

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-15.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/14/2009	REV. B: 8/26/2010	REV. C:
TITLE: Recording Data in the Case Report Form			Page 1 of 2	

1. PURPOSE

To standardize the process of data entry in the Case Report Form (CRF) and control for error.

2. SCOPE

Applies to all site personnel involved in the implementation and coordination of sponsored clinical investigations involving human Study Participants (SPs).

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

3. RESPONSIBILITIES

The primary responsibility for the accurate completion of CRFs is the PI, who may delegate the process to study staff trained in the process and requirement of absolute accuracy.

4. BACKGROUND

The CRF is the standard way that a clinical research unit transcribes source data from forms collected during study conduct onto the sponsor's forms, which are added to the drug/device development data. This data will eventually be submitted to the FDA for its assessment of the acceptability of the test agent for general use in patients.

5. PROCEDURE

- 5.1. Entries into the CRF are made by the SC or staff trained in the correct transfer of data from source data forms, unless otherwise requested by the sponsor. These entries are made when required prior to the completion of the study.
- 5.2. Most sponsors require that all entries into the CRF must be made with a black ballpoint pen.
- 5.3. If the CRF has carbon copies or pressure-sensitive pages that follow the original, an additional page must be placed after the CRF page to prevent the imprint of the pen from transferring to the following page.
- 5.4. Errors are corrected by drawing one line through the error. The correct entry must be written in and this entry must be initialed and dated. The 'error' must be readily seen and the correction or clarification clear to follow.

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- 5.5. Corrections are signed (initials are sufficient) and dated when they are made. Under no circumstances will any staff pre-date or post-date any correction or addition to either the source data or to the CRFs.
- 5.6. At the completion of the CRF, the PI will sign the CRFs where indicated to verify that the information entered is accurate and complete.
- 5.7. The sponsor may send monitors/auditors to the site to examine the CRFs for errors. If errors are found, they will be queried and then changed/modified to reflect the correct entry.
- 5.8. The SC must examine the entries for accuracy and to decrease the margin of error prior to a site visit by a monitor.
- 5.9. Electronic CRF training and use should follow the instructions provided by the study sponsor and/or vendor of the electronic CRF software.

6. TERMS & ABBREVIATIONS

CRF	Case Report Form
FDA	U.S. Food and Drug Administration
ICH	International Conference on Harmonisation

7. REFERENCES

- 7.1. ICH GCP Guidelines 4.9

8. ATTACHMENTS

None