Submit

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

NAME (Last name, First name - Printed)	RESEARCH TITLE
	Select one
DEGREE	**LICENSURE (for VA only)**
❒ MD ❒ DO ❒ DDS ❒ NP/CNS ❒ PA ❒ BSN ❒ BS ❒ MS ❒ PhD ❒ None ❒ Other:_____	❒ MD ❒ DO ❒ DDS ❒ NP/CNS ❒ PA ❒ RN ❒ LVN ❒ MT ❒ None ❒ Other: _____
SUPERVISOR/SUPERVISING INVESTIGATOR	**DEPARTMENT/DIVISION**
IMMIGRATION STATUS	
❒ US Citizen ❒ Permanent Resident ❒ Visa ❒ Specify Visa Type: _____	

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	Students and other Non-Licensed	STVHCS (VA) Only: Licensed Mid-level Providers (NP/CNS/PA)	STVHCS (VA) Only: Licensed R.N.	STVHCS (VA) Only: Other Licensed & Credentialed	Lab/Bench Staff	Competency Verification
Prepares regulatory documents for UTHSCSA IRB, STVHCS R&D committee, UHS Research Committee and/or sponsor	☐	☐	☐	☐	☐		
Develops and/or implements recruitment methods to be utilized in the study	☐	☐	☐	☐	☐		
Prepares study initiation program, materials and activities	☐	☐	☐	☐	☐		
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)	☐	☐	☐	☐	☐		
Maintains screening logs (requires HIPAA and Information Security Training)	☐	☐	☐	☐	☐		
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)	☐	☐	☐	☐	☐		
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)	☐	☐	☐	☐	☐		Select
Obtains information from subject pertinent to research protocol (study specific training required; training must be documented in protocol regulatory documents)	☐	☐	☐	☐	☐		
Checks and records vital signs (requires competency verification by observation by a clinician with appropriate privileges for non-licensed individuals)	☐	☐	☐	☐	☐		Select
Performs physical examination (within limits of license)	☐		☐				
Evaluates acute health problems, including possible adverse events (within limits of license)	☐		☐				
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 (requires Delineation of Physical Assessment Tasks for Non-Licensed Research Personnel Form)		☐		☐	☐		Select
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)	☐	☐	☐	☐	☐	☐	Select
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)	☐	☐	☐	☐	☐	☐	Select
Ships biological materials (Requires IATA training Register through the Knowledge Center) ❒Attached	☐	☐	☐	☐	☐	☐	
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.	☐		☐	☐	☐		
Reports laboratory results and other diagnostic testing (e.g., radiography, clinical pathology) to study sponsor and appropriate personnel in a timely manner	☐		☐	☐	☐		
Maintains specimen inventory and ensures appropriate storage conditions and security	☐	☐	☐	☐	☐	☐	
Orders, alters, or adjusts inpatient and outpatient medications or investigational drugs (practitioner prescribing study medication must be named on drug record form)	☐		☐				

Routine Duties (may require competencies or credentials)	Medical Fellows & Residents	Students and other Non Licensed	STVHCS (VA) Only: Licensed Mid-level providers (NP/CNS/PA)	STVHCS (VA) Only: Licensed R.N.	STVHCS (VA) Only: Other Licensed & Credentialed	Lab/Bench Staff	Competency Verification
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)].**	☐	☐	☐	☐	☐		Select
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)	☐	☐	☐	☐	☐		Select
Establishes intravenous (IV) access (competency verified by observation a clinician with appropriate privileges)	☐		☐	☐	☐		Select
Administers intravenous (IV) solutions and medications (limited by license; competency verified by observation by a clinician with appropriate privileges)	☐		☐	☐	☐		Select
Schedules participant research visits and study procedures	☐	☐	☐	☐	☐		
Enters research documentation progress notes into electronic medical record, under appropriate headings or titles (requires authorized access)	☐	☐	☐	☐	☐		
Obtains and organizes data such as tests results, diaries/cards or other necessary information for the study.	☐	☐	☐	☐	☐		
Maintains complete and accurate records: including data collection records, source documents, and case report forms.	☐	☐	☐	☐	☐	☐	
Prepares/manages payments to research participants (Requires "Overview of Managing Payments to Research Participants" training if funds are administered through UTHSCSA Register through the Knowledge Center)	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	Select
	☐	☐	☐	☐	☐	☐	Select
	☐	☐	☐	☐	☐	☐	Select
	☐	☐	☐	☐	☐	☐	Select
	☐	☐	☐	☐	☐	☐	Select
	☐	☐	☐	☐	☐	☐	Select
	☐	☐	☐	☐	☐	☐	Select
	☐	☐	☐	☐	☐	☐	Select

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 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.

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 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.

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**********

Director of OCR Signature	Date
VA ACOS for Research and Development Signature	Date