SOP-02: Delegation of Responsibilities

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-02 describes the responsibilities of the PI and the procedures for identifying and delegating specific responsibilities to research team members for conducting clinical research. Attachment templates include

A: Delegation of Authority Log
B: Study Team Training Log

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           Clinical Research Coordinator
Sub-Investigator               Associate Clinical Research Coordinator
Clinical Research Manager      Data Coordinator and Regulatory Specialist
Clinical Research Supervisor   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. Investigator Responsibilities

The PI will conduct and/or supervise the clinical research study to ensure that it is conducted according to the signed investigator statement/form FDA 1572 (if applicable), IRB approved protocol, institutional policies, GCP, and applicable regulations.

During and following a subject's participation in a study, the PI will ensure that adequate medical care is provided to the subject.

The PI is ultimately responsible for the conduct of the research study but may delegate tasks to qualified research personnel when appropriate. The PI and delegated research team members will perform the following tasks.

Delegation of Authority, Training, and Regulatory Compliance

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the study.
- 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, job description, and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.
- Disclose financial interests or relationships with sponsors as required by federal regulations and institutional policies.
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant research study-related duties (See Attachment A Delegation of Authority Log)
- Ensure that individuals are approved by the IRB as key personnel or Sub-Investigators for the research tasks they will be performing prior to engaging in such tasks.
- Conduct study activities only after IRB approval and in accordance with the approved protocol, and ensure all regulatory requirements are fulfilled.
- Ensure all persons assisting with the research study are adequately trained about the protocol, the investigational product(s), and their study-related duties and functions (See Attachment B Study Team Training Log)
- Ensure an adequate number of qualified staff and adequate facilities are available for the foreseen duration of the study to conduct the research properly and safely.
- Implement modifications in approved research only after review and approval of the modification by the IRB, except when necessary to eliminate immediate hazards to subjects.

Human Protection and Protocol Compliance

- Be aware of and comply with GCP, applicable regulatory requirements, and institutional policies and procedures.
- Protect the rights, safety, and welfare of subjects under the investigator's care.
- Maintain attributable, legible, contemporaneous, original, accurate, and complete records.
- Ensure timely reporting of data and pertinent information to the subjects, sponsors, and regulatory authorities.
- Ensure adequate control and accountability of an investigational product.
• Ensure adequate control and security of protected health information (PHI) and study data.
• Ensure only a qualified physician, who is an investigator or a sub-investigator, will be responsible for all related medical care
• Ensure data reported on the CRFs are consistent with the source documents and discrepancies will be explained in detailed documentation
• Report to the IRB/Sponsor/FDA unforeseen events that may present risks or affect the safety and welfare of subjects or others, or that may affect the integrity of the research.
• Ensure biospecimens are collected, processed, and stored in accordance with the protocol, institutional policies, OSHA standards, and Good Laboratory Practice (GLP).
• Retain all pertinent study-related records as required by the sponsor, federal agency, and/or institution.
• Ensure protocol compliance (e.g., subject eligibility, consent, and randomization).
• Ensure appropriate business and financial oversight to meet grant, contract, and billing requirements.
• Register and report results of research study to ClinicalTrials.gov, if required.

Additional Responsibilities
• Any additional activities required to ensure patient safety and study compliance.

B. Procedure for Delegation of Research Responsibilities

The PI is the individual who assumes the authority and responsibility for the conduct of a clinical research study. However, the PI has the authority to delegate responsibilities to individual members of the research team, if appropriate.

The PI will select Sub-Investigators with appropriate education and training to ensure the investigation is conducted according to the signed investigator statement, the investigational plan, GCP, institutional policies, and applicable regulations.

The PI will determine the appropriate delegation of authority to specific research team members for each clinical research study conducted at this investigational site.

Delegation of specific responsibilities will be documented appropriately and kept on file with the regulatory documents for each clinical research study (See Attachment A Delegation of Authority Log). General responsibilities commonly delegated to research team members are outlined in the individual job descriptions and will be kept on file.

All members of the research team who are delegated specific responsibilities will have regular communication with the PI to ensure they are informed in a timely manner of all study-related activities.

Individual research team members will have regular evaluations of performance to ensure they are performing delegated tasks appropriately and meeting COE expectations.

C. Information Required on Delegation of Authority Log

At a minimum, the Delegation of Authority Log should contain the individual's full name, signature, initials, duties assigned, date duties assigned, dates duties completed (if applicable) and signature of
PI indicating that they have reviewed the duties delegated to an individual. The log must be updated with any staff changes that would result in a change or termination of duties as it pertains to that particular protocol.

Issued: 01-SEP-2021
Revised:
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Signature: [Signature]
Date: 9/21/21