# PREPARING SOURCE DOCUMENTATION WORKSHEETS FOR SITES

1. **PURPOSE**

 To describe the guidelines and requirements for preparing source document worksheets for a specific clinical trial conducted by <name of Sponsor/Investigator>.

1. **SCOPE**

 Applies to all designated individual <insert title> who monitor clinical studies for <name of Sponsor/Investigator>.

## BACKGROUND

Sponsor/Investigators are required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each subject. Source documents include all original records from which clinical trial data collection forms/CRFs are completed and all medical charts and records available to the clinical investigator.

 To aid Sponsor/Investigators / sites in the capture of clinical trial data, source documentation worksheets may be developed to ensure all protocol required data that is not captured in the medical record is recorded to support data for the clinical study.

 **In accordance with:**

 Title 21 CFR 50.26 ‑ Documentation of Informed Consent

 Title 21 CFR 54.155 ‑ Records Regarding Subjects

 Title 21 CFR 312.62 ‑ Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials

 Title 21 CFR 812.140 ‑ Investigator Record Keeping and Record Retention for Device Trials

 ICH GCP Consolidated Guideline ‑ Part 4.9 Records and Reports

 Clinical Investigational Site SOP CL 007 and CL 008 ‑ Informed Consent

1. **PROCEDURE**
	1. <Title of Person> at <name of Sponsor/Investigator> in conjunction with data management, the medical director and <insert other personnel here> will review protocol requirements, data collection forms/CRF entries and standard medical records for the condition (symptoms, disease, deformity, etc.) under study and develop source documentation worksheets to support clinical trial data collection. These will NOT be a copy of the data collection forms/CRF, but will contain entry blanks for study required data not routinely collected by the investigators such as:
		1. Demographic data not recorded in the medical record.
		2. Evidence supporting the diagnosis or condition for which the subject is being enrolled in a study and all documentation supporting the medical and surgical history of the subject.
		3. Documentation that the subject meets all inclusion criteria and documentation that no exclusion criteria have been met.
		4. Medication history (including start and stop dates) and indications for which the medications are taken. (including OTC and herbal/supplements).
		5. Physical exam findings necessary to document protocol data (i.e. NIH Stroke Scale).
		6. Randomization.
		7. Study kit number or lot / serial number of device.
		8. Calibration checks (if required).
		9. Pre and post assessments (if protocol required).
		10. Adverse event and unexpected adverse drug/device effect findings, follow-up and evaluations.
		11. Other.
	2. The assigned <insert other personnel here> will review protocol requirements and data collection procedures with applicable clinical site research personnel. The <insert correct title>will work closely with clinical staff to ensure protocol compliance and appropriate documentation of protocol‑required data points by training and review of documentation.
	3. All documentation pertaining to clinical assessments and medical evaluations should be signed and dated by the appropriate healthcare practitioner as indicated on the delegation of authority form. Any deviations from this requirement will be captured in a monitoring report.
	4. The monitor or designee will ensure that personal identifying information on copies of source documents to be submitted to the Sponsor/Investigator or IRB in support of data collection forms/CRF entries will be blackened out or obliterated except for the subject's initials and study identification number in order to protect patient confidentiality.