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 1.03 describes the key steps in creating and finalizing a Clinical Trial Agreement (CTA) and budget. When creating a budget for a clinical trial, all pertinent LSU Health policies and Medicare rules must be followed. Standard budget guidelines such as Research Floor Rates for clinical procedures/tests, standard invoiceables, and other non-patient costs shall be strictly adhered to for sponsored studies unless otherwise approved.

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 (CRM)	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.

Clinical Trials Office (CTO): LSU Health Offices at the Health Sciences Center, Healthcare Network and Cancer Center serving as a central resource for initiating and conducting clinical trials for LSU Health investigators.

Contract: A written, dated and signed agreement between two or more involved parties that sets

out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters.

Contract Research Organization (CRO): A person or an organization (commercial, academic or other) contracted by a Sponsor to perform one or more of that Sponsor's clinical study-related duties and functions.

Sponsor: An individual, company, institution or organization that takes responsibility for the initiation, management and/or financing of a clinical study.

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

4. PROCEDURES

A. Clinical Trial Agreement Process

A delegated research team member will obtain the Clinical Trial Agreement ("CTA") template from the study sponsor/CRO and send to the Clinical Trials Office for HSC, the Director of Clinical Trials Office for HN or the Director of the Clinical Trial Business office for SSSCC for review. The responsible individual will redline any changes and comment as necessary, as well as correspond directly with the Sponsor on negotiations, until the CTA is finalized, ensuring any changes to payment terms or exhibits are incorporated. The responsible will obtain executable copies of the finalized CTA and routing instructions from the sponsor and/or CRO. The CTA will be routed for signature internally and then the partially executed CTA will be sent to the sponsor/CRO for full execution. The fully executed CTA will be returned to the Responsible Individual who will send it to the research team and accounting office.

B. Budget Process

A delegated research team member will obtain a budget from study sponsor/CRO and send to the responsible Clinical Trials Office for review. The research team member will collaborate with the responsible CTO to develop Budget Spreadsheet using the Medicare Coverage Analysis ("MCA") for determination of what shall be paid by the sponsor using established research rates. Costs should be incorporated into the sponsor-provided budget template. The responsible Clinical Trials Office will negotiate fees with sponsor, providing rationale for fees as needed. They shall also update payment terms as necessary. Once agreed to, the budget will be incorporated in the CTA prior to partial execution.

- For clinical research sponsored by industry, LSU Health and affiliated hospitals will use their industry pricing to build the budget.
- For clinical research sponsored by academic medical centers, foundations, or other non-industry organizations, LSU Health and affiliated hospitals will use NIH-pricing to build the budget.

5. APPLICABLE REGULATIONS AND GUIDANCE

Regulation/Guidance/Policy	Title
21 CFR 50	Protection of Human Subjects

21 CFR 312.60	General Responsibilities of Investigators
21 CFR 812.110(b)	Specific Responsibilities of Investigators - Compliance
ICH E6(R2)	Compliance with Protocol
ICH E6(R2)	Informed Consent of Trial Subjects

6. MATERIALS

6.1. Budget Template

6.2. Project Number Request Form

6.3. CTO Fee Schedule