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(a) describes the responsibilities and obligations of the Principal Investigator for the conduct and oversight of the trial

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

Principal Investigator (PI): Lead investigator of a team of research personnel who has the ultimate responsibility for the ethical conduct of the research.

Please refer to the SOP Glossary document for other detailed definitions of commonly used clinical research terminology.

4. PROCEDURES

The Principal Investigator (PI) of a clinical trial has responsibilities and obligations for the conduct and oversight of the trial detailed in the Code of Federal Regulations (CFR) and in the Good Clinical Practice (GCP) guidelines, to ensure protection of the rights, safety and welfare of study participants, and to ensure the integrity of study results.

The PI of a clinical trial is required to follow the regulations for the protection of human subjects,

including obtaining informed consent from study participants, and ensuring review and approval by the Institutional Review Board (IRB), as found in the U.S. Food and Drug Administration (FDA) regulations.

Additionally, clinical trial investigators should adhere to the International Council on Harmonization (ICH) GCP guidelines, which provides assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The PI is specifically responsible for compliance with the IRB approved protocol, GCP guidelines, and the applicable federal regulations above. The PI may delegate authority to conduct study tasks to sub-investigators, coordinators, and other qualified study personnel; however, the investigator retains ultimate responsibility of overall study conduct.

A. Investigator Responsibilities

In conducting clinical trials in compliance with federal regulations and GCP, the PI commits to personally conducting or supervising the trial, including:

- Ensuring the clinical trial is conducted according to the signed investigational plan (protocol), investigator statement (form FDA 1572, or Investigator Agreement for device studies), applicable regulations, and ICH guidelines on GCP.
- Protecting the rights, safety, and welfare of subjects under the investigator's care through obtaining informed consent and ensuring initial and ongoing IRB review and approval of the study.
- Providing or ensuring adequate medical care for subjects during and following their participation on the trial.
- Controlling, maintaining, and accounting for drugs, biologics, or devices under investigation.
- Maintaining adequate and accurate study records, and reporting study data, including safety data to the sponsor and/or regulatory agency in a timely manner.

B. Delegation of Tasks

Please review SOP 2.01 Delegation of Responsibilities for information related to the PI delegating tasks to research team members.

C. Supervision and Oversight

The PI should develop a plan for the supervision and oversight of the clinical trial. This plan should include training of study personnel, and ensuring compliance to the study protocol, SOPs, and study specific processes.

- The investigator should ensure that all staff participating in the conduct of the study, including any new staff, have adequate training. To provide adequate training, investigators should ensure that study staff:
    - Are familiar with the purpose of the study and the general objectives of the protocol.
    - Have an adequate understanding of the specific details of the protocol and attributes of the investigational product to perform their assigned tasks.

- Are knowledgeable of the GCPs and applicable regulatory requirements.
- Are competent to perform or have been trained to perform the tasks they are delegated.
- Are informed of any pertinent changes during the conduct of the trial and receive additional training as appropriate.

- The PI should hold routine meetings throughout the clinical trial with study personnel to review study status and progress. These meetings should include sub-investigators, study coordinators, and any other individuals actively supporting the conduct of the clinical trial, and should accomplish the following:
  - Review of enrollment status, and progress and condition of current study participants.
  - Review of the performance of delegated study tasks and duties. Tasks should be reassigned as needed for personnel turnover.
  - Ensure the informed consent process is being conducted and documented appropriately, that IRB approval is maintained, and that conduct of the clinical trial is in compliance with the protocol.
  - Ensure appropriate use, storage and accountability of investigational product(s).
  - Verify that clinical trial source data are complete and accurate, that data captured in the case report form or study database are consistent with source data, and that data queries and discrepancies identified by the study monitor are handled and corrected appropriately.
  - Review of external safety reports, and assessment for IRB reporting criteria.
  - Assessment of deviations or adverse trends, and developing corrective and preventative action when appropriate.
  - Address medical and ethical issues that may arise during the course of the clinical trial.

- It is also important to document these investigator/study staff meetings, including the agenda, additional topics covered, and attendance. This documentation should be maintained with the study records and made available for review if requested.

- If the study is an investigator-initiated trial being conducted at multiple clinical sites, the PI should contribute to effective communication with investigators and study staff at other participating sites to provide direction, training, support, or corrective action as appropriate.

D. Investigator Training

Clinical investigators should receive appropriate instruction and training prior to conducting or being involved in clinical research.

- Investigators may receive training in the conduct of clinical research through working with a more experienced investigator mentor, professional courses or seminars, completing sponsor-required training programs, etc.

- Clinical research investigator training should include the following topics:
  - CITI (Collaborative Institutional Training Initiative) program on human subjects

research and GCP
- Institutional training on Bloodborne Pathogens, HIPAA Privacy in Research, and Conflicts of Interest in Research

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 Institutional Review Board	Research Training Requirements
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
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. None

Approved by:

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