GA-104 – Scope of Practice

1. **PURPOSE:**
   This Standard Operating Procedure (SOP) describes the roles and responsibilities associated with conducting research at UTRGV and to ensure that individuals to whom study tasks are delegated are appropriately licensed, qualified, delegated and trained on the specific task to which they are assigned.

2. **SCOPE:**
   This SOP applies to all investigators and study personnel who interact with research participants within UTRGV or under the purview of the UTRGV IRB. Research personnel must work within their general scope of practice at the institution. Conducting research does not exempt personnel from complying with state requirements for the performance of clinical tasks. If personnel are not qualified to complete a clinical task in general clinical practice, they are not qualified to complete the task for research purposes. Some clinical tasks may require separate licensure or certification.

3. **RESPONSIBLE INDIVIDUALS:**
   Appendix A serves as a reference to help indicate who is qualified to perform tasks related to conducting clinical research within UTRGV. Appendix A is not an exhaustive list. If a question arises about whether it is appropriate to assign a task to a member of the study team, contact the Office of Clinical Research for guidance.

4. **RELATED TERMS AND DEFINITIONS:**

   Adequate Training
   Dispense
   Healthcare License
   Medically Qualified
   Principal Investigator (PI)

   Please reference the Standard Operating Procedure Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT:**
   Completion of clinical research tasks should be approached as a concerted, cooperative and collaborative effort. The PI must ensure that individuals to whom study tasks are

delegated are appropriately licensed, qualified, and trained to perform the specific task of which they are assigned, and that these study tasks are documented and assigned to the employee on the Delegation of Authority Log for each protocol.

5.1 Competency

Some tasks may only be performed by licensed individuals. Licensed research personnel may not perform or be trained to perform procedures outside of those allowed under their respective license and credentialing.

Unlicensed UTRGV research personnel may be trained by a licensed medical professional to perform protocol specific procedures, as long as the tasks are within the background and education of the employee and the training is clearly documented.

5.2 Records

Refer to the Delegation of Authority Log with instructions for documentation of study related tasks.

6. PROCEDURES:

Appendix A contains an example listing of some procedures and the employee(s) responsible for each action.

7. REFERENCES

- UTRGV Research Credentialing
- UTRGV Investigational Pharmacy Policy
- State Medical Board of Texas
- State of Texas Board of Pharmacy
- FDA Guidance – Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects – October 2009

8. FORMS OR ATTACHMENTS

Drug Study Delegation Log
Non-Drug Delegation Log

Appendix A: Scope of Practice

Appendix A: Scope of Practice Study Personnel				
	Medically Licensed			Unlicensed***
	Principal Investigator	MD, DO, PA, NP per state requirements	RN, LPN, LVN, PharmD per state requirements	Research Coordinator, Research Associate, Research Regulatory Specialist, Data Manager, Data Specialist, Medical Assistant, Phlebotomist, Lab Tech
REGULATORY				
Prepare, submit, and maintain regulatory documents for submission, continuing review, and amendments	X	X	X	X
Sign off on regulatory documents for submission, continuing review and amendments	X			
Maintain required and essential study documents through life of study	X	X	X	X
BUDGET/FINANCIAL				
Submit all study documents (protocol, contract, budget template, consent, IB, etc) into START form	X	X	X	X
Respond to Department Review queries (Lab, IDS, Radiology, Pathology, Clinical Units, etc)	X	X	X	X
Review/approve coverage analysis determination and budget matrix	X	X	X	X
Facilitate invoice review and approval for payment	X	X	X	X
STUDY PARTICIPANT MANAGEMENT				
Conduct Informed consent process and document properly	X	X	X	X**
Review participant eligibility (e.g., inclusion/exclusion) and document appropriately	X	X	X	X
Final confirmation and patient eligibility sign off	X	X		
Assign tasks to staff, ensure adequate training and competency of staff for tasks that have been delegated, oversee all aspects of the study	X	X	X	
Document adverse events and concomitant medications	X	X	X	X
Report adverse events	X	X	X	X
Assign causality to adverse events or medically significant events	X	X		
Document Serious Adverse Events (SAEs)	X	X	X	X
Report Serious Adverse Events (SAEs)	X	X	X	X
Collect and process blood, tissue or specimen samples and document appropriately	X	X	X	X*
Perform protocol specific physical exams	X	X		
Perform protocol assessments (e.g., EKGs, scans, etc.*) and document appropriately	X	x	x	x
ORDERS - Labs, Radiology, Medications				
Prescribe treatment per protocol and document	X	X		
Dispense treatment per protocol and document	X	X	X	
Administer treatment per protocol AND per MD order and document appropriately	X	X	X	
Order all tests and procedures per clinical practice guidelines, e.g., medications/study treatments/interventions, radiology, scans, and lab tests	X	X		
Review and sign off on all lab results	X	X		
Conduct questionnaires/surveys and document	X	X	X	X
Call pharmacy with prescriptions fills or refills per MD order and document	X	X	X	
* Some types of assessments may require additional training or certification by the sponsor				
**Risks, benefits, and alternatives to participation must be discussed by an appropriately qualified and licensed physician or medical provider for treatment, therapy or drug studies				
***These individuals may have certifications, specific training, areas of expertise or knowledge, but are still considered unlicensed as defined as one who gives medical advice, one who diagnoses, treats and/or prescribes. They are required to have an appropriate delegation and supervision prior to the execution of any aforementioned research or standard of care tasks listed in this table or in general.				