SECTION: Research and Compliance				NUMBER: CLN-17.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/14/2009	REV. B: 8/26/2010	REV. C:
TITLE: Preparing and Managing Case Report Forms			Page 1 of 3	

1. PURPOSE

To establish requirements for completing and maintaining Case Report Forms (CRFs) at the clinical investigational site.

2. SCOPE

Applies to all personnel involved in the implementation and coordination of sponsored 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 all aspects of a clinical study by maintaining accurate study documentation, including source documents (SDs) and CRFs.

4. BACKGROUND

CRFs are data collection tools utilized to submit clinical data from investigational sites to the study sponsor for data analysis. CRFs are typically designed and supplied by the study sponsor. Clinical research personnel transcribe study data from SDs onto CRFs (paper or electronic). The submission process of completed CRFs is dictated by sponsor Standard Operating Procedures (SOPs). Subsequent changes in clinical data submitted to the trial sponsor must be made in accordance with sponsor policies and with Investigator approval.

5. PROCEDURE

5.1. The PI is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports. The PI may delegate CRF completion and maintenance to appropriate clinical research personnel.

5.2. The SC and/or other designated personnel will provide the sponsor representative with the site's correct shipping address for all clinical supplies that are to be sent to the site.

5.3. The SC and/or other designated personnel will perform an initial inventory upon receipt of the CRFs and related study supplies. Supplies will be unpacked and stored in a secured, limited access area.

5.4. The SC and/or other designated personnel will contact the designated sponsor representative in the event of shipment discrepancies, problems, or need for additional CRFs or other supplies.

5.5. The SC and/or other Investigator-authorized designees will complete CRFs in a timely manner for each subject enrolled in a research trial (recommended within two working days of visit). Data reported on the CRFs should be consistent with the SDs; any discrepancy should be explained.

5.6. The SC and/or other Investigator-authorized designees shall make entries on CRFs according to sponsor guidelines. In the event that written guidelines are not provided to the clinical site research personnel, specific instructions from the sponsor representative should be requested.

5.7. Investigator-authorized designees may make corrections to the CRFs as authorized by the PI. Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections. Records regarding changes and corrections made to clinical data should be retained.

5.8. The PI will sign required signature pages after data is reviewed, documenting that the entries are complete and accurate.

5.9. The SC will submit completed CRFs as instructed by the sponsor. Changes must not be made to the Investigator's copy of CRFs once original CRFs have been submitted to the sponsor, unless specifically requested by the sponsor. If additions or corrections that need to be made after CRF submission are noted by clinical research personnel, the sponsor representative will be notified of the necessary modification(s). Then, changes can be made according to sponsor policy.

5.10. Data clarifications may be requested by the sponsor after submission of the CRFs as part of the sponsor data management edit procedures and data analysis. The PI or designee should process the data queries and clarifications in a timely manner. Copies of all sponsor-requested data edits should be retained with the site's study file as part of the official audit trail. The PI is responsible for the accuracy of all data.

5.11. A legible copy of all CRFs will be maintained at the investigative site or appropriate designated storage facility. The long-term maintenance of the Investigator's copies of the CRFs is the responsibility of the PI who conducted the study. The PI will be required to retain all study documentation until notified in writing by the trial sponsor, according to contractual agreement, but for not less than a period of two years after the

final action of the FDA for the marketing application or two years after the marketing application has been officially discontinued by the sponsor [21 CFR 312.62 (c) and 812.140(d)].

5.12. The Quality Control Coordinator (QCC) or designee should perform a Quality Assurance Audit on all CRFs prior to a sponsor and/or FDA audit. The Office of Research and Compliance must be notified of all impending FDA audits.

6. TERMS & ABBREVIATIONS

CRF Case Report Form
FDA Food and Drug Administration
PI Principal Investigator
SC Study Coordinator
SD Source Documents
SP Study Participant
QCC Quality Control Coordinator

7. REFERENCES

7.1. Title 21 CFR 312.62 - Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
7.2. Title 21 CFR 812.140 - Investigator Record Keeping and Record Retention for Device Trials
7.3. ICH GCP Consolidated Guideline - Part 4.9 Records and Reports
7.4. Clinical Research Site SOP 10.00 - Documenting Delegation of Authority

8. ATTACHMENTS

None