

## **POLICIES AND PROCEDURES**

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|--|----------------------|----------------------|----------------------|---------|
| SECTION:<br>Research and Compliance                            |                      |                      | NUMBER:<br>CLN-6.00  |         |
| CHAPTER:<br>Clinical Research Standard Operating<br>Procedures | ISSUED:<br>7/28/2008 | REV. A:<br>4/21/2009 | REV. B:<br>8/25/2010 | REV. C: |
| TITLE:<br>Site Monitoring Visits                               |                      |                      | Page 1 of 2          |         |

### **1. PURPOSE**

To outline activities required for facilitating monitoring visits during the course of a clinical investigation involving human Study Participants (SPs).

### **2. SCOPE**

Applies to all site personnel involved in the implementation and coordination of sponsored 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**

### **4. BACKGROUND**

Sponsors conduct monitoring visits to ensure that PIs are compliant with the clinical protocol and Good Clinical Practices (GCPs), that data are of high quality and integrity, and that the facilities and staffing are adequate for continued participation in the study.

### **5. PROCEDURE**

5.1. The Investigator or designee will:

- 5.1.1. Schedule and arrange monitoring visits as requested by the sponsor. Monitoring visits are conducted at intervals defined by sponsor Standard Operating Procedures (SOPs) and are often dependent upon enrollment. The dates of monitoring visits should be scheduled at mutually convenient times and every attempt should be made to accommodate monitoring deadlines. Participants will include the PI and Investigators whenever possible, the SC, and other clinical research personnel and ancillary staff as appropriate.
- 5.1.2. Schedule appointments with the PI, Investigators, pharmacists, and other clinical research personnel as appropriate.
- 5.1.3. Confirm with the sponsor representative prior to the monitoring visit which cases will be reviewed so that appropriate documentation and files can be obtained.
- 5.1.4. Ensure that all available requested study subject source documents and Case Report Forms (CRFs) are provided for the sponsor representative(s) to review.
- 5.1.5. Ensure that an appropriate work area is available for the sponsor representative(s) during the monitoring visit.
- 5.1.6. Ensure that access to medical records will be available during the visit. This may include prior authorization for electronic records.

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- 5.1.7. Accompany the sponsor representative(s) to the investigational product (IP) storage area and be available to assist with product accountability review, if requested.
- 5.1.8. Schedule time to work with the sponsor representative(s) during the monitoring visit to review and complete any data clarifications, as necessary.
- 5.1.9. Submit CRFs and study-related documents to the sponsor according to sponsor SOPs. If copies of source documents are to be submitted to the sponsor, then all subject-identifying information must be blacked out to protect patient confidentiality.

- 5.2. The PI or designee should acknowledge in writing receipt of sponsor reports, if applicable, and document steps taken to correct any deficiencies.

### **6. TERMS & ABBREVIATIONS**

|            |                              |
|------------|------------------------------|
| <b>CRF</b> | Case Report Forms            |
| <b>GCP</b> | Good Clinical Practices      |
| <b>IP</b>  | Investigational Product      |
| <b>SC</b>  | Study Coordinators           |
| <b>SOP</b> | Standard Operating Procedure |
| <b>SP</b>  | 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 5.18 Investigator Selection

### **8. ATTACHMENTS**

None