

SOURCE DOCUMENTS

1. **OBJECTIVES:** Describe procedures to create and maintain source documents for study participants in order to verify data integrity
2. **DEFINITION:** Source documents are any forms, records or documents where the subject's study data is first recorded. The information captured in source documents includes clinical findings, observations, and other study activities and is used to complete the Case Report Forms (CRFs)
3. **RESPONSIBILITIES:** Principal Investigators and/or designee are responsible for maintaining complete and accurate Source Documents
4. **WHY ARE SOURCE DOCUMENTS IMPORTANT?**
 - a) To verify that the subject is a participant in the study
 - b) To increase data consistency and ensure that information required for transcription to the CRFs is captured accurately.
 - c) To verify data integrity and that the study is being conducted properly
 - d) It is a "Good Clinical Practice" and is FDA required
 - e) Inadequate source documents can result in inadequate research
5. **PROCEDURES**
 - a) Each Investigator should create source documents for each subject to ensure consistency with documentation. Each source document page should be signed and dated.
 - b) Study data should NOT be entered directly onto Case Report Forms (CRFs) unless the data is not normally recorded as primary source documents (e.g. self administered forms)
 - c) If CRFs are used as the source document, the protocol or study operations manual should indicate so. It is advised to write a note in the study file reflecting this
 - d) Some sponsors may provide study-specific source documents to the site
 - e) If creating your own source documents, consider using copies of progress notes, lab results, procedure reports, etc.
 - f) It is advisable to use the study ID and to delete any subject's identifying information in source documents wherever you can
 - g) Corrections should be crossed out with one line and initialed and dated by the person making the correction
6. **INFORMATION CAPTURED IN SOURCE DOCUMENTS INCLUDE:**
 - a) ALL activities needed for evaluation of the research study
 - I. Sponsor communications
 - II. Test article accountability (if applicable)
 - III. Subjects who are lost to follow-up and the attempts to contact the subject

- IV. If something was attempted and not completed
- b) In regards to **study procedures**, document:
 - I. Completion of diaries and/or questionnaires
 - II. Completion of all protocol-specific procedures; include dates, times, and results
 - III. Any items that are defined in the protocol
 - IV. vital signs (if applicable)
- c) In regards to **completing a diary** and other study-specific instructions:
 - I. Document any instructions provided to the subject (or relative)
 - II. Document the assessment of the subject's understanding
- d) In regards to **medical history**:
 - I. Verify the study inclusion/exclusion criteria and document
 - II. Establish a baseline
 - III. Verify and record study-specific medical history
- e) In regards to **physical exam**:
 - I. Record any changes since last exam
 - II. Record the date of exam
 - III. Record vital signs
 - IV. Document any items defined in the protocol
- f) In regards to **medications**:
 - I. Record all prescribed and over the counter medications as indicated by the subject's medical record
 - II. Record route, frequency, dose, start & stop dates, and indication of all medications
 - III. Verify and record that the subject is not taking drugs excluded by the study
- g) In regards to **study drugs**:
 - I. Document any instructions given to the subject about taking, storing, and returning study drug
 - II. Document any discussion with the subject of consequences of non-compliance
- h) In regards to **study visits**:
 - I. Record date and time of scheduled visits
 - II. Document subject appointment no shows, and attempts made to re-schedule
- i) Other documentation may include:
 - I. Protocol deviations
 - II. Explanation of missing or lost medication, diaries, etc.
 - III. Phone calls or emails relevant to the study