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), 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 2.04 describes the process for conducting Site Initiation Visits for clinical research.

2. RESPONSIBILITY

The HSC, SSSCC and HN Clinical Trials Offices 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 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 Trial Agreement (CTA): A legally binding agreement that manages the relationship between the sponsor that may be providing the study drug or device, the financial support and /or proprietary information and the institution that may be providing data and/or results, publication, input into further intellectual property.

Institutional Review Board (IRB): An independent body constituted of medical, scientific and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a research study by, among other things, reviewing, approving and providing continuing review of studies, of protocols and amendments and of the methods and material to be used in obtaining and documenting informed consent of the study subjects.

Investigational Products: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used

or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. Also, a device, including a transitional device that is the object of an investigation.

Protocol: A document that describes the objective(s), design, methodology, statistical considerations and organization of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents.

Site Initiation Visit (SIV): Visit that occurs after the study sponsor has already selected the site for participating in a clinical trial. This visit ensures that all required trial authorizations and documentation are in place and that the protocol and trial procedures are reviewed with the Investigator and the Investigator's research team in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement prior to the start of enrollment.

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

4. PROCEDURES

The Site Initiation Visit (SIV) prepares the research site to conduct the research study. This meeting generally takes place after the investigational site has received IRB approval and a Clinical Trial Agreement (CTA) has been fully executed. In addition, the SIV should occur prior to the first subject enrollment. The PI or member of the research team will schedule and arrange the SIV which can be conducted in person, on-line, or via conference call at the discretion of the sponsor. The SIV is led by the sponsor representative and provides protocol training for the PI, Sub-I(s), and delegated research team members.

Delegated research team members involved in supervising, managing, or conducting study-related activities should have all required study documents available for review prior to and during the SIV.

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, will 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 and/or other relevant documentation requested by the sponsor, the IRB and/or other regulatory authorities.

The PI and delegated research team members will ensure all persons assisting with the research study are adequately informed about the protocol, the investigational products, and their research study-related duties and functions. These individuals will be informed about their obligations, will have adequate education and training to conduct the tasks delegated, and delegation will be documented appropriately.

Aspects of conducting the clinical research study will be reviewed at the SIV including, but not limited to the following:

- Study objectives
- Regulatory requirements

- Regulatory documents and file management
- Appropriate patient screening procedures
- Inclusion and exclusion criteria
- Schedule of events
- Study procedures and study specific forms
- Investigational product accountability and management
- Adverse events and protocol deviation reporting
- Source documentation
- Case report form completion
- Data management

The Sponsor representative will obtain the investigator's agreement to conduct the research study in compliance with GCP, applicable regulatory requirements, and the protocol which has been agreed to by the sponsor and approved by the IRB.

The Sponsor representative will ensure the investigator and delegated research team members agree to comply with procedures, expected turn-around time for data reporting, and permit study monitoring, auditing, and inspection. The sponsor and the investigator/institution should sign the protocol, or an alternative document/contract, to confirm these agreements.

The PI or delegated research team members will document the details of the SIV. After the SIV is complete, follow up on any outstanding items. Once all outstanding items have been addressed the site should be officially activated by the sponsor to begin subject enrollment.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC Institutional Review Board	LSUHSC HRP Policies & Procedures
LSUHSC HRP Policies & Procedures	5.03 Research Personnel, Definition, Roles & Training
LSU System	LSU PM #36 Information Security Plan
LSUHSC Office of Compliance Programs	Information Security Requirements
LSUHSC Institutional Review Board	Research Training Requirements
LSUHSC Clinical & Translational Research Center (CTRC)	PM 202 SOP for Protocol Start-up and Implementation

Federal/International Regulation/Guidance/Policy	Title
21 CFR 312.55	Investigational New Drug Application: Informing Investigators
21 CFR 312.66	Investigational New Drug Application: Assurance

	of IRB Review
21 CFR 812.40	Investigational Device Exemption: General Responsibilities of Sponsors
21 CFR 812.110	Investigational Device Exemption: Specific Responsibilities of the Investigators
ICH E6(R2)	Guideline for Good Clinical Practices E6 Integrated Addendum
FDA Forms 3454, 3455	Certification & Disclosure: Financial Interest and Arrangements of Clinical Investigators
FDA Guidance for Industry	Frequently Asked Questions – Statement of Investigator Form FDA 1572

6. MATERIALS

6.1. None

Approved by:

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