Title: Study Team Roles and Responsibilities	Version: 1.0	Effective Date: 1 Jun 2023	Page 1 of 4

1. Purpose

The purpose of this standard operating procedure (SOP) is to outline roles and responsibilities of various members of the study team.

2. Scope and Responsibility

This SOP applies to study personnel including investigators and research staff who are involved in conduct of clinical research.

3. Definitions

3.1 **Investigator:** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and is called the principal investigator.

4. Policy

4.1 The Principal Investigator (PI) is responsible for the conduct of the clinical trial at a trial site. Study team members may only perform study tasks and procedures delegated to them by the PI.

4.2 If any study procedures will be performed at a facility in the Memorial Hermann System (MHH), study team members are required to get MHH research credentialing or allied health credentialing to conduct research activities.

5. Procedure

5.1 Principal Investigator – The Principal Investigator is responsible for the conduct of the clinical trial.

5.1.1 Should be qualified by education, training, and experience to assume responsibility for the proper conduct of the research.

5.1.2 Should ensure availability of adequate time, resources and staff to conduct the clinical research.

5.1.3 Should ensure that a qualified physician (or dentist) is responsible for all research-related medical (or dental) decisions.

5.1.4 Should be thoroughly familiar with the study protocol, Investigator's Brochure and other study documents.

5.1.5 Assures that study specific tasks and procedures are delegated appropriately to individuals who are appropriately licensed and/or trained.

5.1.6 Should obtain IRB approval prior to study initiation and should comply with IRB reporting requirements during the course of the study.

5.1.7 Should conduct the research in accordance with the approved protocol.

5.1.8 Should document and explain any deviation from the approved protocol.

5.1.9 Should be thoroughly familiar with the appropriate use of the investigational product, as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources.

5.1.10 Is responsible for investigational product(s) accountability, including receipt, storage, dispensing and disposition as described in SOP on Investigational Drugs and Devices.

5.1.11 Should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol.

5.1.12 Should obtain informed consent from participants prior to any study procedures, as described in SOP on Informed Consent.

5.1.13 Should maintain adequate and accurate source documents and research records that include all pertinent observations on each of the site's trial subjects, as specified in SOP on Source Documents.

5.1.14 Should maintain research documents as specified in SOP on Study Documentation.

5.1.15 Is responsible for identification, management, documentation and reporting of adverse events, as described in SOP Adverse Events.

5.1.16 Maintains adequate and accurate records and make records available for inspection to external and internal monitors. Meet with auditors (FDA, sponsor and internal) at the conclusion of their audits to review findings and to implement changes to correct weaknesses or deficiencies.

5.2 Co-Investigator, Sub-Investigator or Collaborator

5.2.1 Designated and supervised by the investigator to perform all or some of the functions of the PI.

5.2.2 May play a key role in study scientific development of the protocol in investigator-initiated research.

5.3 **Clinical Research Coordinator -** A Clinical Research Coordinator is responsible for managing conduct of the clinical trial with in-depth knowledge of the protocol and GCP per federal regulations. Responsibilities include, but are not limited to, the following:

5.3.1 Assist the PI with study feasibility.

5.3.2 Coordinate the development of the clinical trial budget coverage analysis with various administrative offices including departmental representatives, Clinical Research Finance and Administration team, MHH CIRI research team.

5.3.3 Should be thoroughly familiar with the protocol, consent document and other study documents.

5.3.4 Ensure all study approvals are obtained prior to study initiation as described in SOP Study Initiation.

5.3.5 Develop study flowsheets and checklists to facilitate study conduct.
5.3.6 Develop appropriate recruitment strategies and tracks study enrollment.
5.3.7 Maintain the regulatory documents as specified in SOP Study Documents. .
5.3.8 Communicate with the IRB as appropriate.
5.3.9 Communicate with study sponsor as appropriate.
5.3.10 Screen and enroll study participants.
5.3.11 Schedules and maintains study visits with participants.
5.3.12 Obtain informed consent research subjects before performing any study related procedures.
5.3.13 Assure proper handling of the investigational product (IP).
5.3.14 Assure proper handling and accurate processing of samples (e.g. blood and tissue).
5.3.15 Track participant compliance with the research drug, device or procedure.
5.3.16 Complete source documents and case report forms (CRFs) in an accurate and timely manner.
5.3.17 Track, report and monitor adverse events and deviations as appropriate.
5.3.18 Participate in quality assurance activities of the sponsor, the FDA, other regulatory agencies.
5.3.19 Train and supervise other clinical research personnel as appropriate.
5.3.20 Protect all research data in accordance with UTHealth Houston privacy and security requirements.
5.3.21 Assist with study close out.
5.3.22 Oversee study closure and reporting of results.
5.3.23 Meet with the representatives of the sponsor to discuss planned and ongoing studies.

5.4 **Research Nurse -** A research nurse may also perform tasks of a clinical research coordinator Additional responsibilities include, but are not limited to, the following:
5.4.1 Adverse event identification and reporting to PI or other study investigators.
5.4.2 Perform study tasks such as collection of vital signs, phlebotomy etc.
5.4.3 Administer study drugs.

5.5 **Investigational Pharmacist -** The Investigational Drug Service (IDS) is responsible for providing the following services in compliance with local, state and federal laws and sponsor requirements.
5.5.1 Consultation for investigator-initiated studies
5.5.2 Study design/protocol development
5.5.3 Randomization
5.5.4 Investigational product procurement, storage, preparation and distribution
5.5.5 Maintenance of product accountability and study-related records

5.5.6 Product/placebo compounding
5.5.7 Maintenance and control of investigational product inventories
5.5.8 Return of used/unused product to sponsors or destruction of product for pharmacy-managed protocols
5.5.9 Development of educational materials
5.5.10 Participation in study initiation and close-out visits
5.5.11 Participation in audit processes
5.5.12 Descriptive reports of pharmacy services

5.6 Data Coordinator

5.6.1 Enter study data into appropriate database and perform review of discrepancy output and validation listings.
5.6.2 Review and respond to queries to address problematic data identified during data review activities; apply proper correction/modification.
5.6.3 Apply quality control procedures and ensure data quality standards are achieved.
5.6.4 Create, update, track, and maintain study-specific trial management files, tools, and systems.
5.6.5 Maintain awareness of contract and scope of work for assigned project(s).
5.6.6 Assist local team members with administrative activities as required, including filing, document maintenance, and ordering and maintaining adequate supplies for project.
5.6.7 Track site performance metrics (e.g., patient screening, enrollment, retention, etc.) .

6. References

6.1 ICH Good Clinical Practice Guidelines

7. Appendices

7.1 Delegation of Authority Log

If you find errors in this document, contact clinicaltrials@uth.tmc.edu

Document Number:	401-003
Developed by:	Good Clinical Practice SOP Workgroup
Approved by:	AVP, Research Compliance
Revision History:	1 Jun 2023