Sioux FallsVA Health Care System (SFVAHCS)
Research Scope of Practice

Researchers Information			
Name *(Last, First, MI)*:			
Degree:		Licensure/Certificate/Registration:	
Service Line/Job Title:			
SFVAHCS Resident?	☐ Yes ☐ No, if yes, specify training level:		
Principal Investigator (PI)/Primary Supervisor			
Name *(Last, First, MI)*:			
Project Number(s)			

Will this researcher be accessing VA computer systems?	☐ Yes	☐ No
***If yes,** the researcher must complete VA Privacy and Information Security Awareness training*		
Will this researcher be accessing PHI or PII?	☐ Yes	☐ No
***If yes,** the researcher must complete Privacy and HIPAA Focused Training*		

SECTION 1: Will this researcher be performing any of the following duties related to HUMAN RESEARCH? (If NO, please skip to Section 2.) *Requires documented competencies	☐ Yes	☐ No
☐ 1. * Collects objective information relevant to the research protocol by interviewing research subjects.		
☐ 2. * Maintains screening logs.		
☐ 3. * Provides education regarding study to patient, relatives, and medical staff as required per protocol.		
☐ 4. * Obtains informed consent from research subjects.		
☐ 5. * Performs venipuncture to obtain specific specimens required by study protocol.		
☐ 6. * Provides education and instruction for study medication use, administration, storage, side effects, and for notifying researchers of adverse drug reactions.		
☐ 7. Enters progress notes into VISTA/CPRS, schedules subject visits and/or procedures.		
☐ 8. 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.**		
☐ 9. Collects and/or processes human specimens or performs any laboratory work with human tissues or specimens.		
☐ 10. Prepares regulatory documents for submission to SFVAHCS research (sub)committees & sponsor, develops recruitment methods for the study, prepares study initiation activities.		
☐ 11. 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.		
☐ 12. Checks and records vital signs.		
☐ 13. Completes research visits in a non-VA location such as the subject's home or other venue.		
Will this researcher be performing any of the following research on Humans?	☐ Yes	☐ No
***If yes,** the researcher must be privileged by SFVAHCS Medical Privileging Process*		
☐ 14. SFVAHCS licensed, credentialed privileged provider who conducts a medical interview of the research subject.		
☐ 15. Performs physical examinations.		
☐ 16. Orders inpatient and outpatient medication (including study medication). Orders diagnostic testing, including laboratory processing of samples, X-ray, MRI, etc., as outlined in the research protocol— subject to signature of responsible M.D.		
☐ 17. Reports laboratory results and other diagnostic testing (e.g., radiography, clinical pathology, etc.) to study sponsor and appropriate personnel in a timely manner.		
☐ 18. Initiates intravenous (IV) therapy and administers IV solutions and medications.		

Research Service Use Only

This Research Scope of Practice must be renewed annually in its entirety and expires on _____

SECTION 2: Will this researcher be performing any of the following duties related to ANIMAL RESEARCH? (If NO, please skip to Section 3.)	☐ Yes	☐ No
☐ 1. Administers euthanasia to research animals.		
☐ 2. Administers analgesics, anesthetics, injections, and/or test substances.		
☐ 3. Performs animal husbandry activities.		
☐ 4. Identifies humane endpoints - determines when protocol endpoints are reached, as described in approved protocol.		
☐ 5. Identifies research animals and performs ear clips, tail clips, tags, or tattooing.		
☐ 6. Uses infectious, toxic, hazardous agents in animals as described in protocol.		
☐ 7. Performs surgery according to approved protocol.		
☐ 8. Performs antemortem blood/tissue collection.		
☐ 9. Works with animal cells or animal tissues or biological specimens.		
☐ 10. Other (list) _____		

SECTION 3: Will this researcher be performing any LABORATORY RESEARCH in a Wet Lab? (If NO, please skip to Section 4.)	☐ Yes	☐ No
☐ 1. Maintains laboratory equipment, performs calibration, and ensures appropriate cleanliness.		
☐ 2. Maintains lab areas. Maintains a safe working environment.		
☐ 3. Keeps inventories of laboratory supplies, orders supplies.		
☐ 4. Carries out research activities as described in approved research protocols.		
☐ 5. Works with ionizing or non-ionizing radiation as specified in approved research protocols.		
☐ 6. Works with microbes or microbial agents.		
☐ 7. Works with DNA, RNA, or other synthetic or natural genetic material.		
☐ 8. Works with chemicals or chemical hazards.		
☐ 9. Works with controlled substances.		
☐ 10. Works with human or animal cell lines.		
☐ 11. Is exposed to physical hazards.		
☐ 12. Any other use of infectious, toxic, hazardous agents in the lab as specified in approved research protocols (list) _____		

SECTION 4: - Will this researcher be SHIPPING BIOLOGICAL MATERIALS?	☐ Yes	☐ No
***If yes,** the researcher must complete trainings DOT1, DOT2, DOT3, and DOT4 at www.tms.va.gov*		

Section 5: OTHER DUTIES - Please list any other duties which may be performed:

Research Service Use Only

This Research Scope of Practice must be renewed annually in its entirety and expires on _____

ASSURANCES OF RESEARCH EMPLOYEE and PRINCIPAL INVESTIGATOR/SUPERVISOR:

This Scope of practice outlines general tasks the Research Employee is permitted to undertake under the supervision of the Principal Investigator in conjunction with an approved protocol. The Research Employee and the Principal Investigator understand that performing tasks beyond this scope of practice without specific authorization may lead to disciplinary action.

By signing this Scope of Practice, both the Research Employee and the Principal Investigator affirm

- Understanding that all research must be approved by the SFVAHCS R&D Committee and subcommittees.
- Familiarity with all duties and procedures granted in this Scope of Practice.
- Commitment to abide by the parameters of this Scope of Practice and all applicable SFVAHCS Policies and Regulations.
- That the Research Employee has completed all of the necessary training and education and possesses all clinical competencies, qualifications and individual skills needed to safely perform all of the aforementioned duties and procedures.
- Awareness of the policies and procedures in VHA Handbook 1058.02 ("Research Misconduct"), issued on February 7, 2014.

By signing this Scope of Practice, the Principal Investigator further affirms

- Understanding that conducting research at SFVAHCS without IRB and R&D approval may affect his/her standing at the VA.
- Understanding that ethical breaches in the conduct of his/her research may affect his/her ability to do research with the VA in the future.
- Understanding that a new Scope of Practice is required whenever the Research Employee's duties and responsibilities or utilization guidelines and/or hospital policies change.
- That he/she accepts responsibility at all times for the conduct of the Research Employee.
- The research duties listed for the Research Employee are commensurate with the Research Employee's training, experience, and competence.
- Awareness of the policies and procedures in VHA Handbook 1058.02 ("Research Misconduct"), issued on February 7, 2014.

Print Name of Researcher	Signature of Researcher	Date
Print Name of Principal Investigator/Supervisor	Signature of PI/Supervisor	Date

OFFICE USE ONLY: INSTITUTIONAL APPROVALS - The Research Personnel listed above is a current VA employee or has a current WOC appointment and his/her Credentials have been verified:

Print Name	AO of Research (Signature)	Date

☐ Approve ☐ Disapprove

Print Name	Coordinator/R&D (Signature)	Date

Research Service Use Only

This Research Scope of Practice must be renewed annually in its entirety and expires on _____