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| SOP Number:  [SOP NUMBER] – [VERSION] | Page Number:  1 of [X] | Effective Date:  [DATE] |

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| Originated by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |
| Reviewed by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |
| Approved by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |

##### Standard Operating Procedure (SOP)

**Study Source Documentation**

***Please note that italic font is used within templates to indicate areas where site-specific information must be included and to describe the type of information needed.***

1. SCOPE

This SOP applies to all research records and study documentation as applicable to clinical research studies conducted by Principal Investigators and research team members.

1. PURPOSE

The purpose of this SOP is to describe the process of documentation of study visits, study data and how to manage subject-specific documentation.

1. DEFINITIONS AND/OR ABBREVIATIONS & ACRONYMS (optional)
2. **Subject research record:** A set of documents needed to adequately support and verify data for a clinical research study for each study participant.
3. **Source data:** All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.
4. **Source document:** The original document, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing record, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files and records kept at the pharmacy, laboratories and medico-technical departments involved in the clinical trial).
5. **Case report form (CRF):** A printed, optical or electronic document designed to record all the information required to be reported by the protocol to the sponsor for each trial subject. A CRF is also considered a source document if it is where those source data are located.
6. **Certified copy:** A copy (regardless of the type of media used) of the original record that has been verified (e.g., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content and structure, as the original.
7. **Chart notes:** A summary of the clinic visits, including discussions with the subject and/or parents/legal guardian; lab results; vitals; etc. that paints a picture of what occurred during that visit.
8. **De-identified information:** Health information that does not identify an individual and provides no reasonable basis to believe that the information can be used to identify an individual.
9. GENERAL STANDARDS (Optional)
10. The site should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site’s trial participants.
11. All subject research records are the property of this institution and do not leave the hospital campus *[or other appropriate term for your facility]* except with the permission of the PI or research leadership. *[Add in your institutional policies regarding research records rules.]*
12. Templates for source documents should be used whenever possible.
13. Certified copies of some source documents may be requested by and supplied to the sponsor/CRO in a *DE-IDENTIFIED* manner compliant with HIPAA privacy regulations.
14. All source documents should include page numbers, subject ID and date of the study visit.
15. The protocol or PI should identify which research data points are to be captured in the source documentation.
16. Source documentation must be complete, dated and follow “ALCOA” principles:
    * + 1. Attributable
        2. Legible
        3. Contemporaneous
        4. Original [or exact (certified) copy]
        5. Accurate
17. Source documentation must use the following rules for error corrections:
    * + 1. Draw a single line through the incorrect information; initial, date and state reason for change (if necessary); and insert the correction.
        2. Never use pencil to write entries.
        3. Never use “white-out.”
        4. Never obliterate entries that require correction.
        5. Never destroy original documents, even if they require error correction.
        6. Do not post-date source document notes.
        7. Erroneous information should be crossed out with a single line to preserve legibility of the original data, then initialed and dated. Changes to the information should be noted adjacent to the cross-out, along with the reason for the change.
18. PROCESS AND PROCEDURES
19. Case Report Forms Used as Source Documentation
    1. CRFs used as source documents are not meant to replace ALL source documentation; there will be a need for documents from the medical record, if this is where the data are first documented.
    2. Data obtained after a study visit and recorded on the CRF as source documentation must be signed/initialed and dated.
    3. CRFs can be used as source documents if they are signed and dated by the person who completed the form.
    4. If data are transcribed from another source onto the CRF, the CRF is not considered to be the original source document and cannot be used as source documentation. Examples of data that are routinely transcribed from other sources include laboratory results, radiology reports and histories documented in referral letters.
    5. If the CRF is used as source documentation, it should be used consistently as source documentation during the trial for all subjects at the site.
    6. CRFs used as source documentation must be maintained and made available for all types of reviews in the same manner as other research-essential documents.
20. Medical Record Notes
    1. This refers to all notes related to study visits that are entered in the research or medical record by site staff (e.g., progress note, nursing note, clinic note).
    2. Documentation should include adequate details to permit evaluation of the conduct of a study and the quality of the data produced.
    3. Progress notes should be concise but provide enough information to clearly demonstrate the participant’s study-related activities as well as the order of their study events.
    4. This does NOT apply to source documents that originate outside of the site, since the individuals making the notations may not be involved with the study.
    5. All data entries must be signed/initialed and dated by the person making the entry each time a new entry is made.
       * 1. Subsequent entries by different people must be signed/initialed and dated by the individual making the entry.
         2. Exceptions:
21. Multiple entries to a source document made by the same person on the same day require only one signature/initials and date on the page.
22. A single date on a document with multiple entries is permitted if all entries were made on that same date.
    1. *Follow your institution’s record-keeping procedures if they are more stringent.*
23. Laboratory Records
    * + - 1. Keep all study-related laboratory records.
          2. Keep all study-related central laboratory records.
          3. Document any abnormal laboratory values and how they were clinically managed.
          4. All laboratory results should be reviewed and signed in a timely manner by the PI.
24. Pharmacy Records
    1. Refers to copies of pharmacy prescriptions that are signed by all appropriate parties.
    2. Document the following information:
       1. Who dispensed the investigational product.
       2. The dosage of the investigational product.
       3. How the investigational product was administered.
       4. Any reactions to the investigational product and the clinical management.
25. Supporting Documents
26. HIPAA Privacy Rule - §164.514(a)-(b).
27. 21 CFR 312.62 - Investigator recordkeeping and record retention
28. ICH E6 (R2) - Good Clinical Practices: Consolidated Guidance
29. REFERENCES (if applicable)

Include both local and federal regulations cited to create the SOP.

1. ATTACHMENTS
2. Attachment 1 – Attachment title: List of Source Documents
3. REVISION HISTORY

Major changes should be identified. Show history in descending order of versions.

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| Version Number | Summary of Changes | Replaces |
|  |  | Document Number, Revision Number |
| 02 | Enter the summary of changes in a bulleted list, highlighting the major changes | SOP XXX-###, 01 |
| 01 | Original Document |  |

1. FOOTER

[Version number], [Version date], [Page count], [Any sort of a confidentiality statement]