Print Form

# South Texas Veterans Health Care System
# University Health System
# University of Texas Health Science Center at San Antonio
# Scope of Practice for Research Personnel

| NAME | JOB TITLE |
|---|---|
| | |
| **DEGREE** | **LICENSURE** |
| ☐ MD ☐ DO ☐ DDS ☐ NP/CNS ☐ PA ☐ BSN<br>☐ BS ☐ MS ☐ PhD ☐ None ☐ Other:_____ | ☐ MD ☐ DO ☐ DDS ☐ NP/CNS ☐ PA ☐ RN<br>☐ LVN ☐ MT ☐ None ☐ Other:_____ |
| **PRINCIPAL INVESTIGATOR (PI)** | **DEPARTMENT/DIVISION** |
| | |

**COMPLETON OF EDUCATIONAL REQUIREMENTS**

CITI Training in Research Ethics and Good Clinical Practice Date of Completion:_____

UTHSCSA Clinical Research Training Date of Completion:_____

The Scope of Practice is specific to the duties and responsibilities of each research employee/staff as an agent of the listed Principal Investigator(s) for a term not to exceed two years. 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 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 Principal Investigator remains responsible at all times for the conduct of the employee and must complete, sign and date this Scope of Practice.

**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 original signed copy of this document will be maintained in the employee's file in the UTHSCSA Office of Clinical Research and/or the STVHCS Research Office and /or the UHS Research Office. Check the appropriate boxes for routine duties that apply to the research employee. (The Scope of Practice will be required for STVHCS and UHS employees, residents and medical students listed on all research conducted at STVHCS and UHS sites).

**NOTE:** Other licensed and Credentialed may include Optometrists, Dentists and Podiatrists as applicable.

Non-licensed personnel include research coordinators who are not credentialed, research assistants, biostatisticians, administrative assistants, etc. Non-licensed M.D.s who are not enrolled in an approved training program 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 covey to the research participant or staff that he/she is a licensed practicing physician.

Competency verification must be performed by the Principal Investigator or other supervising co-investigator by direct observation of the research employee for the specific task(s) requested. PI or supervising investigator should indicate competency verification by placing initials in blank provided 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 Principal 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.

Employee Name:_____

| **Routine Duties** (may require competencies or credentials) | Licensed MD , DO, DDS | N.P. / CNS / PA | R.N. | Other Licensed and Credentialed | Non Licensed | 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 (requires competency verification by observation by PI) | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| 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 (requires competency verification by observation by PI) | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| Obtains informed consent from research participant (requires knowledge and application of informed consent process; requires competency verification by observation by PI) | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| Obtains information from subject pertinent to research protocol (requires competency verification by observation by PI) | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| Checks and records vital signs (requires competency verification by observation by PI) | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| Performs physical examination (within limits of license) | ☐ | ☐ | | | | | |
| Evaluates acute health problems, including possible adverse events (within limits of license) | ☐ | ☐ | | | | | |
| Performs physical assessment (for RNs within limits of license; **for non-licensed individual attach list with delineation of specific task(s)** to be performed, and competency verification by observation by PI) | | | ☐ | ☐ | ☐ | | |
| 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 PI) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Collects and/or processes human specimens per protocol, including blood, urine, sputum, buccal swabs, etc. (requires competency verification by observation by PI) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Ships biological materials (**Attach certificate of IATA training**) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| 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, etc.) 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 for VA study must be named on VA 10-9012 form in pharmacy) | ☐ | ☐ | | | | | |

Employee Name: _____

| **Routine Duties** (may require competencies or credentials) | Licensed MD , DO, DDS | N.P. / CNS / PA | R.N. | Other Licensed and Credentialed | Non Licensed | 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 PI, and dispensing agreement with research pharmacy**. Research drugs/medications must be handled and/or coordinated as per the respective institution's policy and pharmacist, (e.g. UHS, STVHCS, CSR, CTRC)].** | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| 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 PI or organization) | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| Establishes intravenous (IV) access (Nursing staff: competency verified by Nursing Education; other licensed providers: competency verified by observation by PI) | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| Administers intravenous (IV) solutions and medications (limited by license; Nursing staff: competency verified by Nursing Education; Other licensed providers: competency verified by observation by PI) | ☐ | ☐ | ☐ | ☐ | | | |
| 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 vouchers for participant payment (must comply with IRB-approved schedule) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| **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) | | | | | | | |
| | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |

