# DOCUMENTING DELEGATION OF AUTHORITY

1. **PURPOSE**

To establish guidelines and requirements for documentation of delegation of authority by the principal investigator to investigational clinical site research personnel.

1. **SCOPE**

This SOP applies to all clinical studies conducted by <name of Sponsor/Investigator>.

1. **BACKGROUND**

The Sponsor/Investigator is responsible for the overall conduct of a research study at the clinical site however; delegation allows other investigators and site personnel to actively participate in the implementation and conduct of a clinical trial.

**In accordance with:**

21CFR312 & 812 Responsibilities of Sponsor/Investigators

ICH GCP Consolidated Guideline ‑ Part 4. Investigator

1. **PROCEDURE**
   1. The Sponsor/Investigator will assume full responsibility for the clinical investigation by his/her signature on the Form FDA 1572 for investigational drug research (21 CFR 312) or on the investigator’s agreement for medical device research (21 CFR 812) and the clinical trial agreement (contract).
   2. *(Sponsor/Investigators may select sub‑investigators to assist with an investigation.)* Sub‑investigators may conduct the procedures and activities required by the protocol under the supervision of the investigator. Sub‑investigators are listed on the Form FDA 1572 or will sign a separate investigator’s agreement as appropriate.
   3. Original signed investigator agreements or FDA 1572 documents must be signed prior to the start of a study. Sponsor/Investigator regulatory staff will keep an orginal at the site in their regulatory files.
   4. If Sponsor/Investigators use multiple research facilities for study evaluations, these locations must be listed on the Form FDA 1572 (if a drug study) or on the site information list if a device study.
   5. A list of appropriately qualified persons to whom the Sponsor/Investigator has delegated significant study‑related duties (ICH GCP 4.1.5) will be completed by research personnel prior to the start of the study. The <insert correct title> will be responsible for making sure this is completed. This list may be in the form of a site personnel sign in sheet or a Delegation of Authority Form, and will be maintained as part of the official site regulatory files. This form should be updated as personnel change during the course of the clinical trial. It is the responsibility of the <insert correct title> at the site to ensure this is done.