SOP-05: Site Qualification Visit

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-05 describes the process for conducting a site qualification visit, also known as a pre-study site visit. Attachment templates include:

A: Site Qualification Visit Agenda
B: Checklist for a Site Qualification Visit
C: Site Qualification Visit Summary

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

A. Site Qualification Questionnaires

The PI, in collaboration with the other research team members, will complete a site questionnaire that provides basic information for the study sponsor to perform a cursory evaluation of the site. Site qualification questionnaires are used to assess staff experience, facilities, and other operational needs necessary to perform a clinical research study. Often, the questionnaires request basic information related to the Investigator, Sub-Investigator(s), Study Coordinator, and/or Pharmacy, as well as details about the IRB. Questions specific to the disease/therapeutic area being studied and expected enrollment numbers are also often requested.

B. Preparing for a Site Qualification Visit

If the PI wishes to pursue the clinical research study and the sponsor requests a site qualification visit, the delegated research team members will work with the PI and sponsor to find a mutually agreed upon date. The PI will identify key research personnel who will be involved in the conduct of the clinical research study. In preparation of the visit, a Site Qualification Visit Agenda should be completed, if not provided by the sponsor or sponsor representative, and the Checklist for a Site Qualification Visit reviewed (See Attachments A and B).

C. Site Qualification Visit

The PI, Sub-Investigator, and delegated research team members will meet in person or participate in an online meeting or conference call with the sponsor or representative. The research site should be prepared to review

- the protocol,
- recruitment, retention, and enrollment goals,
- the Investigator's Brochure (if applicable),
- case report forms,
- source documents (if being provided), and
- A monitoring and communication plan for the sponsor/CRO and investigational site.

The PI or research team members will

- provide the sponsor representative with copies of the current CVs from key site personnel, as requested,
- ensure the sponsor representative has a chance to tour the research facility, as requested, including exam rooms, lab areas, special testing areas, pharmacy, hospital unit, work areas for research team members, storage area for investigational product, space used for processing and shipping research samples, and data entry area,
- document the details of the site qualification visit and address any follow-up questions the sponsor representative may have, and
- ensure all persons assisting with the research study are adequately informed about the protocol, the investigational product(s), and their study-related duties and functions. These
individuals will be informed about their obligations and will have adequate and appropriate education and training to conduct the tasks delegated.

The PI and delegated research team members will be qualified by education, training, and experience to assume responsibility for the proper conduct of the 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 the regulatory authorities.

Following the Site Qualification Visit, a visit summary should be completed (See Attachment C: Site Qualification Visit Summary).

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

Signature

Date

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