**PURPOSE:** To establish guidelines and requirements for completing and maintaining source documentation and case report forms (CRFs) at the site.

**SCOPE:** Applies to all site personnel involved in the implementation and coordination of clinical research.

**PERSONNEL RESPONSIBLE:**  Principal Investigator --and when delegated by the Principal Investigator--Sub-Investigators, Study Coordinator and/or other pertinent staff. The Principal Investigator is responsible for the data reported to the sponsor in the CRF. The Principal Investigator may delegate appropriate personnel to complete this task.

**PROCEDURES:**

* Case Report Forms will be completed and maintained in accordance with the applicable GCP regulations (listed below in “resources” section)

**RESOURCES**:

* 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

**TOOLS:**

* Source documents
* Case Report Forms
* Sponsor provided Case Report Form Instructions