SS-201 STANDARD OPERATING PROCEDURE FOR ACCESSING PROTOCOL FEASIBILITY

I. INTRODUCTION AND PURPOSE

A clinical protocol that meets scientific and ethical standards is a fundamental requirement of clinical investigations. The site must determine the scientific, ethical and financial merits of conducting the study. The sponsor must compensate the site for the resources necessary to perform all study-related procedures according to the requirements of good clinical practice (GCP). This standard operating procedure (SOP) describes the steps for fulfilling the regulatory, medical, and ethical requirements for assessing the feasibility of implementing a protocol at this investigative site.

2. SCOPE

This SOP applies to the activities involved in assessing protocols for studies conducted at this investigative site subject to investigational new drug (IND) regulations for drugs and biologics during all investigational phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109	IRB review of research
21 CFR 56.111	Criteria for IRB approval of research
21 CFR 312.21	Phases of an investigation
21 CFR 312.23	IND content and format
21 CFR 312.60	General responsibilities of investigators

4. REFERENCES TO OTHER APPLICAPBLE SOP'S

GA-102	Responsibilities of the Research Team
PM-301	Site-Sponsor/CRO Communications

5. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in conducting clinical trials at this research site. This includes the following:

- Principal Investigator
- Sub-Investigator
- Research Director/Manager

- Research Coordinator

6. DEFINITIONS

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

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline, the term protocol refers to protocol and protocol amendments.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Investigational Product: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Well-being (of trial subjects): The physical and mental integrity of the subjects participating in a clinical trial.

7. PROCESS OVERVIEW

A. Based upon the established review process, evaluate the feasibility of carrying out the protocol at this investigative site.

8. PROCEDURES

A. EVALUATE THE PROTOCOL AND THE INVESTIGATIONAL ARTICLE, ASSESS THE POTENTIAL IMPACT UPON SUBJECTS, AND REVIEW THE BUDGET.

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research Director/Manager Research Coordinator	Based upon the established review process, determine the scientific, ethical and financial merits of conducting the study at this investigational site. Distribute the protocol and assessment tools to key research team members for their assessment (Attachment A, Protocol Assessment Checklist and Attachments B, C and D for budget calculations).
PI Sub-Investigator	Review comments from research team and determine feasibility.

Research Director/Manager	
Research Director/Manager Research Coordinator	Notify the sponsor of the site's decision.