SOP-16: Data Management

1. Objective

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 Ochsner Health, hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research. The objective of this SOP is 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 related to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies.

SOP-16 describes the process for data management including quality control, Case Report Form completion, data query resolution, and record retention for clinical research.

2. Responsibility

Ochsner Research develops, implements, and maintains 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 Centers of Excellence (COEs) and research teams conducting human subjects’ research. COEs 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 Principal Investigator (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
- Sub-Investigator
- Clinical Research Manager
- Clinical Research Supervisor
- Clinical Research Coordinator
- Associate Clinical Research Coordinator
- Data Coordinator and Regulatory Specialist
- Other Research and Administrative Support Staff

3. Definitions

Please refer to the SOP Glossary document for 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.

The OHRPP policy states that all research-related records need to be maintained for at least 3 years after the research has ended unless longer is required by other entities (sponsor, contractual requirement, patent requirements, publication, FDA, etc.). However, the primary research data, as outlined in the research data policy, must be retained at Louisiana State for a minimum of 5 years after final project closeout.

For an FDA regulated study:

**Drugs/Biologics:** An investigator shall retain records for a period of 2 years following the date a marketing application is approved for the drug indication being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

**Device** An investigator or sponsor shall maintain the records for a period of 2 years 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 ALCOAC criteria (attributable, legible, contemporaneous, original, accurate, and complete).
All source documentation should clearly identify the research subject and contain the signature of the person who created the source document and date.

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 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.

**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 a ball-point pen 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 or data clarification forms will be kept on file.

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.

Sponsor monitors and auditors may be granted limited view-only access to subject medical records to verify source documentation.

**C. Data Security**

Please refer to Ochsner Health data policies and other regulations to determine how to securely save research data.
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Revised:

Approved by W Mark Roberts, MD, Dean of Research

Signature  

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