

**South Texas Veterans Health Care System
(STVHCS)**

**Scope of Practice for Research Team
Member Involved in Clinical Research**

NAME (Last name, First name - Printed)	RESEARCH TITLE
DEGREE	LICENSURE
<input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> DDS <input type="checkbox"/> NP/CNS <input type="checkbox"/> PA <input type="checkbox"/> BSN <input type="checkbox"/> BS <input type="checkbox"/> MS <input type="checkbox"/> PhD <input type="checkbox"/> None <input type="checkbox"/> Other: _____	<input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> DDS <input type="checkbox"/> NP/CNS <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> LVN <input type="checkbox"/> MT <input type="checkbox"/> None <input type="checkbox"/> Other: _____
SUPERVISOR/SUPERVISING INVESTIGATOR	DEPARTMENT/DIVISION
IMMIGRATION STATUS	
<input type="checkbox"/> US Citizen <input type="checkbox"/> Permanent Resident <input type="checkbox"/> Visa <input type="checkbox"/> Specify Visa Type: _____	

The Scope of Practice is specific to the duties and responsibilities of each research team member. The research team member is specifically authorized to conduct research involving human subjects with the responsibilities approved below in conjunction with approved research protocols. This document does not waive the responsibility to secure STVHCS clinical Credentialing & Privileging for any licensed independent provider under VHA Directive 1100.19. The Scope of Practice is governed by the policies and procedures outlined in the STVHCS Hospital Policy. The Supervisor and the Principal Investigator associated with the studies that the individual is working on remain responsible for the conduct of the research team member at all times.

PROCEDURES:

A research team member may be authorized to perform the following duties and procedures on a regular and ongoing basis under protocols approved by the IRB and STVHCS R & D Committee. The signed copy of this document will be maintained in the research team member's file in the STVHCS Research Office. Check the appropriate boxes for routine duties that apply to the research team member.

Foreign medical graduates that are not licensed in the U.S. are considered non-licensed personnel. Non-licensed M.D.s may not display the M.D. designation on a name tag, consent form, contact information, or in any other way convey to the research participant or staff that he/she is a licensed practicing physician.

Competency verification must be performed by an individual with appropriate credentials or a clinician with appropriate privileges; this may be the research team member's supervisor or a supervising investigator. Competency verification must be by direct observation of the research team member for the specific task(s) requested. The research team member's supervisor or supervising investigator should indicate competency verification by initialing in the block by each corresponding task(s) requested. Items indicated as requiring competency anticipate that the supervisor or supervising investigator has reviewed any applicable certifications, observed and documented the research team member's skill in these areas and periodically reviews and documents the research team member's performance.

Routine Duties (may require competencies or credentials)	Medical Fellows & Residents	Students and other Non- Licensed	Licensed Mid- level Providers (NP/CNS/PA)	Licensed R.N.	Other Licensed & Credentialed	Lab/Bench Staff	Competency Verifier's Initials
Prepares regulatory documents for the IRB, STVHCS R&D committee and/or sponsor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Develops and/or implements recruitment methods to be utilized in the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Prepares study initiation program, materials and activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing patients (study specific training required; training must be documented in protocol regulatory documents)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Maintains screening logs (requires HIPAA and Information Security Training)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Provides education regarding study activities to patient, relatives, and Medical Center staff as necessary per protocol (study specific training required; training must be documented in protocol regulatory documents)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Obtains informed consent from research participant (requires knowledge and application of informed consent process; requires competency verification through observation by an individual with appropriate credentials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Obtains information from subject pertinent to research protocol (study specific training required; training must be documented in protocol regulatory documents)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Checks and records vital signs (requires competency verification through observation by a clinician with appropriate privileges for non-licensed individuals)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Performs physical examination (within limits of license)	<input type="checkbox"/>		<input type="checkbox"/>				
Evaluates acute health problems, including possible adverse events (within limits of license)	<input type="checkbox"/>		<input type="checkbox"/>				
Performs physical assessment (requires competency verification through observation by a clinician with appropriate privileges) for licensed individuals within limits of license; for non- licensed individuals (requires Delineation of Physical Assessment Tasks for Non-Licensed Research Personnel Form)		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		
Performs venipuncture to obtain specific specimens required by study protocol (requires formal training program through clinical laboratory, or a history of previous training and competency verification by observation through an individual with appropriate credentials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Collects and/or processes human specimens per protocol, including blood, urine, sputum, buccal swabs, etc. (requires competency verification by observation by an individual with appropriate credentials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ships biological materials (Requires IATA training Register through the Knowledge Center) <input type="checkbox"/> Attached	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Orders diagnostic testing including laboratory processing of samples, X-ray, etc. as outlined in the research protocol – subject to co-signature of responsible M.D.	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Reports laboratory results and other diagnostic testing (e.g., radiography, clinical pathology) to study sponsor and appropriate personnel in a timely manner	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Maintains specimen inventory and ensures appropriate storage conditions and security	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Orders, alters, or adjusts inpatient and outpatient medications or investigational drugs (practitioner prescribing study medication must be named on drug record form)	<input type="checkbox"/>		<input type="checkbox"/>				

