

**South Texas Veterans Health Care System
University Health System
University of Texas Health Science Center at San Antonio
Scope of Practice for Research Personnel
Involved in Clinical Research**

NAME	JOB 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 Human Research Protective Program (HRPP) online course provides an overview of the HSC Human Research Protection Program. Completion is a prerequisite for obtaining an approved Scope of Practice at UTHSCSA. To complete the course [Register through the Knowledge Center](#).

The Scope of Practice is specific to the duties and responsibilities of each research employee/staff. The employee 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 UT Medicine, STVHCS, and UHS clinical Credentialing & Privileging for any licensed independent provider under VHA Directive 1100.19, UHS Policy 9.000 or other appropriate institutional privileging directives. The Scope of Practice is governed by the policies and procedures outlined in the STVHCS Hospital Policy, UHS Policy and the UTHSCSA Policy: Research Scope of Practice for Study Personnel. The Supervisor and the Principal Investigator associated with the studies the individual is working on remain responsible at all times for the conduct of the employee.

PROCEDURES:

An employee may be authorized to perform the following duties and procedures on a regular and ongoing basis under protocols approved by the UTHSCSA IRB and STVHCS R & D Committee (VA studies) and the UHS Research Committee (UHS studies). The signed copy of this document will be maintained in the employee's file in the UTHSCSA Office of Clinical Research and will be made available to the STVHCS Research Office and /or the UHS Research Office. Check the appropriate boxes for routine duties that apply to the research employee.

Non-licensed personnel include research coordinators who are not credentialed, research assistants, biostatisticians, administrative assistants, students, etc. 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. Medical fellows, residents, and students are required to have a Scope of Practice.

Competency verification must be performed by an individual with appropriate credentials or a clinician with appropriate privileges; this may be the employee's supervisor or a supervising investigator. Competency verification must be by direct observation of the research employee for the specific task(s) requested. The employee's supervisor or supervising investigator should indicate competency verification by selecting 'verified' for each specific task(s) requested. Credentialing & Privileging is institution specific—privileges granted at another institution are not transferable. Items indicated as requiring competency anticipate the supervisor or supervising investigator has reviewed any applicable certifications, observed and documented the employee's skill in these areas and periodically reviews and documents the employee's performance.

Routine Duties (may require competencies or credentials)	Medical Fellows & Residents	Licensed MDs without clinical privileges	Students and other Non- Licensed	STVHCS (VA) Only			Lab/Bench Staff	Competency Verification
				Licensed Mid- level Providers (NP/CNS/PA)	Licensed R.N.	Other Licensed & Credentialed		
Prepares regulatory documents for UTHSCSA IRB, STVHCS R&D committee, UHS Research Committee and/or sponsor	<input type="checkbox"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<input type="checkbox"/>		
Obtains informed consent from research participant (requires knowledge and application of informed consent process; 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"/>		
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"/>	<input type="checkbox"/>		
Checks and records vital signs (requires competency verification by 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"/>	<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 by observation by a clinician with appropriate privileges) for licensed individuals within limits of license; for non- licensed individuals attach Delineation of Physical Assessment Tasks for Non-Licensed Research Personnel Form <input type="checkbox"/> Attached		<input type="checkbox"/>	<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 by an individual with appropriate credentials)	<input type="checkbox"/>	<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"/>	<input type="checkbox"/>	
Ships biological materials (Requires IATA training Register through the Knowledge Center If training was not completed in the Knowledge Center, attach certificate of completed IATA training) <input type="checkbox"/> Attached	<input type="checkbox"/>	<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"/>	<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	Licensed MDs without clinical privileges	Students and other Non Licensed	STVHCS (VA) Only			Lab/Bench Staff	Competency Verification
				Licensed Mid-level providers (NP/CNS/PA)	Licensed R.N.	Other Licensed & Credentialed		
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 as per the respective institution's policy and pharmacist, (e.g. UHS, STVHCS, CSR, CTRC)].	<input type="checkbox"/>	<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 by observation by a clinician with appropriate privileges)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Establishes intravenous (IV) access (competency verified by 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 by 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"/>	<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"/>	<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"/>	<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"/>	<input type="checkbox"/>	
Prepares/manages payments to research participants (Requires "Overview of Managing Payments to Research Participants" training Register through the Knowledge Center ; "Making CASH Payments to Research Participants" training, if applicable; "Using GIFTS and Incentives to Pay Research Subjects" training, if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Additional Duties (Note: Clinical procedures that routinely require informed consent at the STVHCS, or at other UTHSCSA affiliated institutions, even if performed for only research purposes, may only be performed by a Licensed Independent Practitioner)								
	<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

NOTICE TO LICENSED PROFESSIONALS:

Individuals found to be working outside their privileges as granted by the STVHCS, UTHSCSA, UHS or other UTHSCSA-affiliated institutions will be subject to disciplinary action and possible reporting to the National Practitioner Data Bank.

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 UTHSCSA IRB, and that research performed at the STVHCS also requires approval by the STVHCS R&D Committee and research performed at UHS requires approval of the UHS Research Office. If I have questions or concerns, I am encouraged to contact the STVHCS Research Office, UHS Research Office or the UTHSCSA Office of Clinical Research. 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.

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 UTHSCSA, UHS, or 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 Office of Clinical Research.

Supervisor or Supervising Investigator Signature

Date

Signature of Clinician with Appropriate Privileges Verifying Competency*
*if other than the Supervisor or Supervising Investigator

Date

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

Director of OCR Signature

Date

VA ACOS for Research and Development Signature

Date