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 2.03 describes the process for conducting a site qualification visit, also known as a pre-study site visit.

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

Case Report Form (CRF): A printed, optical or electronic document designed to record protocol-required data for each study subject and sent to the Sponsor for purposes of statistical analysis.

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.

Investigator's Brochure (IB): A document that is provided by a clinical study Sponsor to investigators participating in that study. It is a compilation of the clinical and non-clinical data on the

investigational product(s) relevant to the study of the investigational product(s) in human subjects.

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 Qualification Visit: A meeting between the site and sponsor to assess if the site has the qualifications and facilities to execute all elements of the protocol. This visit occurs after the site has decided to participate in a trial and prior to receiving a site selection letter.

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

4. PROCEDURES

A. Site Qualification Questionnaires

The PI, in collaboration with the other research team members, will complete a site questionnaire that provides basic information for the study sponsor to perform a cursory evaluation of the site. Site qualification questionnaires are used to assess staff experience, facilities, and other operational needs necessary to perform a clinical research study. Often, the questionnaires request basic information related to the Principal Investigator, Sub-Investigator(s), Clinical Research Coordinator (CRC), and/or Pharmacy, as well as details about the IRB. Questions specific to the disease/therapeutic area being studied and expected enrollment numbers are also often requested.

B. Preparing for a Site Qualification Visit

If the PI wishes to pursue the clinical research study and the sponsor requests a site qualification visit, the delegated research team members will work with the PI and sponsor to find a mutually agreed upon date. The PI will identify key research personnel who will be involved in the conduct of the clinical research study. In preparation of the visit, a Site Qualification Visit Agenda should be completed, if not provided by the sponsor or sponsor representative, and the Checklist for a Site Qualification Visit reviewed.

C. Site Qualification Visit

The PI, Sub-Investigator and delegated research team members will meet in person or participate in an online meeting or conference call with the sponsor or representative. The research site should be prepared to review:

- Protocol
- Recruitment, Retention and Enrollment Goals
- Investigator's Brochure (if applicable)
- Case Report Forms
- Source Documents (if being provided)
- A monitoring and communication plan for the sponsor/CRO and investigational site

The PI or research team members will:

- Provide the sponsor representative with copies of the current CVs from key site personnel, as requested.
- Ensure the sponsor representative has a chance to tour the research facility, as requested, including: exam rooms, lab areas, special testing areas, pharmacy, hospital

unit, work areas for research team members, storage area for investigational product, space used for processing and shipping research samples, and data entry area.
- Document the details of the site qualification visit and address any follow-up questions the sponsor representative may have.
- Ensure all persons assisting with the research study are adequately informed about the protocol, the investigational product(s), and their study-related duties and functions. These individuals will be informed about their obligations and will have adequate and appropriate education and training to conduct the tasks delegated.

The PI and delegated research team members will be qualified by education, training, and experience to assume responsibility for the proper conduct of the 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 the regulatory authorities.

Following the Site Qualification Visit, a Site Qualification Visit Summary should be completed.

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
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. Site Qualification Visit Agenda

6.2. Checklist for a Site Qualification Visit

6.3. Site Qualification Visit Summary

Approved by:

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