Routine Duties (may require competencies or credentials)	Medical Fellows & Residents	Students and other Non Licensed	Licensed Mid- level providers (NP/CNS/PA)	Licensed R.N.	Other Licensed & Credentialed	Lab/Bench Staff	Competency Verifiers Initials
Drug Accountability: Delivers oral study medication from pharmacist, after order by licensed provider, to participant [requires competency verification by observation by a clinician with appropriate privileges]. Research drugs/medications must be handled and/or coordinated per the STVHCS institution's policy and pharmacist.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Provides participant education and instruction on use of study medication, including administration, storage, side effects and how to notify researcher of adverse drug reactions (competency verified through observation by a clinician with appropriate privileges)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Establishes intravenous (IV) access (competency verified through observation a clinician with appropriate privileges)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Administers intravenous (IV) solutions and medications (limited by license; competency verified through observation by a clinician with appropriate privileges)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Schedules participant research visits and study procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Enters research documentation progress notes into electronic medical record, under appropriate headings or titles (requires authorized access)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Maintains complete and accurate records: including data collection records, source documents, and case report forms.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Prepares/manages payments to research participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ELECTRONIC MEDICAL RECORD ACCESS NEEDED (should be requested through primary Service):

No access needed Access needed; Already have access

Rationale for access requested (be specific):

Scope of Practice Signature Page

RESEARCH EMPLOYEE'S STATEMENT:

This Scope of Practice outlines general tasks I am permitted to undertake in conjunction with an approved protocol. I understand that all research must be approved by the IRB, and that research performed at the STVHCS also requires approval by the STVHCS R&D Committee. If I have questions or concerns, I am encouraged to contact the STVHCS Research Office. I also understand that performing tasks beyond this scope of practice, without specific authorization, may lead to disciplinary action. Both the supervisor or supervising 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.

Name of Research Employee

[Last name, First name] - Printed

Research Employee Signature

Date

SUPERVISOR OR SUPERVISING INVESTIGATOR STATEMENT:

The foregoing Scope of Practice was reviewed and discussed with the employee on the date shown below. After reviewing the education, clinical competency, qualifications, research experience involving human subjects (including tissue or data), peer reviews, and individual skills, I certify that this employee possesses the skills to safely perform the aforementioned duties and procedures. Both the employee 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.

I further understand that conducting research at the STVHCS without IRB and other committee approvals may affect an individual's standing at the institution and that ethical breaches in the conduct of research may affect an individual's ability to do research with the institution in the future.

This Scope of Practice will be reviewed regularly and if amendments are needed to reflect changes in the research employee's duties and responsibilities and utilization guidelines and/or hospital policies, a new Scope of Practice form will be submitted to the STVHCS Research Office.

Name of Supervisor/Supervising Investigator

[Last name, First name] - Printed

Supervisor/Supervising Investigator Signature

Date

*Name of Clinician with Appropriate Privileges

Verifying Competency [Last name, First name] - Printed

*if other than the Supervisor/Supervising Investigator

Clinician Signature

Date

*****For Office Use Only*****

VA ACOS for Research and Development Signature

Date