1. PURPOSE

To establish the requirements for documentation of delegation of authority by the Principal Investigator (PI) to clinical research personnel.

2. SCOPE

Applies to all clinical site research personnel involved in the implementation and coordination of clinical investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for the training of all Investigators and clinical research staff.

4. BACKGROUND

The PI is responsible for the overall conduct of a research study at the clinical site; however, delegation allows Investigators, Study Coordinators (SC), and other clinical research personnel to actively participate in the implementation and conduct of a clinical trial.

5. PROCEDURE

5.1. The PI will assume full responsibility for the clinical investigation. This may be evidenced by his/her signature on the Form FDA 1572 for investigational drug research, or on the Investigator's Agreement for medical device research.

5.2. PIs may select additional Investigators to assist with an investigation. Investigators may conduct the procedures and activities required by the protocol under the supervision of the PI. Investigators are to be listed on the Form FDA 1572 or Investigator's Agreement, but are not required to sign the Form FDA 1572.

5.3. Investigators may use multiple research facilities for study evaluations. These locations must be listed on the Form FDA 1572. If multiple research facilities are used, then the PI and/or additional Investigators should be involved in the prescriptive treatment of the subjects at those locations, or be responsible for the supervision of the research study team who work there.

5.4. PIs, Investigators, SCs, and other designated clinical research personnel may collect the protocol-required data and interact with the study subjects. Regardless of who completes the Case Report Forms (CRFs), the PI must review the source data and the

data reported on the CRFs and sign the bottom of the source documentation for validation.

5.5. The SC should assist the PI to develop a list of appropriately qualified persons to whom the Investigator has delegated significant trial-related duties [ICH GCP 4.1.5]. This list may be in the form of a study personnel identification sheet, as required by many sponsors, or a Delegation of Authority Documentation Log, and will be maintained as part of the Investigator regulatory files. Activities are officially deemed as delegated once the PI signs the completed Delegation of Authority Documentation Log.

5.6. Research staff who perform only standard-of-care procedures in connection with a protocol (e.g., EKG technicians, hospital nursing staff) are not required to be listed on the Delegation of Authority Documentation log.

5.7. The Regulatory Document Specialist (RDS) should place the signed, completed Delegation of Authority Documentation Log in the Investigator regulatory files.

5.8. The SC will be responsible for updating documents pertinent to delegation of authority. In the event of clinical research personnel changes, all applicable documents in the Investigator regulatory files will be revised, appended, or re-executed. These documents include, but are not limited to, the study personnel identification sheet, Form FDA 1572 or Investigator's Agreement, Informed Consent Form, Institutional Review Board (IRB) application, and patient education/instructional materials.

6. TERMS & ABBREVIATIONS

CRF Case Report Form
FDA Food and Drug Administration
IRB Institutional Review Board
PI Principal Investigator
RDS Regulatory Document Specialist
SC Study Coordinator

7. REFERENCES

7.1. Title 21 CFR 312.60 - General Responsibilities of Investigators
7.2. Title 21 CFR 312.61 - Control of the Investigational Drug
7.3. Title 21 CFR 812(e) - Responsibilities of Investigators
7.4. GCP Consolidated Guideline - Part 4. Investigator

8. ATTACHMENTS

8.1. Delegation of Authority Log