SOURCE DOCUMENTATION
PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES

Source documentation is wherever subject study data is first recorded and contains all the information pertaining to the subjects study participation. Source documents are necessary to verify the integrity of study data, protocol compliance, subject eligibility and participation. Investigators are required to maintain accurate and complete documentation. All information entered on a CRF or data collection sheet must be supported by source documentation.

Source documents include but are not limited to:

- Hospital records
- Progress notes
- Admission and discharge summaries
- Pathology, Radiology and Surgical reports
- MD referral letter
- Subject diaries
- X- rays

Investigator Responsibilities:

- Document subject eligibility and the process by which informed consent was obtained prior to the performance of any study procedures. All subjects enrolled in a study must have adequate documentation in their study file and/or medical record indicating that they have been included or excluded appropriately.
- Record details of every subject visit. Include relevant e-mails and written correspondence.
- Ensure that information requiring medical judgment, such as out-of-range lab values, causality of adverse events or significant change from baseline are signed/initialed and dated by a qualified investigator.
- Record all adverse events, subject complaints, protocol deviations/violations. Documentation should support details reported to the IRB.
- When using a checklist or data collection sheet as source, complete all entries. To avoid leaving blanks, where appropriate use “n/a” to indicate not applicable; “n/d” to indicate not done or “unk” to indicate unknown.
- Include subject identification on each page.
- Ensure that documentation is legible, signed and dated by the individual recording the information.
- Use ink to complete entries. Do not use pencil.
- Ensure that all CRF/data collection sheets are initialed/signed and dated by person making the entry, reviewing and/or validating information the document contains.

- Initial and date any cross-outs/corrections made in source documents. Do not use correction fluid. Use a single-line cross-out to ensure that the correction being made does not obscure the original entry.
- Missing data or data discrepancies should be explained.

Additional helpful hints for completing CRFS:

- All CRF entries must be verifiable by the source document supporting it.
- CRF data should be entered in a timely fashion.
- Anyone entering information or signing off on a CRF must be included on the signature log.
- Do not write in the margins of a CRF. Record additional information in the appropriate section such as “comments” or additional information”.
- Comply with sponsor’s guidelines/instructions for completing CRFs.

NOTE: If data is recorded directly on a CRF there should be at a minimum, an entry in the subject's medical record or subject file that records the date information was obtained, how (e.g. physical exam) and by whom.