1. OBJECTIVE

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 as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies. 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 LSU Health New Orleans, including the Health Sciences Center (HSC), the Stanley S. Scott Cancer Center (SSSCC) and the Healthcare Network (HN), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP 2.01 describes the responsibilities of the PI and the procedures for identifying and delegating specific responsibilities to research team members for conducting clinical research.

2. RESPONSIBILITY

The HSC, SSSCC and HN Clinical Trials Offices develop, implement, and maintain 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 departments and research teams conducting human subjects' research. Departments 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 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 (PI)	Clinical Research Coordinator (CRC)
Sub-Investigator (Sub-I)	Other Research Staff
Clinical Research Nurse Coordinator (CRNC)	Administrative and Support Staff

3. DEFINITIONS

Clinical Research Coordinator (CRC): Oversees and coordinates the daily activities of clinical research studies

Clinical Research Nurse Coordinator (CRNC): Carries out some of the same responsibilities as the Research Coordinator while fulfilling nursing tasks as required by the research study

Engaged: An individual who intervenes or interacts with living individuals for research purposes, or obtains individually identifiable private information for research purposes.

Investigator: A person who participates in the conduct of the clinical study at a study site.

Key Personnel: Any individual responsible for the design, conduct, or publication/ presentation of research results.

Principal Investigator (PI): Lead investigator of a team of research personnel who has the ultimate

responsibility for the ethical conduct of the research.

Regulatory Coordinator: Typically drafts or edits the protocol document and submits new protocols, amendments, continuing reviews and safety reports to the appropriate IRB for review

Statement of Investigator (FDA Form 1572): An agreement signed by the Investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

Sub-Investigator (Sub-I): An investigator who performs all or some of the PI functions, but does not accept primary responsibility for the research study

Please refer to the SOP Glossary document for other 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 (*Note: this is not a comprehensive list*):

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 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

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. 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 he/she is 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 department 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 he/she has 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.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC Institutional Review Board	LSUHSC HRP Policies & Procedures
LSUHSC HRP Policies & Procedures	1.01 Federal, State, and University Regulations Related to the IRB
LSUHSC HRP Policies & Procedures	5.01 Further Investigator Responsibilities
LSUHSC HRP Policies & Procedures	5.02 Record Keeping by Investigators
LSUHSC HRP Policies & Procedures	5.03 Research Personnel Definition, Roles, and Training
LSUHSC Institutional Review Board	Research Training Requirements
LSUHSC Office of the Chancellor	Chancellor's Memorandum #35
LSUHSC Conflicts of Interest Office	Conflicts of Interest in Research
LSUHSC Office of Compliance Programs	Compliance Training Policy
LSUHSC Clinical & Translational Research Center (CTRC)	GA 102 SOP for Responsibilities of the Research Team

Federal/International Regulation/Guidance/Policy	Title
21 CFR 312.60	Investigational New Drug Application: General Responsibilities of Investigators
21 CFR 812.100	Investigational Device Exemption: General Responsibilities of Investigators
21 CFR 812.110	Investigational Device Exemption: Specific Responsibilities of Investigators

45 CFR 46	Protection of Human Subjects
45 CFR 94	Responsible Prospective Contractors
ICH E6(R2)	Guideline for Good Clinical Practice E6 Integrated Addendum
FDA Guidance for Industry	Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects
FDA Guidance for Industry	Frequently Asked Questions – Statement of Investigators (Form FDA 1572)

6. MATERIALS

6.1. Delegation of Authority Log

6.2. Study Team Training Log

Approved by:

Jawed Alam, PhD, MBA
Executive Director, Office of Research Services