SS-204 STANDARD OPERATING PROCEDURE FOR PROTOCOL START-UP

1. INTRODUCTION AND PURPOSE

The initiation of a clinical study marks the beginning of subject accrual. Prior to enrolling the first subject, all regulatory and institutional requirements must be met, and preparations for protocol procedures must be complete. In addition, the research staff and others involved in recruitment, selection of subjects and enrollment must receive appropriate training. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements of starting-up a study.

2. SCOPE

This SOP describes the steps taken to organize and prepare this clinical site 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 sponsor selects the site for a clinical study until recruitment of subjects begins.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.68	Inspection of investigator's records and reports

4. REFERENCES TO OTHER APPLICABLE SOP'S

PM-303	Regulatory Files and Subject Records
SM-402	Subject Recruitment and Screening

5. ATTACHMENTS

A. Protocol Start-Up Checklist

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in starting up clinical studies. 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.

Contract: A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

8. PROCESS OVERVIEW

A. Determine facility readiness
B. Establish site readiness
C. Begin recruitment and screening activities

9. PROCEDURES

A. DETERMINE FACILITY READINESS

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research Director/Manager Research coordinator	Ensure that the contract is executed. Ensure that a final budget has been negotiated. Conduct in-service training for referring and support staff (e.g., physicians, nurses, and lab technicians).

B. ESTABLISH SITE READINESS

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator Support staff	Review regulatory files for completeness. Establish the receipt of adequate investigational drug supplies. Inventory supplies of case report forms, central lab supplies. Develop or utilize sponsor- generated worksheets, checklists. Review study procedures with assigned research staff (Attachment A, Protocol Start-Up Checklist).

C. BEGIN RECRUITMENT AND SCREENING ACTIVITIES

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Notify sponsor of launch date for recruitment and screening activities as required Assemble screening/enrollment materials.

	Activate recruitment plan.

Attachment A

Protocol Start-Up Checklist

Documents required

- ❑ Signed Form FDA 1572
- ❑ CVs of investigators listed on the Form FDA 1572
- ❑ Signed protocol title page
- ❑ Investigator's brochure
- ❑ IRB approval letter
- ❑ IRB letter of assurance, if applicable
- ❑ IRB-approved consent form
- ❑ Laboratory certification and range of normal values
- ❑ Budget
- ❑ Contract

Protocol preparation

- ❑ Follow-up worksheets
- ❑ Patient logs (screening, enrollment and follow-up)
- ❑ Protocol summary sheets (purpose, inclusion/exclusion criteria)
- ❑ Study drug administration sheets (adverse effects, administration)
- ❑ Special lab work requisitions (if required by the institution)
- ❑ Randomization table, as appropriate

Ancillary staff inservice

- ❑ Pharmacy _____ (contact name)
- ❑ Nursing _____ (contact name)
- ❑ Physicians _____ (contact name)
- ❑ Laboratory _____ (contact name)

Inventory

- ❑ Study drug supplies
- ❑ Laboratory supplies (central and/or hospital)
- ❑ Case report forms