SECTION: Research and Compliance				NUMBER: CLN-14.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/14/2009	REV. B: 8/26/2010	REV. C:
TITLE: Document Completion			Page 1 of 4	

1. PURPOSE

To standardize documentation procedures to a) maintain a level of performance for research staff consistent with Good Clinical Practice (GCP), b) provide documentation expectations for research staff, and c) ensure that the activities related to the conduct of a study (staff performance), as well as Study Participant (SP) safety and welfare, are correctly and completely documented.

2. SCOPE

Applies to all site personnel involved in the implementation and coordination of clinical investigations involving human 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 PI is responsible for all aspects of a clinical research study by maintaining accurate study documentation, including source documents and Case Report Forms (CRFs).

4. BACKGROUND

The PI is responsible for the information from a study that is recorded on all source documents. She/he must take great care in seeing that all clinical research staff know and understand the importance of research data.

The goal of the research unit is to conduct studies with human volunteer SPs that are safe for the SPs and error-free in the recording of the data generated from the study. The goal is to have all recorded data ALCOA:

Accurate
Legible
Contemporaneous
Original
Attributable

5. PROCEDURE

5.1. Recording of Data

5.1.1. All recording is in blue or black ink, unless otherwise specified.

5.1.2. All copies of multiple-copy forms must be legible.

5.1.3. All data entered into CRFs must be legible.

5.1.4. Appropriate units are used to record lab results.

5.1.5. Errors are crossed out with a single line and error corrections are initialed and dated.
5.1.6. No whiteout or erasures are permitted.
5.1.7. Dates are recorded as MM/DD/YY (e.g., 03/21/05) or DD/MMM/YY (e.g., 21/MAR/05), or as otherwise specified by the study sponsor.
5.1.8. Omissions are explained in writing either as "not done," "not applicable," or "unknown."
5.1.9. All entries on records of any type are dated, signed, and printed by the person who made the notation (attributable) at the time they are done (contemporaneous).
5.1.10. All pertinent observations or communications (verbal or otherwise [e.g., phone, email, faxes]) must be documented appropriately on standardized 'Note to File (NTF)' or communication log.
5.1.11. All original documentation (raw data) must be included with source documents.

5.2. Source Documents
5.2.1. Raw data are all records of original observations, measurements, and activities (e.g., laboratory notes, evaluations, data recorded by automated instruments) without conclusions or interpretations. (e.g., even notes written on any pieces of paper, etc.).
5.2.2. Source documents are those original pieces of subject information that are needed to adequately support and verify subject information to be recorded on the CRF.
5.2.3. Source documents are crucial because they are used to document that all original data have been accurately recorded on CRFs and that the study was performed as outlined in the protocol.
5.2.4. Source documents are documents used for information collected on all studies (e.g., demographics, phone logs, deviation forms).
5.2.5. Anything heard, said, or done during the study must be recorded on a source document. "If it is not documented/written, it wasn't done and didn't happen."

5.3. Case Report Forms (Data Collection Forms)
5.3.1. CRFs are final, study-specific documentation forms, typically provided by the sponsor.
5.3.2. In most instances, CRFs are not used as source documents, unless:
5.3.2.1. The CRF calls for data that would not usually be recorded in a data source document (e.g., all items in the Visual Analog Scale).

5.3.2.2. The protocol identifies specific data that are to be entered directly on the CRF.

5.3.2.3. Copies of portions of the CRF may be used for source documents if allowed by the sponsor.

5.4. Direct-to-Computer Data Entry

5.4.1. Subject data entered directly into a computer are considered to be the original or true copy of the raw data, whether printed as a hard copy or stored in the computer.

5.4.2. Conditions for use:

5.4.2.1. The software permits only authorized staff access

5.4.2.2. The software is validated and "tamper-proof"

5.4.2.3. A hard copy of the data can be produced easily

5.4.2.4. If not already provided by the sponsor, instructions are obtained on access restrictions and security, frequency of data transfer, computer location, computer maintenance instructions, etc.

5.4.2.5. Confidentiality is maintained consistent with federal (HIPAA) and local regulations

5.5. Data Resolution

5.5.1. Staff is responsible for checking subject data for completeness, accuracy, and consistency, and for verifying CRF data against source data prior to sponsor submission.

5.5.2. Any sponsor-requested changes/corrections to CRF data will not be considered unless made in writing.

5.5.3. Staff will not make any changes/corrections to CRFs unless they agree that the changes/corrections are consistent with the facts as recorded in the source data.

5.5.4. Any work product (including changes) requested after contract expiration must be referred to the Grants and Contract Coordinator for determination of the need for "out of scope" billing and approval of staff time.

6. TERMS & ABBREVIATIONS

CRF Case Report Form
GCP Good Clinical Practice
HIPAA Health Insurance Portability and Accountability Act
NTF Note to File
PI Principal Investigator
SP Study Participant

7. REFERENCES

7.1. ICH GCP Guidelines 4.9

8. ATTACHMENTS

None