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 2.13 describes the process for data management including quality control, Case Report Form completion, data query resolution, and record retention 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

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.

Source Data: All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical study/trial necessary for the reconstruction and evaluation of the study.

Source Documents: Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files and records kept at the pharmacy, the laboratories and medico-technical departments involved in the clinical study).

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

4. PROCEDURES

The PI or delegated research team members will create and maintain study-specific subject files for each clinical research study subject consented. This file will contain required original essential documents such as source documents used for Case Report Form (CRF) data elements, original signed informed consents, assents, HIPAA authorization forms, protocol deviations, Adverse Event and SAE reports and Notes to File.

LSUHSC policy states that all research-related records need to be maintained for at least 10 years after the research has ended unless longer is required by other entities (sponsor, contractual requirement, patent requirements, publication, FDA, etc.).

For a FDA regulated study:
Drugs/Biologics: An investigator shall retain records per the clinical trial agreement following the date a marketing application is approved for the drug indication being investigated; or, until after the investigation is discontinued and FDA is notified.

Device: An investigator or sponsor shall maintain the records per the clinical trial after the latter of the following two dates:

1. The date on which the investigation is terminated or completed, or
2. The date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

A. Source Documentation

Source data is information from the original records, or certified copies of original records, with clinical findings, observations, or other activities in a clinical research study necessary for the reconstruction and evaluation of the clinical research study. Source data are contained in source documents (original records or certified copies).

Source documents are the original documents containing data for a clinical research study. These documents may be paper or electronic.

All source documents and data containing protected health information (PHI) will be kept confidential and secured per institutional policies.

Examples of acceptable source documentation may include, but are not limited to, the following examples of original documents, data, and records:

- Electronic Medical Records
- Paper Medical Records
- Pharmacy Records
- Subject Diaries or Questionnaires
- Lab Reports
- Physician Progress Notes
- Radiology Images and Reports
- Nurse Notes
- Research Notes

- Notes to File
- Emails
- Clinical Research Study Flow Sheets and Worksheets
- Original Signed Informed Consent Forms

All pertinent source documentation should be recorded, handled, and stored in a manner that allows accurate reporting, interpretation, and verification. The investigator should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should meet ALCOA-C criteria:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete

All source documentation should clearly identify the research subject and contain the signature and date of the person who created the source document.

Any change or correction to a source document will be dated, initialed, and explained (if necessary) and will not obscure the original entry. There will be a single line through the error in a paper source document with the initials of the person correcting the error and the date corrected. Any changes to electronic record will reflect the user, date and time, but the original entry will be maintained. An audit trail will be visible for all source documents.

The PI is required to prepare and maintain adequate and accurate case histories that record all observations and data pertinent to the investigation for all subjects participating in a clinical research study.

Case histories include CRFs and supporting source documentation including signed and dated consent forms, coordinators' notes, and medical records (such as progress notes of the physician, the individual's hospital chart(s), and the nurses' notes). The case history for each individual shall document that informed consent was obtained prior to participation in the study.

When working with hospitals and clinics, follow their site-specific SOPs. For non-electronic records, official documents should be stamped as "Certified Copy," and signed and dated.

B. Data Entry

CRFs may be provided by a sponsor and can either be electronic or paper. If CRFs are not provided they will be developed by the investigational site based on the protocol and in collaboration with the PI and biostatistician. CRFs will not be used as source documents.

CRFs collect relevant data in a specific format to allow for easy statistical analysis in accordance with the protocol and in compliance with regulatory requirements. Final CRFs for investigator-initiated clinical research studies will be submitted to the IRB at the time of initial protocol review. CRFs will be updated and approved as needed.

Data recorded on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained. The investigator will ensure the

accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

Any change or correction to a CRF will be dated, initialed, and explained (if necessary) and will not obscure the original entry. An audit trail will be visible. This applies to both written and electronic changes and corrections.

Data should be collected, entered and submitted promptly and within the timeframe required by the sponsor or specified in the protocol, if applicable. Data should be completed using an ink pen (nothing that can be erased) when using paper CRFs.

If queries or data clarification forms are issued by the sponsor they should be resolved promptly and within the timeframe provided by the sponsor. Errors will be corrected and submitted according to the method provided by the sponsor. Copies of queries can be stored in EDC; data clarification forms (i.e., Note to File) will be kept in the study subject record/shadow chart.

Upon request of the monitor, auditor, IRB, or regulatory authority, the PI and delegated research team members will make available direct access to all requested clinical research study related records including original source documents and CRFs for review during a monitoring visit or an audit.

If sponsor monitors or auditors need access to subject medical records to verify source documentation, follow the clinic or hospital's policy on access to patient records.

C. Data Security

Please refer to university data policies and other regulations to determine how to securely save research data.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC HRP Policies & Procedures	2.05 IRB Records
LSUHSC HRP Policies & Procedures	4.05 Confidentiality of Data and HIPAA Privacy Rule
LSUHSC HRP Policies & Procedures	4.06 Research Data Protection Plan
LSUHSC HRP Policies & Procedures	5.02 Record Keeping by Investigators
LSUHSC Institutional Review Board	HIPAA & Research
LSUHSC Institutional Review Board	HIPAA Data Guidelines
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 Office of Compliance Programs	Penalties for Violating HIPAA Regulations
LSUHSC Office of Compliance Programs	Compliance Training Policy
LSU System	LSU PM #36 Information Security Plan

LSUHSC Policy	Records Retention and Disposition Policy
Louisiana Secretary of State	Records Retention Schedule

Federal/International Regulation/Guidance/Policy	Title
21 CFR 11	Electronic Records; Electronic Signature
21 CFR 312.50	Investigational New Drug Application: General Responsibilities of Sponsors
21 CFR 312.56	Investigational New Drug Application: Review of Ongoing Investigations
21 CFR 312.60	Investigational New Drug Application: General Responsibilities of Investigators
21 CFR 312.62	Investigational New Drug Application: Investigator Recordkeeping and Record Retention
21 CFR 312.64	Investigational New Drug Application: Investigator Reports
21 CFR 312.68	Investigational New Drug Application: Inspection of Investigator's Records and Reports
21 CFR 312.70	Investigational New Drug Application: Disqualification of a Clinical Investigator
ICH E6(R2)	Guideline for Good Clinical Practice E6 Integrated Addendum
FDA Guidance for Industry	Computerized Systems used in Clinical Investigations
FDA Guidance for Industry	Part 11, Electronic Records, Electronic Signatures – Scope and Application
FDA Guidance for Industry	Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials
FDA Guidance for Industry	Electronic Source Data in Clinical Investigations

6. MATERIALS

6.1. None

Approved by:

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