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 2.02 describes the process for reviewing feasibility for 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

Confidential Disclosure Agreement (CDA): A document used when transferring confidential or proprietary information from one party to another for review only (no further use or dissemination), generally for the purpose of evaluating the potential for a future relationship between the parties.

Informed Consent Form (ICF): The form on which the process of conducting and achieving informed consent from potential study subjects is documented.

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. Protocol Feasibility

The delegated clinical research team members will ensure the site has received critical study documents such as the protocol, informed consent template, the Investigator's Brochure (if applicable), lab, pharmacy and/or other manuals (if applicable), Case Report Forms (CRF(if available), sample budget worksheet, and a draft contract after the Confidential Disclosure Agreement (CDA) has been executed by the Office of Innovation and Partnership (OIP).

The PI, in collaboration with the other research team members, will review the protocol and applicable study-related materials to assess the feasibility of conducting the study at this site using protocol feasibility tools provided by the Sponsor; if the sponsor does not provide feasibility tools, the study team may use the LSUHSC Protocol Feasibility Tool and LSUHSC Protocol Feasibility Score Card to document the feasibility assessment. The following will be met:

- Must be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
- Must have sufficient time to properly conduct and complete the research study within the agreed study period.
- Must have an adequate number of qualified staff available and adequate facilities for the foreseen duration of the study to conduct the study properly and safely.

If the PI wishes to pursue the clinical research study and the sponsor requests a site qualification visit, the research team members will work with the PI and sponsor to find a mutually agreed upon date. The PI, in collaboration with the research team members, will identify key research personnel who will be involved in the conduct of the clinical research study.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC Institutional Review Board	HRP-2200 Request for Review of PHI Prepatory to Research
LSUHSC HRP Policies & Procedures	5.03 Research Personnel Definition, Roles, and Training
LSUHSC Clinical & Translational Research Center (CTRC)	PM 201 SOP for Assessing Protocol Feasibility

Federal/International Regulation/Guidance/Policy	Title
21 CFR 11	Electronic Records; Electronic Signatures
21 CFR 312.60	Investigational New Drug Application: General Responsibilities of Investigators
21 CFR 812.110	Investigational Device Exemptions: Specific Responsibilities of Investigators
ICH E6(R2)	Guideline for Good Clinical Practices E6 Integrated Addendum

6. MATERIALS

6.1. Protocol Feasibility Tool

6.2. Protocol Feasibility Score Card

Approved by:

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