***TITLE: Data Management***

***SOP*** CL XX.XX

***Author(s):***

***Developed by Date***

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| **Instructions for modifying this template:**   1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit. 2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance. 3. After you have modified this SOP template, do not forget to remove the “**Instructions for modifying this template**” table. 4. Number the SOP using you own guidelines for numbering. |

**I. SCOPE/PURPOSE** The scope of this SOP is to describe the methods for the collection, receipt, and management of data for clinical trials at UAB research sites The purpose of SOPs is to assure consistency and rigor with the design, conduct and implementation of clinical trials at UAB by providing standards and guidelines for the staff. This SOP will describe the development and implementation of SOPs by the CTO Research Group SOP Committee.

**II. ALLOWABLE EXCEPTIONS**

This SOP will be adhered unless exceptions are required. Exceptions will be noted in a formal note to file (see relevant SOP).

**III. RELEVANT REGULATIONS/GCPS**

*ICH-GCP:* 5.1.2; 5.1.3 Sponsor QA/QC; 5.5 Trial Management, Data handling, Record Keeping; 4.9 Records and Reports; 5.18 Monitoring; 6.10 Direct Access to Source Data/Documents

**IV. DEFINITIONS/ACRONYMS**

1. **Investigator** - the individual who is responsible and accountable for conducting the clinical trial. The PI assumes full responsibility for the treatment and evaluation of human subjects, and for the integrity of the research data and results.

2. **Case Report Forms (CRF’s)** - Case report forms (CRFs) are the forms designed by the Sponsor to collect information required by the protocol. Information includes, but is not limited to: medical histories, physical exams, concomitant therapy, current illnesses, and study test article use.

3. **Adverse Event (AE)** - Unfavorable changes in health, including abnormal laboratory findings, that occur in trial participants during the clinical trial or within a specified period following

the trial.

4. **Serious Adverse Event (SAE)** - Serious Adverse Events include adverse events that result in death, require either inpatient hospitalization or the prolongation of hospitalization, are

life-threatening, result in a persistent or significant disability/incapacity or result in a congenital anomaly/birth defect.

5.  **Source Documents** - A source document is a document in which data collected for a clinical trial is first recorded. These data are usually later entered in the case report form. The ICH-GCP guidelines define source documents as "original documents, data, and records."

6. **Electronic Medical Record (EMR)** - An electronic medical record (EMR) is a digital version of the traditional paper-based medical record for an individual.

The EMR represents a medical record within a single facility, such as a doctor's office or a clinic.

**V. RESPONSIBLE PERSONNEL**

* The Investigator is responsible for accurate and complete collection, support, and storage of the data generated during a clinical study, for the clinical review and interpretation of the clinical data and for the secure collection and maintenance of all electronic records in accordance with applicable regulations (as applicable).

* The Clinical Research Coordinator is responsible for collecting accurate and complete clinical study data, and for maintaining the electronic or paper source documentation
* The Data Manager and/or the Clinical Research Coordinator are responsible for the data entry of all data collection from source documents into the study specific electronic or paper CRF.

**VI. DETAILS**

Human subject research data must be maintained and securely stored in order to ensure that the validity and integrity of the data can be demonstrated, allow for the access ofdata when required, protect the privacy and security of personal health information, and to meet regulatory requirements. Direct access to all requested trial-related records should be made available upon request of the monitor, auditor, Institutional Review Board (IRB) of record and/or regulatory authority, and the investigator/institution.

Study Subject Recruitment and Screening

Data collection begins with screening forms that are designed for effective and efficient screening of potential study subjects for a protocol.

Study Subject Information

The following information is obtained and maintained on study subjects continuing in the study:

* Screening Log
* Enrollment Log: A log of all study subjects, their current status in the study and their visit progress.
* Test article accountability and administration logs.
* Physician Notes
* Physician Orders
* Nurses’ Notes and/or flow sheets
* Testing results to include labs, scans, EKG’s, pathology and other reports
* Hospital records
* Medical history and outside medical records
* Adverse Event log
* Concomitant medication log
* Any other source documentation
* Accurate and completed data are collected in the source documents and recorded on the case report forms.
* Copies of completed and signed informed consent forms are maintained in the study subject's file and medical record (if applicable). The original consent form is maintained with the regulatory documents/binder (May change based on unit policy).
* 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, at the laboratories and a medico-technical departments involved in the clinical trials) are considered source documents and should be kept with the subject records (ICH 1.52).
* In order to ensure accuracy, all case report forms (CRFs) are completed during the study subject visit, per protocol or contract requirements, or as soon as possible (i.e. 3-5 days) after the visit.
* An accurate and complete test article disbursement log is maintained at all times for each study subject. At the end of the study a closing inventory is tallied with notes on the rationale for missing containers or medication.

