| SECTION: Research and Compliance | | | | NUMBER: CLN-9.00 |
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| CHAPTER: Clinical Research Standard Operating Procedures | ISSUED: 7/28/2008 | REV. A: 4/21/2009 | REV. B: 8/25/2010 | REV. C: |
| TITLE: Role of the Study Coordinator | | | Page 1 of 2 | |

## 1. PURPOSE

To describe the duties required of a Study Coordinator (SC).

## 2. SCOPE

All SCs who conduct study-related procedures involving human Study Participants (SPs).

## 3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for the training of all Investigators, Study Coordinators (SCs), and other clinical research staff.

## 4. BACKGROUND

Delegation of clinical research activities by the PI allows research personnel to actively participate in the implementation and conduct of a clinical trial.

## 5. PROCEDURES

5.1. **Recruitment.** SCs are responsible for recruiting and enrolling SPs into clinical trials, as well as following their progress throughout the study. Recruitment of SPs may be performed via Institutional Review Board (IRB)-approved*:

- 5.1.1. Advertising
- 5.1.2. Phone interviews
- 5.1.3. Clinician referrals
- 5.1.4. Posting of fliers
- 5.1.5. Chart review

*The type of strategy utilized is based upon the type of the study.

5.2. **Patient Screening.** The SC is responsible for the initial screening of the SP.

- 5.2.1. This may take place by a phone screen or on-site pre-screen visit with the SP.
- 5.2.2. Any documentation generated from this process must be kept in accordance with sponsor requirements, if applicable.
- 5.2.3. From this initial screening, the SC and/or designee is responsible for scheduling a screening visit with the SP and the study physician or PI.

5.3. **Informed Consent.** At the screening visit, the first item to be completed is the initial informed consent process (See SOP CLN-12.00, “Obtaining and Documenting Informed Consent”). No study procedures shall commence until the informed consent process has been completed.

5.4. **Study Procedures.** After the subject (or legal representative) has provided written informed consent, the SC may proceed with the conduct of the study.

5.4.1. Appropriate forms must be completed by the SC and PI (see SOPs CLN-16.00, "Preparing and Managing Source Documents" and CLN-17.00, "Preparing and Managing Case Report Forms (CRFs)").

5.4.2. The SC and/or designee is responsible for scheduling follow-up visits, coordinating the PI's schedule to that of the SP.

5.4.3. The SC and/or designee will perform assigned duties related to the study, such as conducting rating scales, measuring vital signs, drug accountability, drawing blood, obtaining urine samples, monitoring adverse events, shipping laboratory samples, performing electrocardiograms (ECG), and all other protocol-mandated acts or procedures.

5.4.4. SCs shall identify reportable unanticipated problems, including protocol-defined serious adverse events (SAEs), protocol violations, and deviations and other reportable events, according to IRB Policy 134, "Reportable New Information."

5.5. **Study Document Maintenance.** In addition to assisting in the conduct of the study, the SC and/or designee is responsible for keeping current on all study documentation, including regulatory documentation.

5.6. **Interacting with Monitors.** The SC will also be responsible for interacting with the clinical research associate (study monitor) during monitoring visits and responding to any data queries that are generated.

## 6. TERMS & ABBREVIATIONS

**CRF** Case Report Form
**IRB** Institutional Review Board
**SAE** Serious Adverse Event
**SC** Study Coordinator
**SP** Study Participant
**PI** Principal Investigator
**SOP** Standard Operating Procedure

## 7. REFERENCES

7.1. ICH GCP Guidelines Section 4.2.3
7.2. ICH GCP Guideline Section 4.2.4

## 8. ATTACHMENTS

None