PM-301 STANDARD OPERATING PROCEDURE FOR SITE SPONSOR/CRO COMMUNICATIONS

I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the various ways of communicating with the sponsor/CRO as all regulatory, medical and ethical requirements are fulfilled, including telephone and written interactions.

2. SCOPE

This SOP applies to communications between this site and sponsors/CROs with regard to any clinical study subject to investigational new drug (IND) regulations for drugs and biologics during all phases of development. These communications serve to protect the safety and well-being of subjects by keeping sponsors/CROs fully apprised of study activities and to ensure that the studies are carried out appropriately.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.32	IND safety reports
21 CFR 312.33	Annual reports
21 CFR 312.44	Termination
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards

4. REFERENCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team
SS-201	Assessing Protocol Feasibility
SS-202	Prestudy Site Visit
SS-203	Investigator and Site Initiation Meetings
SS-204	Protocol Start-Up
PM-302	Interactions with the Institutional Review Board
PM-303	Regulatory Files and Subject Records

SM-404	Adverse Event Reporting

5. ATTACHMENTS

N/A

6. 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 coordinator
- Support staff

7. DEFINITIONS AND GLOSSARY

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

Contract Research Organization (CRO): A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

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

8. PROCESS OVERVIEW

A. Communications overall
B. Prestudy communications
C. Communications while the study is ongoing
D. Communications when the study is completed

9. PROCEDURES

A. COMMUNICATIONS OVERALL

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Communicate regularly and appropriately with sponsor/CRO about all study-related issues. Document important conversations (Attachment A, Telephone Contact Log).
Research coordinator Support staff	Keep originals or photocopies of all relevant documentation, including facsimile confirmations, and file in the study binder with appropriate documents.

B. PRESTUDY COMMUNICATIONS

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Send sponsor/CRO signed confidentiality agreement. Notify sponsor/CRO of decision to participate in the study by telephone, fax, letter or electronic mail and file documentation Send sponsor/CRO signed protocol signature page (if appropriate).
Research coordinator	Submit all prestudy regulatory documents (Attachment A, Protocol Start-Up Checklist in SS-204). Send updated/revised documents as necessary.

C. COMMUNICATIONS WHILE THE STUDY IS ONGOING

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Inform sponsor/CRO about SAE(s) immediately.
Research coordinator Support staff	Inform sponsor/CRO about the study progress through screening/enrollment forms by whatever means (fax, e-mail) requested (Attachment B, Screening/Enrollment Form, SM-401). Forward CRFs to sponsor/CRO as requested. Respond promptly to data queries as requested (fax, e-mail, remote data entry query resolution procedures).
Research coordinator Support staff	Copy sponsor/CRO on IRB communications such as SAEs, IND safety reports, IRB acknowledgment of reports received, amendment approvals, revised informed consent form, continuing approval for study.

D. COMMUNICATIONS WHEN THE STUDY IS COMPLETED

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Inform sponsor/CRO promptly if notified by FDA of impending inspection. Provide copies of all FDA documentation (Form FDA 483, letters) generated as a result of the inspection.