB and the Dayton VA R&D Committees. If I have questions or concerns, I am encouraged to contact the Research Compliance Officer or the R&D Office. I also understand that performing duties beyond this scope of practice without specific authorization may lead to disciplinary action. Both the principal investigator and I are familiar with all duties and procedures granted in this Scope of Practice. I agree to abide by the parameters of this Scope of Practice and all-applicable hospital policies and regulations.

I also understand that I may not perform any procedures which constitute the practice of a profession for which I may be eligible for but did not obtain the license, registration, or certification for that profession. (e.g.: unlicensed physician may not do any procedures that would be considered the practice of medicine)

Research Employee’s Signature

Date

PRINCIPAL INVESTIGATOR’S STATEMENT:

This Scope of Practice for _____ (*Research Staff Name*) was reviewed and discussed with the employee on the date shown below. After reviewing his/her education, competency, qualifications, research practice involving duties checked above, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties and procedures. Both the Research Staff Member and I are familiar with all duties and procedures granted in this Scope of Practice. We agree to abide by the parameters of this Scope of Practice and all-applicable hospital policies and regulations.

As a principal investigator, I further understand that conducting research without DVAMC R&D Committee or subcommittee approvals may affect my standing at the VA and that ethical breaches in the conduct of my research may affect my ability to do research with the VA in the future.

A new Scope of Practice should be submitted **every year** and amended as necessary to reflect changes in the research staff member’s duties and responsibilities and/or hospital or research policies.

Principal Investigator (PI)

Date

Service Chief (PI SOP Only)

Date

Annual Review	Date
PI Sign _____ Employee Sign _____	
PI Sign _____ Employee Sign _____	
PI Sign _____ Employee Sign _____	
PI Sign _____ Employee Sign _____	
PI Sign _____ Employee Sign _____	
PI Sign _____ Employee Sign _____	
PI Sign _____ Employee Sign _____	

_____ Office Use Only _____	
INSTITUTIONAL APPROVALS:	
_____ C/Research and Development	_____ Date: