SUBJECT: Scopes of Practice

1. PURPOSE:

The purpose of this SOP is to outline the processes for ensuring that all individuals conducting research at the Minneapolis VA Health Care System (MVAHCS) are conducting their duties in accordance with an approved scope of practice document.

2. DEFINITIONS:

AO/R: Administrative Officer for Research
ACOS/R: Associate Chief of Staff for Research
IACUC: Institutional Animal Care and Use Committee
IRB: Institutional Review Board
PI: Principal Investigator
R&D: Research and Development
RDC: Research and Development Committee
SRS: Subcommittee on Research Safety
VA Research: Research conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

3. OVERVIEW:

This SOP is based on VHA Directive 1200.05.

Each member of the research team must have a research scope of practice statement that has been approved by the individual's PI or immediate supervisor and the ACOS/R. This statement defines the duties the individual is allowed to perform for research purposes and is required for all research personnel (clinical and non-clinical). The research scope of practice must be consistent with the occupational category under which the individual was hired and it must not include any duties for which the individual is not qualified. Current scopes of practice must be retained by the Research Office, the employee and the PI or immediate supervisor.

MVAHCS requires that all members of the research team, even those with clinical privileges, a functional statement or equivalent, have a separate research scope of practice.

4. PROCEDURES:

a) **Coverage:** All research personnel, including clinicians with clinical scope of practice statements, or clinical privileges, or clinical functional statements, must have a research scope of practice statement as described herein.

   i) Anyone providing clinical services (e.g. cognitive behavioral counselling, medication prescription, diagnostic evaluations, therapeutic interventions) under the auspices of an IRB-approved research protocol must be credentialed and have appropriate clinical privileges at the Minneapolis VA unless the individual provides the services under the supervision of another VA provider, named on the protocol, who has the requisite privileges at the Minneapolis VA.

ii) If research personnel are involved in more than one study, the research scope of practice statement may be written to cover multiple studies (i.e. personnel do not need a research scope of practice statement for each protocol).

iii) Research personnel must have all required licenses, registrations, or certifications to perform a given procedure, intervention, or other activity in the research setting and practice only within the scope allowed by such licenses, registrations, or certifications.

b) **Revisions:** Research scopes of practice must be revised whenever duties are added or removed. It is the responsibility of the individual and his/her immediate supervisor or PI(s) to update his/her scope of practice any time duties are added or removed.

c) **Review and Signatures:** Each completed scope of practice must be reviewed and signed by the individual's supervisor or PI. If the scope of practice covers projects that are directed by more than one PI, all PIs must review, edit, and sign the statement. The scope will be reviewed and signed by the Deputy ACOS/R. A copy of the fully signed document will be returned to the research team member and the immediate supervisor or PI(s).

d) **Initial Review:** It is the responsibility of the administrative staff of the committee of record (i.e. RDC, IRB, IACUC or SRS) to ensure that each person listed as research personnel on a project submitted for initial review has a scope of practice on file with the research office.

e) **Record Retention:** It is the responsibility of the employee and the immediate supervisor or PI(s) to maintain a copy of the scope of practice. The Research Service office will also keep a copy of all signed scopes of practice.

f) **Annual Reminder:** The Research Service office will send an annual email to all research personnel reminding them that they must submit updated scopes of practice if their research duties or the duties of any of their research employees have changed.

g) **Annual Review:** Principal Investigators will verify that each employee's scope of practice is up-to-date by endorsing an item on the continuing review form from the relevant oversight committee (IRB, IACUC, SRS, or RDC) for each project.

h) **Scopes of Practice Database:** To facilitate scope of practice reviews, the Research Service will maintain a database that includes a record of each individual's name, contact information, date of initial scope of practice, date of any amended scopes of practice, and a copy of the most recent signed scope of practice.

5. APPENDICES: Scope of practice form

6. REFERENCES:

VHA Directive 1200.01 "Research and Development Committee" (24 January 2019)

VHA Directive 1200.05 "Requirements for the Protection of Human Subjects in Research" (07 January 2019)

VHA Directive 1058 "Office of Research Oversight" (08 November 2024)

7. **Date of Research & Development Committee approval:** 07 January 2025

8. **RESCISSION:** Minneapolis Research Service SOP R&D-008 "Scopes of Practice" (03 November 2020).

9. **EXPIRATION DATE:** N/A

10. **FOLLOW-UP RESPONSIBILITY:** Research and Development (R&D) Committee

SCOPE OF PRACTICE FOR RESEARCH DUTIES AND RESPONSIBILITIES

MINNEAPOLIS VA HEALTH CARE SYSTEM

Employee's Name: First:	**Last:**	**Degree(s):**
Job Title:		
Phone #:	**Routing #:**	
Supervisor's Name: First:	**Last:**	
☐ **New** – This form has not been completed for this Employee before **Date:**	☐ **Revised** – This Employee has changes in duties and/or Supervisor **Date:**	

For the purposes of this form, the term "Employee" will refer to the individual named at the top of this form. The term "Supervisor" will refer to the individual responsible for evaluating and/or approving the Employee's VA appointment. Each Employee will have only one designated Supervisor responsible for approving duties outlined below, even if the specific duty is overseen by someone other than the designated Supervisor.

The Scope of Practice for Research Duties and Responsibilities is specific to the duties and responsibilities of each member of the research team; as such, he/she is specifically authorized to conduct research with the responsibilities outlined below in conjunction with approved research protocol(s). This form does not confer authorization to perform duties that exceed the limits of the Employee's current license/certificate.

The Supervisor must ensure that the Employee: (a) is appropriately qualified to perform the assigned duties; (b) has a current VA appointment (i.e., VA, WOC, IPA); and (c) has agreed to meet all applicable requirements for training, competencies, licensure, credentialing, and privileging prior to engaging in research at the Minneapolis VAHCS.

Instructions:

- Each Employee should have one Scope of Practice that includes all anticipated research duties, on all projects.
- The Supervisor and employee must complete, sign, and date this Scope of Practice.
- This form must be reviewed by the Supervisor at least annually.
- This form must be re-signed and dated by both the Supervisor and employee if there is a change, including addition and/or deletion of duties.
- A digitally signed copy will be kept on file in the Research Office. Copies are to be retained by the employee and his/her Supervisor.

Important Note: Any Employee who may exercise independent clinical judgment or perform procedures that require clinical privileges as part of his/her research duties must obtain such clinical privileges through the Credentialing Office at the Minneapolis VA.

Type(s) of research in which this Employee will be involved at the Minneapolis VAHCS: *Check all that apply; at least one category must be selected.*	
☐	**Human Subject Research:** The Employee's research duties will involve (a) obtaining data through intervention or interaction with a living individual, or (b) accessing or using identifiable private information about living individuals. **Complete Part I; Complete Parts III and IV, if applicable**
☐	**Animal Research:** The Employee's research duties will involve working with laboratory animals for research, testing, or training. **Complete Part II, III, and IV**
☐	**Laboratory/Bench/Other Research:** The Employee's research duties will involve chemical, biological, radiation, or physical hazards, OR the Employee is part of a Record Only study and will have no contact/interaction with human or animal subjects or hazards. **Complete Part III and IV**

PART I: HUMAN RESEARCH DUTIES AND RESPONSIBILITIES *Check all that apply*	
☐	Serves as the PI on Human Subjects research, thereby providing oversight of the study and all study staff
☐	Performs duties that require clinical credentials: ☐ Places IV line *(RN, LPN, MD, DO – **competency required**, biannual competency check recommended)* ☐ Administers IV medications *(RN, MD)* ☐ Administers controlled substances *(RN, MD)* ☐ Performs physical exams *(within limits of current clinical license – nurse, physician, therapist, etc.)*
☐	Draws blood for research purposes *(**competency required**, biannual competency check recommended)*
☐	Checks and records vital signs *(**competency required** for personnel without clinical license)*
☐	Prepares/maintains regulatory documents, research records, case report forms, & source documents *(competency recommended)*
☐	Communicates with study sponsor
☐	Develops study initiation program, materials, & activities
☐	Trains or supervises others in carrying out research activities
☐	Obtains and organizes data such as test results and other information needed for the study
☐	Performs statistical analysis
☐	Develops articles or presentations of research results
☐	Develops recruitment materials/methods
☐	Initiates contact with patients or others for research purposes, including recruitment
☐	Screens patients to determine study eligibility
☐	Maintains screening and consent logs
☐	Obtains informed consent from research participants *(competency recommended)*
☐	Obtains medical history
☐	Reviews participant medical information
☐	Orders diagnostic testing (with physician approval)
☐	Initiates and/or expedites requests for consultation, special tests, or studies, following PI approval
☐	Initiates adverse event (AE) reporting *(competency recommended)*
☐	Collects and/or processes human biological specimens for research purposes *(competency recommended)*
☐	Maintains specimen inventory, storage and security
☐	Acts as director of a data or specimen repository
☐	Ships or transports biological materials *(shipping training may be required)*
☐	Orders study medications
☐	Obtains medication from Pharmacy, provides medication to participants, counts returned medication, and disposes of returned medication per VA and sponsor policies
☐	Instructs participants on proper use of study medication or device
☐	Handles controlled substances
☐	Educates/instructs patients or others regarding study activities
☐	Uses VISTA/CPRS to schedule participant visits, initiate orders/consults, etc. *(scheduling training may be required)*
☐	Enters research progress notes into VISTA/CPRS
☐	Sets clinical alerts in VISTA/CPRS for participants in drug or device studies
☐	Reports laboratory and other diagnostic test results to the PI, study sponsor and appropriate personnel
☐	Prepares vouchers for participant payment
☐	Performs other human research duties not listed on this form *Specify:*

PART II: ANIMAL RESEARCH DUTIES AND RESPONSIBILITIES *Check all that apply*	
☐	Serves as the PI on Animal Subjects research, thereby providing oversight of the study and all study staff
☐	Works with animals or animal tissues Species: ☐ Mice ☐ Pigs ☐ Rats ☐ Rabbits ☐ Non-human primates ☐ Other – *specify*
☐	Trains or supervises others in carrying out research activities
☐	Assesses health status of laboratory animals
☐	Evaluates animals for signs of potential pain/distress
☐	Determines if endpoint criteria are met
☐	Performs routine animal care tasks such as weighing and grooming
☐	Performs routine housekeeping duties such as feeding, watering, changing bedding, cleaning animal housing rooms, etc.
☐	Performs ear tagging, tail snipping, tattooing or other procedures for identification of animals
☐	Uses restraint techniques or devices
☐	Performs gavage
☐	Performs venipuncture
☐	Performs retro-orbital blood collection (under anesthesia)
☐	Performs antemortem tissue collection
☐	Collects fecal samples
☐	Performs dosing calculations
☐	Administers analgesic drugs
☐	Administers test substances Routes of administration: ☐ Oral ☐ Intravenous ☐ Topical/transcutaneous ☐ Intraperitoneal ☐ Vaginal or rectal ☐ Intrathecal ☐ Subcutaneous ☐ Intracardiac (under anesthesia) ☐ Intramuscular
☐	Provides preprocedural care and monitoring
☐	Induces anesthesia
☐	Maintains/monitors anesthesia during procedures
☐	Preps animals for surgery, including surgical site preparation
☐	Performs surgical procedures
☐	Provides postoperative care and monitoring
☐	Performs, assists or observes radiological procedures
☐	Handles or administers controlled substances
☐	Performs or confirms euthanasia
☐	Performs postmortem perfusion and tissue collection
☐	Disposes of uncontaminated animal carcasses
☐	Disposes of contaminated animal carcasses and bedding
☐	Performs tissue studies
☐	Performs statistical analysis
☐	Develops articles or presentations of research results
☐	Performs other animal research duties not listed on this form *Specify:*

PART III: LABORATORY/BENCH/OTHER RESEARCH DUTIES AND RESPONSIBILITIES *Check all that apply*	
☐	Serves as the PI on Laboratory or Record Only research, thereby providing oversight of the study and all study staff
☐	Prepares/maintains regulatory documents
☐	Trains or supervises others in carrying out research activities
☐	Maintains research records
☐	Collects and/or maintains data, lab notebooks, databases, etc.
☐	Obtains and organizes data such as test results, database searches, and other information needed for the study
☐	Performs statistical analysis
☐	Develops articles or presentations of research results
☐	Initiates and/or expedites requests for consultation, special tests, or studies, following PI approval
☐	Performs general lab duties including labeling, media preparation and cleaning
☐	Prepares lab for research activities
☐	Handles biological materials or chemicals in the lab
☐	Uses infectious, toxic or hazardous agents in the lab
☐	Maintains or calibrates lab equipment
☐	Uses radioactive materials or radiation-generating equipment in research
☐	Generates waste in the lab that could be considered hazardous
☐	Maintains Safety Data Sheets (SDS)
☐	Maintains laboratory chemical inventory
☐	Serves as laboratory point of contact for hazard communication
☐	Orders biological materials or chemicals
☐	Ships or transports biological materials outside the Medical Center
☐	Handles or administers controlled substances
☐	Works with recombinant DNA, including PCR and/or use of transgenic organisms.
☐	Performs other research duties not listed on this form *Specify:*

PART IV: REQUEST FOR AUTHORIZED ACCESS TO LABORATORY/ANIMAL RESEARCH AREAS *Check all that apply*	
☐	Authorization to access secured areas of Minneapolis VAHCS is necessary to accomplish duties of the position defined by the Scope of Practice Duties defined by the Scope of Practice require work to be performed in: *(check all that apply)* ☐ Non-laboratory secured space (e.g. office, secured clinical research area, etc.) ☐ BSL-1 Laboratory ☐ BSL-2 Laboratory ☐ Animal Care Facility

PART V: ADDITIONAL DUTIES AND RESPONSIBILITIES	
☐	Other duties or responsibilities not listed elsewhere on this form *Specify:*

NOTICE TO NON-LICENSED / NON-PRIVILEGED CLINICAL PROFESSIONALS

Individuals who by virtue of their education and training are eligible to obtain, but do not hold licensure, registration, or certification, and do not hold current privileges at the Minneapolis VAHCS, may not perform any duties or procedures that may be considered practicing their specific health care profession as defined by the state of Minnesota. As VA research staff, whether VA-paid, WOC, or under an IPA, you must not practice beyond that which is allowed for the occupational category under which you were hired/appointed. Individuals found to be working outside their Scope of Practice or privileges as granted by the Minneapolis VAHCS will be subject to disciplinary action and possible reporting to the National Practitioner Data Bank.

EMPLOYEE DECLARATION:

I certify that I will engage only in work activities that are consistent with my approved Scope of Practice of Research Duties and Responsibilities. I agree that any job duties requiring training or certification will not be performed unless training and/or certification has been completed. I understand that my Scope of Practice of Research Duties and Responsibilities cannot be construed to authorize any activity that would require the exercise of independent clinical judgment or the performance of procedures or activities that would require clinical privileges at the Minneapolis VAHCS. I understand that my Scope of Practice for Research Duties and Responsibilities must be renewed any time that I change supervisors, or any time that my duties and/or responsibilities are substantively modified.

Employee signature:

SUPERVISOR STATEMENT:

This Scope of Practice for Research Duties and Responsibilities has been reviewed and discussed with the Employee. The Employee possesses the necessary training and/or education required for this position, and meets all applicable requirements for training, competencies, licensure, credentialing, and privileging necessary to safely perform the indicated duties/procedures. This Scope of Practice will be reviewed and amended whenever necessary to reflect changes in the research Employee's duties/responsibilities within the VA Research Program.

☐ Clinical credentials required: I certify that the employee named here has the clinical credentials required to perform the duties specified above.

☐ Competency required: I certify that the employee named here will demonstrate competency in duties specified above, and that competencies will be evaluated as indicated.

Supervisor signature:

ACOS/R&D APPROVAL:

ACOS/R&D:

Signature: