SECTION: Research and Compliance				NUMBER: CLN-4.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/21/2009	REV. B: 8/26/2010	REV. C:
TITLE: Site Qualification Visit			Page 1 of 3	

1. PURPOSE

To outline the activities required to facilitate the investigational site selection process.

2. SCOPE

Applies to all site personnel involved in the implementation and coordination of clinical investigations involving human subjects that have site-specific requirements from a study sponsor.

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

3. RESPONSIBILITIES

4. BACKGROUND

Sponsors conduct pre-study qualification visits, generally referred to as "site visits," to select qualified Investigators and to determine the investigative site's ability to conduct the clinical investigation prior to commencement of the study. In order to be selected, Investigators must be qualified by training, education, and experience and have adequate resources, staffing, and facilities to conduct the proposed investigation. In some instances, sponsors elect to allow some combination of Investigator meetings and/or an initiation visit to suffice as a pre-study qualification visit.

5. PROCEDURE

The Investigator or designee will:

5.1. Schedule and arrange the site visit as requested by a sponsor representative. Attendees may include sponsor representative(s), the PI, Investigators, other clinical research personnel, pharmacy, and other ancillary staff as deemed necessary by the sponsor.

5.2. Schedule a tour of the facilities to be conducted during the pre-study qualification visit. The tour should establish that the necessary equipment and capabilities for equipment (e.g., internet lines, phone lines, etc.) are available, that there is adequate space to conduct the study, and that there is a secure, limited-access area for study supplies and investigational product storage. All study medication should be double-locked/temperature controlled. Daily temperature logs for all equipment and drug storage should also be mentioned. Also regarding equipment, maintenance should be

mentioned, including how often equipment (e.g., centrifuge and scales, sphygmomanometers, etc.) is calibrated.

5.3. Provide copies of relevant, appropriate study-related materials (i.e., copy of protocol and study visit schedule) to all meeting attendees prior to the pre-study qualification visit.

5.4. Obtain documentation to demonstrate that the site has the potential to recruit the appropriate number of subjects within the time frame specified in the study protocol [ICH GCP 4.2].

The RDS will:

5.5. Provide the sponsor representative with documentation of the local clinical laboratory's current licensure or accreditation, along with current normal reference ranges for applicable tests.

5.6. Provide the sponsor representative(s) with current copies of clinical site research personnel's curricula vitae (as required by sponsor).

5.7. Provide the sponsor representative other certifications and/or training (e.g., International Air Transport Association (IATA) training, dry ice certification, etc.).

5.8. Provide the sponsor representative(s) with information specific as to how research activities are conducted at the site, including the responsibilities of clinical site research personnel [ICH GCP 4.2].

5.9. Provide the sponsor representative(s) with Institutional Review Board (IRB) requirements and scheduled meeting dates.

The PI and/or applicable clinical research site personnel will:

5.10. Verbalize the Investigator's responsibility for obtaining IRB approval for the study protocol, consent form, any modifications or revisions, IRB renewal, patient education materials, and any advertisements to be used for the recruitment of study subjects.

5.11. Verbalize the Investigator's responsibility for safety reporting and record keeping.

6. TERMS & ABBREVIATIONS

IRB Institutional Review Board
PI Principal Investigator
RDS Regulatory Document Specialist
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