University Health System (UHS)
UT Health San Antonio (UTHSA)
Scope of Practice for Non-licensed Research Team Member Involved in Human Subject Research

NAME (Last name, First name - Printed)	
E-MAIL *(Required)*	DEPARTMENT/DIVISION
DEGREE	
☐ MD ☐ DO ☐ DDS ☐ NP/CNS ☐ PA ☐ BSN ☐ BS ☐ MS ☐ PhD ☐ None ☐ Other:_____	
SUPERVISOR/SUPERVISING INVESTIGATOR	E-MAIL *(Required)*
CLINICIAN WITH APPROPRIATE PRIVILEGES	E-MAIL *(Required for any routine duties selected on page 3)*
IMMIGRATION STATUS	
☐ US Citizen ☐ Permanent Resident ☐ Visa 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 UHS and UT Medicine clinical Credentialing & Privileging for any licensed independent provider under UHS Policy 9.000 or other appropriate institutional privileging directives. The Scope of Practice is governed by the policies and procedures outlined in the UHS Policy and the UTHSA Research Scope of Practice 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:

The Scope of Practice is required for non-licensed personnel who will be interacting or intervening with living individuals. This includes medical residents/fellows working under a training permit and not cleared through the standard credentialing process. 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.

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 UHS Research Committee (UHS studies) and the UTHSA Office of Clinical Research (UTHSA studies). The signed copy of this document will be maintained in the research team member's file in the UTHSA Office of Clinical Research and will be made available to the UHS Research Office. Check the appropriate boxes for routine duties that apply to the research team member.

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 or clinician with appropriate privileges indicates by signing this form and initialing each duty that that they have reviewed any applicable certifications, observed and documented the research team member's skill in these areas and will periodically review and document the research team member's performance. Credentialing & Privileging is institution specific—privileges granted at one institution are not transferable to another.

The research team member's supervisor or supervising investigator's signature indicates that competency verification has been performed by an individual with appropriate credentials and will be periodically reviewed and documented for each item selected below.

This is study specific training and must be documented in the protocol regulatory documents.

Routine Duties (may require competencies or credentials)	Medical Fellows & Residents	Students and other Non-Licensed	Lab/Bench Staff
Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing patients and maintains screening logs	☐	☐	
Provides education regarding study activities to patient, relatives, and Medical Center staff as necessary per protocol	☐	☐	
Obtains informed consent from research participant (requires knowledge and application of informed consent process)	☐	☐	
Obtains information from subject pertinent to research protocol	☐	☐	
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 through observation by an individual with appropriate credentials)	☐	☐	☐
Collects and/or processes human specimens per protocol, including blood, urine, sputum, buccal swabs, etc.	☐	☐	☐
Maintains specimen inventory and ensures appropriate storage conditions and security	☐	☐	☐
Obtain vital signs, height, weight, body measurements with the use of automated equipment	☐	☐	
Drug Accountability: Delivers oral study medication from pharmacist, after order by licensed provider, to participant**.** **Research drugs/medications must be handled and/or coordinated as per the respective institution's policy and pharmacist, (e.g. UHS, CSR, Mays Cancer Center).**	☐	☐	
Provides participant education and instruction on use of study medication	☐	☐	
Enters research documentation progress notes into electronic medical record, under appropriate headings or titles (requires authorized access)	☐	☐	
Completes protocol required documentation (i.e. data collection records, IVRS, case report forms)	☐	☐	
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

The research team member's supervisor or supervising investigator's signature indicates that competency verification has been performed by a clinician with appropriate privileges and will be periodically reviewed and documented for each item selected below.

A signature from a clinician with appropriate privileges verifying competency is also required for all items listed below (if other than the supervisor or supervising investigator).

This is study specific training and must be documented in the protocol regulatory documents.

Routine Duties (may require competencies or credentials)	Medical Fellows & Residents	Students and other Non Licensed	Lab/Bench Staff
Performs physical assessment Obtain vital signs, height, weight, body measurements without the use of automated equipment OR Assess (observe, palpate and auscultate) signs or systems *(No medical decisions may be based on the physical assessments of non-licensed research personnel)* For licensed individuals, within limits of license		☐	
Performs physical examination (within limits of license) *Includes physical assessment*	☐		
Evaluates acute health problems, including possible adverse events (within limits of license)	☐		
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. (within limits of license)	☐		
Reports laboratory results and other diagnostic testing (e.g., radiography, clinical pathology) to study sponsor and appropriate personnel in a timely manner (within limits of license)	☐		
Orders, alters, or adjusts inpatient and outpatient medications or investigational drugs (within limits of license, practitioner prescribing study medication must be named on drug record form)	☐		
Establishes intravenous (IV) access (within limits of license)	☐		
Administers intravenous (IV) solutions and medications (within limits of license)	☐		
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

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)**:**

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Page 4 (signature page) will be inserted by OCR and routed through DocuSign for signatures to the emails provided on page 1 of this form