Adverse Events

* Adverse event data are collected in a timely manner at every visit. The Investigator is responsible for recording all new clinical experiences, exacerbations, and/or deterioration of any existing clinical condition occurring after a study subject has entered the study on the appropriate form in the case report forms.
* If the adverse event is serious, the Principal Investigator is also responsible to report all serious adverse events to the Sponsor immediately and comply with the reporting requirements of the local IRB requirements regarding the reporting of adverse events. The Investigator will also provide follow-up information on all adverse events until resolution or an appropriate end point is reached.
* In the case of a serious adverse event, the Sponsor, and Institutional Review Board (IRB), are notified within 24 hours or according to the applicable reporting requirements.
* All staff members are responsible for communicating reports of any adverse events to the Principal Investigator for review and follow-up.
* Reporting Procedures: Any clinical study experience that is judged to be an adverse event (any new clinical symptom or exacerbation of a current condition) should be reported on the CRF and/or adverse event form (as applicable) during the course of the study. The Clinical Research Coordinator assures this information is captured during every study subject visit. This form and the information remains a part of the case report form case record and filed appropriately.

As much information as possible is obtained from subjects that drop out of the study. The primary pieces of information may include:

* adverse events details
* concomitant medication status
* return of study test article or amount left
* Last day of study drug and compliance

· Case Report Forms (CRF’s)

Paper CRFs:

* When corrections are necessary on paper CRFs, a single line is made through the error and the error is initialed and dated. The correct answer is written next to the error. If necessary, a notation for the correction is added. DO NOT USE WHITE-OUT OR ‘SCRIBBLES’.
* A copy of each completed paper CRF is retained by Sponsor and by the clinical trial site.
* If a correction or additional information is needed after the Sponsor has retrieved their copy of the paper CRF, corrections are made as directed by the Sponsor to insure the correction is the same on the copy retained by the Sponsor and the copy retained by the clinical trial site.
* These CRFs are reviewed by the Data Manager and/or Clinical Research Coordinator with the Sponsor to ensure accurate interpretation of the requirements of the form.

Electronic CRFs:

* Electronic CRFs will be completed by the Data Manager and/or Clinical Research Coordinator as indicated in the protocol or specified by the sponsor. The data will be entered after training on the database is complete and secure log in and password is obtained from the sponsor.
* These CRFs are reviewed by the Data Manager and/or Clinical Research Coordinator with the Sponsor to ensure accurate interpretation of the requirements of the form.
* Queries generated by the database or monitor will be answered by the Data Manager in a timely manner or as required in the protocol and/or by the sponsor.

Electronic Medical Records (EMR)

Electronic data requires administrative, physical and technical safeguards to ensure its confidentiality, integrity, and security. The Principal Investigator will document and ensure that the following parameters are met:

* Each member of the research team is responsible for collecting data and will be fully trained on the electronic system operations prior to study initiation.
* Each member will have proper security privileges assigned prior to entering data into the system.
* No member with security privileges will grant access to another person under their identity and password.
* Only personnel with proper security access will have access to any electronic record system.

To facilitate monitoring visits, source documents may be printed from the EMR, reviewed, signed and dated by the investigator. If acceptable to the monitor/sponsor, this printed copy of the source data may be utilized for verifying case report form entries. As appropriate a monitor representing a sponsor may, if appropriately trained, and with secure access, review source documentation directly from the electronic medical record.

Documentation

Retention Requirements

* Research data will be kept in compliance with all Health System policies, Storage, and Archiving of Human Subject Research Data which requires that the Principal Investigator
* Preserve data for a minimum of seven (7) years for adult subjects and ten (10) years for pediatric subjects after the final project close-out. The original data may be retained indefinitely when feasible.
* The Investigator will obtain written notification from the sponsor prior to any record destruction. Guidance on destruction could also be defined in the study contract.
* Copies of all case report forms are retained by the Investigator as above since federal regulations require that copies of these forms be made available in the event of an FDA or other regulatory audit. CRFs should be retained for study subjects including those who died during a clinical study or those who did not complete the study as a result of an adverse event.

**VII. QA**

None

**VIII. APPENDICES / RESOURCES**

None

**IX. RELATED SOPS**

None