SS-203 STANDARD OPERATING PROCEDURE FOR INVESTIGATOR AND SITE INITIATION MEETINGS

I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at this investigative site when the sponsor of a potential study conducts a study initiation meeting to:

- Prepare site personnel to implement the protocol according to GCP requirements,
- Review study drug administration and accountability,
- Provide instruction in any specialized procedures such as diagnostic tests and special computer programs,
- Provide direction for CRF completion.

2. SCOPE

This SOP applies to 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 study initiation meeting is scheduled by a sponsor until all follow-up activities associated with the meeting 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 312.60	General responsibilities of investigators
21 CFR 312.66	Assurance of IRB review
21 CFR 312.68	Inspection of investigator's records and reports

4. REFERNCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team
SS-201	Assessing Protocol Feasibility
SS-202	Prestudy Site Visits
PM-301	Site-Sponsor/CRO Communications
PM-303	Regulatory Files and Subject Records

5. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in managing or participating in the site initiation meeting. This includes the following:

- Principal investigator
- Sub-investigator
- Research coordinator
- Drug Preparer (if complicated study, drug blinding and preparation procedures are required)

6. 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.

I**nvestigator**: 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.

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.

Subinvestigator: 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).

7. PROCESS OVERVIEW

The study initiation meeting is a meeting arranged and conducted by the sponsor to complete the final orientation of the study personnel to the study procedures and GCP requirements. It occurs after the prestudy site visit when all study arrangements have been concluded or are in process, and the study is about to start.

A. Preparing for the site initiation meeting
B. Participating in the site initiation meeting
C. Following-up after the site initiation meeting

8. PROCEDURES

A. PREPARING FOR THE SITE INITIATION MEETING

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research Coordinator Support Staff	Identify key clinical research personnel likely to be involved in conducting the study under consideration.
PI Research Director/Manager Research Coordinator	Assign study to appropriate clinical research personnel. Ensure that all documentation and materials associated with the study are provided to these individuals assigned to the study.
Research Director/Manager Research Coordinator	Ensure that travel arrangements are in order for those who will be attending the multicenter investigators' meeting or That arrangements have been made for sponsor personnel to orient the study on-site.
Research Coordinator Support Staff	Ensure that any materials needed for the meeting (annotated CRFs, sample study medication) are available.

B. PARTICIPATING IN THE SITE INITIATION MEETING

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Key study personnel attending the meeting	Be prepared to provide sponsor with an update on any study-related issues.

C. FOLLOWING UP AFTER THE SITE INITIATION MEETING

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research Coordinator	Ensure that the sponsor/CRO sends written documentation summarizing important agreements made during the meeting.
Research Coordinator Support Staff	Prepare the following: IRB submission Final budget

Research Director/Manager	Submit the clinical trial agreement for signoff. Track documents appropriately.
Research Coordinator Support Staff	Create appropriate study files. File documents as they become available.