***TITLE: Source Documents***

***SOP :*** CL XX.XX

***Author(s):***

 ***Approved by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

 ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Approval:***

 ***Approved by Date***

 ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

 ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Annual review of current version Review date Comment***

 ***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

 ***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

|  |
| --- |
| **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 purpose of source documents is to document the existence of the research subject and substantiate the integrity of the research data collected. Source documents should include original documents related to the research, to medical treatment and to the history of the subject.

**II. ALLOWABLE EXCEPTIONS**

This SOP will be adhered unless exceptions/waivers are obtained. Waivers/Exceptions will be noted in a formal note to file (see relevant SOP). Written verification from the Sponsor will be required.

**III. RELEVANT REGULATIONS/GCPS**

ICH Good Clinical Practice Guidelines

**IV. DEFINITIONS/ACRONYMS**

**Source Data:** All the information in original records and certified copies of clinical findings, observations or other activities in a clinical research that is necessary for the construction and evaluation of the research.

**Source Document:** Documents that contain original data/observations that accurately describe all of the conditions and events that occurred during the conduct of the study or as a result of study procedures are called source documents.

**ALCOA Criteria:** Source data should be attributable, legible, contemporaneous, original and accurate.

**Shadow Charts**: A chart made of certified copies of relevant sections of the original paper or electronic medical records.

**Certified Copies:** A copy that is certified to be an accurate and complete representation of the original document

**V. RESPONSIBLE PERSONNEL**

Principal Investigator. The Principal Investigator is responsible and accountable for assuring that source documentation is accurate and complete. The PI may delegate responsibility for source documentation to another qualified researcher involved in the study, but may not delegate accountability.

Sub-Investigators, Clinical Research Coordinator, Clinical Research Nurse, Regulatory Manager, Data Manager,

**VI. DETAILS**

**1.** The IRB approved protocol describes the information to be obtained from each participant during screening and study visits. This information may be obtained by a variety of means including interviewing, assessment procedures and performance of study-specific diagnostic and laboratory tests. These various processes/procedures must be performed according GCP (Good Clinical Practice).

**2.** Original documentation, containing the subject’s health information and medical test results, must be retained in the subject’s medical/study record. Certified copies may be placed in a study record or shadow chart. Documentation should also note if a procedure was not performed and should be accompanied by an appropriate explanation e.g. subject refused, subject had to leave before test could be performed.

**3.** At the start of the study, the collection of source documentation begins. Once each participant has signed the approved informed consent including HIPAA authorization, medical records information may be obtained from the participant’s physicians and other providers, as necessary. This file should be updated at each subsequent visit. Documentation, outlining any issues associated with a specific participant’s involvement in the research study, should be updated as necessary at each subsequent study visit with any new medical conditions or with any past medical history that becomes known to the research team. Documentation should use the ALCOA criteria.

**4.** Examples of source documents are:

* Medical/hospital records
* Clinical and office notes
* Nursing notes and flow sheets
* Any research specific forms
* laboratory reports
* EKG’s
* subjects' diaries or evaluation checklists
* Orders and pharmacy dispensing records
* Photos
* Radiology reports and media
* Other records kept in departments such as pharmacy, laboratories, treatment areas, etc. involved in the research.

**5.** The original study documentation must be completed, signed and dated by the researcher who obtained the data.

**6.** Source documentation should be completed and filed at the end of study visit.

**7.** Assure sponsor requirements for source documents are met or provide justification to the sponsor why the sponsor requirement cannot be adhered to.

**8.** Case Report Forms and source data are maintained separately, but source documents should be available when the case report form is needed for sponsor verification.

**VII. QA**

 **N/A**

**VIII. APPENDICES/RESOURCES**

 **N/A**

**IX. RELATED SOPS**

 **N/A**