**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)**:**

Employee Name: _____

**Scope of Practice Employee 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 principal 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's Signature Date

_____
Research Employee's Printed Name

Employee Name: _____

**SOUTH TEXAS VETERANS HEALTH CARE SYSTEM**

**PRINCIPAL INVESTIGATOR'S STATEMENT (VA Investigator):**
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.

As a principal investigator, I further understand that conducting research at the STVHCS without IRB and STVHCS R&D approval may affect my standing at the VA and that ethical breaches in the conduct of my research may affect my ability to do research with the VA in the future.

This Scope of Practice will be reviewed every two years and amended as necessary to reflect changes in the research coordinator's duties and responsibilities and utilization guidelines and/or hospital policies.

_____ _____
Principal Investigator (Printed Name and Signature) Date

_____ _____
Additional Supervisor/Department Chair/Service Chief Date
(Print Name, Sign, Circle Title)

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

Credentialing and Privileges Status: From _____To _____

_____ _____
ACOS for Research and Development Date

_____ _____
Chief of Staff Date

**EFFECTIVE DATE OF THIS SCOPE OF PRACTICE: FROM:_____TO: _____**

**Addendum**

(Use this space for additional information, e.g. printed names and signatures of additional supervisors)

Employee Name: _____

**UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO**

**PRINCIPAL INVESTIGATOR'S STATEMENT (UTHSCSA Investigator):**
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.

As a principal investigator, I further understand that conducting research at the UTHSCSA without IRB and other required committee approvals may affect my research privileges and that ethical lapses in the conduct of my research may affect my ability to do research at UTHSCSA in the future.

This Scope of Practice will be reviewed every two years and amended as necessary to reflect changes in the duties and responsibilities and utilization guidelines and/or hospital policies.

_____ _____
Principal Investigator (Printed Name and Signature) Date

_____ _____
Additional Supervisor/Department Chair/Service Chief Date
(Print Name, Sign, Circle Title)

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

_____ _____
Jenice N. Longfield, MD, MPH Date
Assistant Vice President for Research Operations

_____ _____
Name: Date
Dean or Associate Dean for Research

**EFFECTIVE DATE OF THIS SCOPE OF PRACTICE:** FROM: _____ TO: _____

**Addendum**

(Use this space for additional information, e.g. printed names and signatures of additional supervisors)

Employee Name: _____

**UNIVERSITY HEALTH SYSTEM**

**PRINCIPAL INVESTIGATOR'S STATEMENT (UHS Investigator):**
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, all-applicable hospital policies and regulations.

As a principal investigator, I further understand that conducting research at **UHS** without IRB and UHS **Research Committee approval** may affect my standing at **UHS** and that ethical breaches in the conduct of my research may affect my ability to do research with **UHS** in the future.

This Scope of Practice will be reviewed every two years and amended as necessary to reflect changes in the research coordinator's duties and responsibilities and utilization guidelines and/or hospital policies.

_____ _____
Principal Investigator (Printed Name and Signature) Date

_____ _____
Additional Supervising Investigator (Printed Name and Signature) Date

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

**UNIVERSITY HEALTH SYSTEM INSTITUTIONAL APPROVALS:**

**DATE APPROVED:**

_____ _____ _____
**CREDENTIALS COMMITTEE** **EXECUTIVE COMMITTEE** **BOARD OF MANAGERS**

**********FOR UHS EMPLOYEES ONLY**********

_____ _____
**NANCY RAY, RN, MA** **DATE**
**CNO/ASSOCIATE ADMINISTRATOR**

**EFFECTIVE DATE OF THIS SCOPE OF PRACTICE:** FROM: _____ TO: _____

**Addendum**

(Use this space for additional information, e.g. printed names and signatures of additional supervisors)