**Purpose**: Properly managing the data collected during a clinical trial ensures the results are complete, accurate, valid, and reproduceable. This SOP defines the process for the collection and storage of data collected during the conduct of a clinical trial at this investigative site.

**Scope:** This SOP applies to Investigators and clinical research team members conducting human subject research at UNC.

**Definitions:**

**Case Report Forms (CRFs) –** a tool used to collect data in a clinical trial

**Electronic Data Capture (EDC) –** a computerized system designed for the collection of clinical data in an electronic format

**Source Documents –** a document in which data collected for a clinical trial is first recorded

**ALCOAC –** fundamental elements that source data should meet: **A**ttributable, **L**egible, **C**ontemporaneous, **O**riginal, **A**ccurate, **C**omplete

**Procedures:**

**General:**

1. Adherence to the University’s policy on information security is implicit in this SOP.

 **Data Collection**

1. The protocol or other manual associated with the study will specify which data elements will be collected.
2. The source for the data collected will be:
	1. Electronic Medical Record
	2. Paper based records created by study team
	3. Direct entry into the database/EDC (i.e., subjects directly entering answers to surveys/questionnaires into the database/EDC)
	4. (Add additional sources as needed)
3. Staff training on the system(s) used to collect and house research data will be completed prior to any collection or transcription into the research database/EDC). (See Training SOP for the way in which this training will be documented)
4. Case report forms will be completed within (X days) of a subject visit.
5. The data will be entered into the EDC/database in a timely manner.

 **Data Storage**

1. Paper source documents and case report forms will be stored (state where documents will be housed; keep in mind what is documented in the IRB application).
2. Electronic source documents and case report forms will be stored (state where documents will be stored (e.g, departmental server); keep in mind the level of security determined by the IRB application).
3. At the end of the trial, all essential documents will be transferred to Iron Mountain (if not Iron Mountain, state location) for the length of time required by the regulations, contract, or university policy.

 **Data Monitoring/QC**

1. Each quarter, a staff member (preferably not associated with the trial) will review for accuracy:
	1. Informed Consent/HIPAA documents
	2. Case report forms with source documents
2. Discrepancies with the data will be documented and reviewed and verified with the PI and/or Project Manager.
3. Corrections will be made as necessary following ALCOAC guidelines.

 **Applicable Policies and Guidelines:**

* UNC Office of Human Research Ethics Standard Operating Procedures
* 21 CFR 11 – Electronic Records; Electronic Signatures
* 21 CFR 50 – Protection of Human Subjects
* 21 CFR 56 – Institutional Review Boards
* 45 CRF 46 – HHS Policy for Protection of Human Research Subjects
* ICH Good Clinical Practices E6 (R2)

|  |
| --- |
| **Revision History** |
| Date of Revision: | Revision Description: |
|  |  |