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 1.01 describes the process for writing, training, and maintaining standard operating procedures 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

Archive File: A file in which the original and all subsequent revised versions of a standard operating procedure (SOP) or other document are maintained, so that the origination and revision history for an SOP or other document is available for review.

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.

Effective Date: The date on which an SOP or other document becomes available for use by personnel, after documented training.

Standard Operating Procedure (SOP): A document that specifies all the operational steps, acceptance criteria, personnel responsibilities and materials required to accomplish a task.

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

research terminology.

4. PROCEDURES

A. Developing and Modifying SOPs

A delegated member of the Clinical Trials Offices' SOP Committee will be responsible for drafting SOPs which the SOP Committee will review and approve. The SOP or RPA content will contain enough details to guide clinical research team members through a particular procedure and establish uniformity in the daily operations of the department. Processes should be established that can be followed without deviation and that can be easily implemented.

The SOP format, at a minimum, will contain the following elements: Title, Effective Date, Approval By, Objective, Responsibility, Definitions, Procedures, Applicable Regulations, Guidelines and References to other SOPs, and Materials.

The SOP Committee will review and approve the final SOP or RPA.

All SOPs will initially be reviewed by the SOP Committee 1 year after the initial release. After that, all SOPs will be reviewed by the SOP Committee to assess applicability and revise and/or edit the document a minimum of every 2 years. If changes are required sooner than the 2 year review, then an ad hoc committee meeting will be called.

The procedures will be followed as outlined above for any revisions or additions to SOPs.

Once a revised SOP is approved, the previous version will be marked "Obsolete." The original document will be retained in the appropriate section of HSC and HN's regulatory/administrative files and an archive file will be maintained via SharePoint with all current and prior versions of SOPs.

B. SOP Implementation

The HSC Clinical Trials Office will notify all research team members about new or revised SOPs via the Clinical Trials Listserv.

All Undeliverable notifications will be filed in the in the appropriate section of HSC's regulatory/administrative files as documentation of who did not receive the new or revised SOPs.

If new SOPs or revisions are extensive, the CTOs will set up training for all affected personnel or their supervisors on the use of the new or revised SOP.

C. SOP Training

SOP training must be completed by all applicable staff involved in clinical research to ensure understanding and adherence to procedures. See SOP XX for specific training details.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC Clinical & Translational Research Center (CTRC)	GA 101 SOP on SOP: Preparing, Maintaining, and Training

Federal/International Regulation/Guidance/Policy	Title
21 CFR 312.62	Investigator Recordkeeping and Record Retention
21 CFR 812.100	General Responsibilities of Investigators
21 CFR 812.110	Specific Responsibilities of Investigators
21 CFR 812.140	Records
21 CFR 812.150	Reports
ICH E6(R2)	Guideline for Good Clinical Practices E6 Integrated Addendum

6. MATERIALS

6.1. SOP Template

Approved by:

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