SOP-04: Protocol Feasibility

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-04 describes the process for reviewing feasibility for clinical research. Attachment templates include:

A: Protocol Feasibility Tool
B: Protocol Feasibility Score Card

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
- DataCoordinator 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. Protocol Feasibility

The delegated clinical research team members will ensure the site has received critical study documents such as the protocol, consent template, the Investigator's Brochure (if applicable), lab, pharmacy and/or other manuals (if applicable), Case Report Forms (if available), sample budget worksheet, and that a draft contract after the Confidential Disclosure Agreement (CDA) has been executed by the Office of Sponsored Programs.

The PI, in collaboration with the other research team members, will review the protocol and applicable study-related materials to assess the feasibility of conducting the study at this site (See Attachment A Protocol Feasibility Tool and Attachment B Protocol Feasibility Score Card) Key requirements include:

- a demonstrated (e.g., based on retrospective data obtained through Slicer/Dicer) potential for recruiting the required number of suitable subjects within the agreed recruitment period,
- sufficient time to properly conduct and complete the research study within the agreed study period,
- adequate number of qualified staff available and adequate facilities for the foreseen duration of the study to conduct the study properly and safely,
- alignment with research goals and needs of the COE,
- the absence of on-going competing studies.

If the PI wishes to pursue the clinical research study and the sponsor requests a site qualification visit, the research team members will work with the PI and sponsor to find a mutually agreed upon date. The PI, in collaboration with the research team members, will identify key research personnel who will be involved in the conduct of the clinical research study.

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Revised.

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

Signature. M. Roberts

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