SOP-09: Protocol Implementation

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-09 describes the process for protocol implementation of clinical research. Attachment templates include:

A: Protocol Implementation 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

After IRB approval and the sponsor Site Initiation Visit (if applicable), the delegated research team members should complete the Protocol Implementation Checklist (See Attachment A Protocol Implementation Checklist) or other similar form. This should be completed prior to enrolling subjects to the clinical research study.

The PI and delegated research team members will ensure that

- the budget is finalized, and the contract is executed with appropriate OSP account created,
- OSP has been notified of the study and the study has been added OnCore to allow for appropriate billing of services and flagging of subjects within the Electronic Health Record,
- all essential regulatory documents are completed, organized, and filed appropriately,
- all Sub-Investigators and key personnel will have IRB acknowledgment for their role in the study,
- written IRB approval for the study and supportive study documents have been received and final documents are available to the study team,
- study activities are conducted only after IRB approval and in accordance with the approved protocol,
- all study products, laboratory supplies, and Case Report Forms (CRFs) have been created or received and have been documented and accounted for,
- all protocol specific documentation, worksheets, and checklist tools are finalized and available to the research team,
- study-specific source documents, as well as screening and enrollment materials, are prepared,
- any applicable in-service and training sessions with the research team members and ancillary support staff have been completed,
- the site is in receipt of an adequate investigational product (IP) supply, records are maintained for delivery and inventory, and appropriate IP security and storage are available,
- a delegated primary research team member has been identified and assigned to the research study,
- if applicable, the PI and all delegated research team members are thoroughly familiar with the appropriate use of the IP, as described in the protocol, in the current Investigator's Brochure, and in other information provided by the sponsor, and
- the Delegation of Authority Log will be updated and outline specific roles and responsibilities delegated by the PI to the research team members.

The PI will personally conduct or supervise the clinical research study to ensure 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. The delegated team members will meet all the qualifications specified by the applicable regulatory and sponsor requirements. Evidence of such qualifications will be provided through a current curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.
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Revised:

Approved by W Mark Roberts, MD, Dean of Research

Signature: [Signature]

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