## SS-202 Revision History

| Date of Revision | Page(s)/Section(s) Revised | Revision Explanation |
|---|---|---|
| 01AUG2011 | | |
| 06JUN2017 | | |
| 31OCT2017 | All | Cosmetic Only |
| 26MAR2019 | All | Minor corrections and updates. |
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# SS-202 STANDARD OPERATING PROCEDURE FOR PRESTUDY SITE VISIT

## I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at this investigative site when the sponsor of a study conducts a pre-study site visit to:

- Meet with study personnel and review their qualifications for the study,
- Assess the facilities of the research site for implementing the study,
- Evaluate the possibility of collaborating on the study.

## 2. SCOPE

This SOP applies to the procedures for conducting the pre-study site

Visit for all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics during all investigational phases of development. It describes the steps followed by this clinical research site from the time a Pre Study Site Visit is scheduled by a sponsor until all follow-up activities associated with the visit have been completed.

## 3. APPLICABLE REGULATIONS AND GUIDELINES

| | |
|---|---|
| 21 CFR 312.50 | General responsibilities of sponsors |
| 21 CFR 312.52 | Transfer of obligations to a contract research organization |
| 21 CFR 312.53 | Selecting investigators and monitors |
| 21 CFR 312.60 | General responsibilities of investigators |
| 21 CFR 312.66 | Assurance of IRB review |
| 21 CFR 312.68 | Inspection of investigator's records and reports |

## 4. REFERENCES TO OTHER APPLICABLE SOP'S

| | |
|---|---|
| GA-102 | Responsibilities of the Research Team |
| SS-201 | Assessing Protocol Feasibility |
| SS-203 | Investigator and Site Initiation Meetings |
| PM-301 | Site-Sponsor/CRO Communications |
| PM-303 | Regulatory Files and Subject Records |

## 5. ATTACHMENTS

A. Checklist of Activities Associated with the Pre-study Site Visit
B. Pre-study Site Visit Follow-up

## 6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in arranging, managing, or participating in the pre-study site visit. This includes the following:

- Principal Investigator
- Sub-Investigator
- Research Coordinator
- Support Staff

## 7. DEFINITIONS

The following definitions from the International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline, apply to this SOP.

**Clinical trial/study:** Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

**Investigator**: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

**Investigator's Brochure (IB)**: A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.

**Protocol**: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.

**Sponsor**: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

**Sub-investigator**: Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

## 8. PROCESS OVERVIEW

A. Preparing for the prestudy site visit
B. Conducting the prestudy site visit

## 9. PROCEDURES

### A. PREPARING FOR THE PRESTUDY SITE VISIT

| RESPONSIBILITY | DESCRIPTION OF PROCEDURE |
|---|---|
| PI<br>Sub-Investigator<br>Research Director/Manager<br>Research Coordinator<br>Support Staff | Identify key clinical research personnel likely to be involved in conducting the study under consideration. |
| PI<br>Research Coordinator | Ensure that the sponsor's Confidentiality Agreement (if applicable) has been signed by the principal investigator and returned promptly to the sponsor. |
| Research Coordinator<br>Support Staff<br>Research Director/Manager | Ensure that the site has received critical study documents, such as the protocol, the investigator brochure, and CRFs (if available), sample budget worksheet, and a draft contract. |
| PI<br>Sub-Investigator<br>Research Coordinator<br>Support Staff | Review the protocol and other study-related materials to assess the feasibility of conducting the study at this site. Consider personnel resources, patient availability, potential benefits to patients, ease of implementing the study. |
| Research Coordinator<br>Support Staff | Determine if the sponsor has any areas of special interest that require advance scheduling, such as:<br>Visiting the treatment site (clinic or hospital), pharmacy, central laboratory, medical records department;<br>Seeing to any specialized equipment needed to implement the study;<br>Meeting briefly with ancillary personnel involved in any specialized data collection; |
| Research Coordinator<br>Support Staff | If not on file, obtain copies of current Curricula vitae and resumes from key site personnel. Provide copies to the sponsor as required. |

### B. CONDUCTING THE PRESTUDY SITE VISIT

| RESPONSIBILITY | DESCRIPTION OF PROCEDURE |
|---|---|
| PI<br>Sub-Investigator<br>Research Coordinator | Meet with sponsor/CRO representatives to review protocol, investigator's brochure, communication plan for sponsor/CRO and clinical site. |

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|---|---|
| PI<br>Sub-Investigator<br>Research Coordinator | Tour the areas of the research facility with sponsor representatives, where the clinical trial will be conducted. |