## 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 1.05** describes the process for creating certified electronic copies.

## 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

**Certified Copies**: A copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original.

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

## 4. PROCEDURES

Research documents should be scanned and saved as PDF files. Research documents should be scanned using parameters that produce the best replication of the original documents.

Copies should be certified by the same person who created the electronic copy. Although it does not have to be the PI, they are ultimately responsible for the quality and integrity of the certified copy.

The certifying person shall review the original document and create a Certified Copy Cover Sheet

that shall also be scanned and saved as a PDF file with the associated research documents. In ensuring that certified copies are exact, certifiers should verify scanned copies are legible and facing in the appropriate direction, hand-written notes and/or signatures are readable, and pages are fully copied and not cut off.

Certified electronic copies and the original research documents should be stored securely and incompliance with institutional and HIPAA regulations. If the research is FDA-regulated, the systems and procedures must be 21 CFR Part 11 compliant.

As study and sponsor requirements will vary, it is the responsibility of the (PI) to ensure SOPs are being used in compliance with the institutional, FDA, and sponsor instructions. The PI should request and document sponsor approval for electronic storage of source documents prior to creating certified electronic copies.

## 5. APPLICABLE REGULATIONS AND GUIDANCE

| LSU Health Guidance/Policy | Title |
|---|---|
| **LSUHSC CTO SOP 2.05** | Essential Document Management & Retention |
| **LSUHSC HRP Policies & Procedures** | 2.05 IRB Records |
| **LSUHSC HRP Policies & Procedures** | 5.02 Record Keeping by Investigators |
| **LSUHSC Office of Compliance Programs** | Electronic Data Interchange Requirements |
| **LSUHSC Office of Compliance Programs** | Privacy Requirements |
| **LSUHSC Office of Compliance Programs** | Information Security Requirements |
| **LSUHSC Policy** | Records Retention and Disposition Policy |
| **Louisiana Secretary of State** | Records Retention Schedule |

| Federal/International Regulation/Guidance/Policy | Title |
|---|---|
| **FDA Guidance** | Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers (March 2023) |
| **FDA Guidance for Industry** | Part 11, Electronic Records; Electronic Signatures - Scope and Application (September 2003) |

## 6. MATERIALS

6.1. Certified Copy Cover Sheet