SOP-08: Site Initiation Visits

1. Objective

This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects' research at Ochsner Health, hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research. The objective of this SOP is to ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities related to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies.

SOP-08 describes the process for conducting Site Initiation Visits for clinical research. Attachment templates include

A: Site Initiation Visit Checklist

2. Responsibility

Ochsner Research develops, implements, and maintains SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to Centers of Excellence (COEs) and research teams conducting human subjects’ research. COEs or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The Principal Investigator (PI) is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. The clinical research team may include but is not limited to the following members.

Research Team Members

Principal Investigator
Sub-Investigator
Clinical Research Manager
Clinical Research Supervisor

Clinical Research Coordinator
Associate Clinical Research Coordinator
Data Coordinator and Regulatory Specialist
Other Research and Administrative Support Staff

3. Definitions

Please refer to the SOP Glossary document for detailed definitions of commonly used clinical research terminology.
4. Procedures

The Site Initiation Visit (SIV) prepares the research site to conduct the research study. This meeting generally takes place after the investigational site has received IRB approval and a Clinical Trial Agreement (CTA) has been fully executed. In addition, the SIV should occur prior to the first subject enrollment. The PI or member of the research team will schedule and arrange the SIV which can be conducted in person, on-line, or via conference call at the discretion of the sponsor. The SIV is led by the sponsor representative and provides protocol training for the PI, Sub-I(s), and delegated research team members.

Delegated research team members involved in supervising, managing, or conducting study-related activities should have all required study documents available for review prior to and during the SIV.

The PI will personally conduct or supervise the clinical research study to ensure that the investigation is conducted according to the signed investigator statement, the investigational plan, GCP, and applicable regulations.

The PI and delegated research team members will be qualified by education, training, and experience to assume responsibility for the proper conduct of the research study, will meet all the qualifications specified by the applicable regulatory and sponsor requirements, and will provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB and/or other regulatory authorities.

The PI and delegated research team members will ensure that all persons assisting with the research study are adequately informed about the protocol, the investigational products, and their research study-related duties and functions. These individuals will be informed about their obligations and will have adequate education and training to conduct the tasks delegated which will be documented appropriately.

Delegated research team members will be instructed by the PI and sponsor representative in all aspects of conducting the clinical research study including but not limited to:

- Study objectives
- Regulatory requirements
- Regulatory documents and file management
- Appropriate patient screening procedures
- Inclusion and exclusion criteria
- Schedule of events
- Study procedures and study specific forms
- Investigational product accountability and management
- Adverse events and protocol deviation reporting
- Source documentation
- Case report form completion
- Data management

The Sponsor representative will obtain the investigator's agreement to conduct the research study in compliance with GCP, applicable regulatory requirements, and the protocol which has been agreed to by the sponsor and approved by the IRB.

The Sponsor representative will ensure that the investigator and delegated research team members
agree to comply with procedures, expected turn-around time for data reporting, and permit study monitoring, auditing, and inspection. The sponsor and the investigator/institution should sign the protocol, or an alternative document/contract, to confirm these agreements.

The PI or delegated research team members will document the details of the SIV. After the SIV is complete, follow up on any outstanding items. Once all outstanding items have been addressed the site should be officially activated by the sponsor to begin subject enrollment.

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Revised:

Approved by W. Mark Roberts, MD, Dean of Research

Signature: [Signature]

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