

**Fargo VA Health Care System
Research Scope of Practice**

Project Title:

Researcher/Investigator's Information		
Name (Last, First, MI):		
Degree:	Licensure/Certificate/Registration:	
Service Line/Job Title:		
Fargo VA Resident?	Yes	No, if Yes, specify training level:
Principal Investigator (PI)		
Name (Last, First, MI):		
Will this Researcher/Investigator be accessing VA computer systems?		Yes No
Will this Researcher/Investigator be accessing PHI or PII?		Yes No

**All researchers must complete VA Privacy and Information Security Awareness, Privacy and HIPAA Training, Ethics, and Technology Transfer Program training in TMS*

SECTION 1		
Will this Researcher/Investigator be performing any of the following duties related to HUMAN RESEARCH? Select all that apply:	Yes	No
Screens / interviews patients to determine if eligible to participate in study		
Develops recruitment methods used in the study		
Maintains screening and consent logs		
Prepares regulatory documents for submission to IRB, R&D Committee and sponsor		
Obtains informed consent from research subjects *Requires documented competency		
Performs venipuncture to obtain specimens required by study protocol *Requires documented competency		
Provides education and instruction for study medication use, administration, storage, side effects, and for notifying researchers of adverse drug reactions		
Provides education regarding study to patient, relatives, and medical staff as required per protocol		
Enters progress notes into VISTA/CPRS, schedules subject visits and/or procedures		
Screens patients/obtains medical history from a patient information database (CPRS, VINCI, other), analyzes data obtained from patients or a patient information database. This includes de-identified data.		
Collects and/or processes human specimens or performs any laboratory work with human tissues or specimens		
Obtains and organizes data such as test results, diaries/cards or other information required for the study, maintains complete and accurate data collection in case report forms and source documents		
Checks and records vital signs		

SECTION 2

Will this Researcher/Investigator be performing any of the following research on Humans	Yes	No
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Select all that apply:

If YES, the Researcher/Investigator must be privileged through the Fargo VA Medical Privileging Process

Fargo VA licensed, credentialed, privileged provider who conducts a medical interview of the research subject

Performs physical examinations

Orders inpatient and outpatient medication (including study medication). Orders diagnostic testing, e.g., laboratory processing of samples, X-ray, MRI, etc., as outlined in the research protocol – subject to signature of responsible M.D.

Reports laboratory results and other diagnostic testing (e.g., radiography, clinical pathology, etc.) to study sponsor and appropriate personnel in a timely manner

Initiates intravenous (IV) therapy and administers IV solutions and medications

SECTION 3

OTHER DUTIES - Please list any other duties which may be performed:

This Scope of Practice will be reviewed annually and amended as necessary to reflect changes in this individual's privileges, duties, responsibilities, utilization guidelines and/or hospital policies.

Researcher/Investigator Statement:

This Scope of Practice outlines general duties that I am permitted to undertake under the supervision of the Principal Investigator in conjunction with a VA approved protocol. I understand that all research must be approved by the USD IRB and the Fargo R&D Committee. If I have questions, I am encouraged to contact the Research Administration Offices. I 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 Research policies and regulations.

Researcher/Investigator Signature

Date

**Note: PI's must sign this section for their personal SOP*

Principal Investigator (PI) Statement:

This Scope of Practice was reviewed and discussed with the Researcher/Investigator. After reviewing the education, clinical competency, qualifications, research practices, peer reviews, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties/procedures. The Researcher/Investigator and I are familiar with all duties and procedures granted or not granted in this Scope of Practice; we agree to abide by the parameters of this Scope of Practice, all applicable Research Service Policies and regulations.

PI's are responsible for ensuring that all members of the research team function strictly within their approved scope of assigned duties.

PI Signature

Date

ACOS/R&D Signature

Date