SECTION: Research and Compliance				NUMBER: CLN-5.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/21/2009	REV. B: 8/25/2010	REV. C:
TITLE: Site Initiation Visit			Page 1 of 2	

1. PURPOSE

To outline activities required when an initiation visit is scheduled at an investigational site.

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 (SC), and other designated site personnel.

3. RESPONSIBILITIES

4. BACKGROUND

Sponsors conduct initiation visits to ensure that the Investigators are prepared to initiate and implement the study. In some instances, sponsors elect to allow a combination of Investigator meetings and/or pre-study qualification visit to suffice as an initiation visit.

5. PROCEDURE

5.1. The PI or designee will schedule and arrange the initiation visit, as requested by the sponsor representative, at a mutually agreeable time. Participants should include sponsor representative(s), PI, additional Investigators, other clinical research personnel, pharmacy, lab, and other institutional staff as deemed necessary by the sponsor.

5.2. If requested by the sponsor, the Investigator or designee will schedule a tour of the facilities, to be conducted during the initiation visit. The tour should establish that the necessary equipment and temperature logs are available, along with documentation of maintenance, that there is adequate space to conduct the study, and that there is a secure, limited-access area for study supplies and investigational product (IP) storage.

5.3. The Investigator or designee should provide copies of relevant, appropriate study-related materials to all meeting attendees prior to the initiation visit.

5.4. Each site participant should prepare for the meeting by reviewing the protocol and noting areas of discussion and any questions.

5.5. When possible, subject screening, randomization, and enrollment procedures should be reviewed in detail with the sponsor representative(s).

5.6. When possible, initial IP inventory should be reviewed with the sponsor representative(s). IP storage, preparation, dispensation, and accountability should be reviewed with the individual(s) who prepare and dispense IP.

5.7. When possible, and as applicable, laboratory specimen collection, processing, and shipping procedures should be reviewed with the individual(s) who process laboratory specimens and the sponsor representative(s).

5.8. The SC should review the Case Report Form (CRF) completion guidelines, monitoring procedures, and expectations with the sponsor representative(s).

6. TERMS & ABBREVIATIONS

CRF Case Report Form
IP Investigational Product
PI Principal Investigator
SC Study Coordinator
SP Study Participant

7. REFERENCES

7.1. Guidelines for Monitoring of Clinical Investigations, 1988
7.2. ICH GCP Consolidated Guideline - Part 4 Investigator
7.3. ICH GCP Consolidated Guideline - Part 5.6 Investigator Selection

8. ATTACHMENTS

None