## 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 2.07** describes the process for protocol implementation of 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

**Protocol**: A document that describes the objective(s), design, methodology, statistical considerations and organization of a study.

**Regulatory Authorities**: Bodies having the power to regulate. In the ICH GCP Guidelines, regulatory authorities include those authorities that review submitted clinical data and those that conduct inspections, such as the FDA.

**Source Documents**: Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files and records kept at the pharmacy, the laboratories and medico-technical departments involved in the clinical study).

**Statement of Investigator**: 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.

*Please refer to the SOP Glossary document for other 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 or other similar form, either provided by the Sponsor or an internal template. 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 account created.
- 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 and that records are maintained for delivery and inventory. 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.
- 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.

## 5. APPLICABLE REGULATIONS AND GUIDANCE

| LSU Health Guidance/Policy | Title |
|---|---|
| **LSUHSC HRP Policies & Procedures** | 1.01 Federal, State, and University Regulations Related to the IRB |
| **LSUHSC HRP Policies & Procedures** | 1.05 Human Subject Protection Educational Policies and Resources |
| **LSUHSC HRP Policies & Procedures** | 5.01 Further Investigator Responsibilities |
| **LSUHSC HRP Policies & Procedures** | 5.03 Research Personnel Definition, Roles, and Training |
| **LSUHSC Clinical Trials Office** | Legal and Financial Review |
| **LSUHSC Accounting Services** | Sponsored Projects |
| **LSUHSC Institutional Biosafety Committee** | IBC Requirements for Human Subjects Research |
| **LSUHSC Institutional Biosafety Committee** | Institutional Biosafety Committee (IBC) and Institutional Review Entity (IRE) for DURC |

| Federal/International Regulation/Guidance/Policy | Title |
|---|---|
| **21 CFR 50** | Protection of Human Subjects |
| **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 |
| **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. Protocol Implementation Checklist

**Approved by:**

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