LIST OF ATTACHMENTS

SOP #	SECTION/TITLE	ATTACHMENT NUMBER	ATTACHMENT TITLE
GA 100	**General Administration**		
GA 101	Assuming and Fulfilling Responsibility for Good Clinical Practice	GA 101-A	List of Key Personnel and Responsibilities At <<Site>>
		GA 101-B	Delegation of Authority <<Protocol>>
		GA 101-C	Form FDA 1572
		GA101-D	Study Training Form
GA 102	Document Development and Change Control	GA102-A	Document Modification Review Form
		GA102-B	Document Change Notification and Confirmation Log
		GA102-C	Notification of Change to SOP/Document
		GA102-D	Document Training Compliance Record
		GA102-E	SOP Template
		GA102-F	SOP Compliance Review
GA 103	Ensuring Qualified Site Personnel and Research Staff	GA 103-A	Job Description – Principal Investigator
		GA 103-B	Job Description – Research Nurse/Coordinator
		GA 103-C	Job Description – Regulatory Specialist
		GA 103-D	Job Description – Data Manager
		GA 103-E	Job Description – Quality Assurance
		GA 103-F	Orientation Checklist
		GA 103-G	Staff Evaluation Form
		GA 103-H	Criteria for Evaluation
		GA 103-I	Curriculum Vitae (CV) Maintenance
		GA 103-J	Training/Continuing Education Funding Request
		GA 103-K	Training/Continuing Education Opportunities
GA 104	Contracts	GA 104-A	Contract Template
		GA 104-B	Contract Review Checklist
GA 105		GA 105-A	Request for Medical Records
		GA 105-B	Request for Password for Electronic Records

	Records Management, Accountability and Retention	GA 105-C	Telephone Contact Log
		GA 105-D	File/Document Access Log
		GA 105-E	Storage Label/Cover Sheet
RA 200	**Regulatory Affairs**		
RA 201	Essential Documents	RA 201-A	Regulatory File Content Checklist
		RA 201-B	Study File Content Checklist
		RA 201-C	Table of ICH Essential Documents
RA 202	Initial and Ongoing Submissions	RA 202-A	Submission and Reporting Requirements
		RA 202-B	IRB Submission Checklist
		RA 202-C	IRB Submission Application
		RA 202-D	Amendment Submission Requirements
RA 203	Reporting Requirements	RA 203-A	AE/SAE Report Form
		RA 203-B	IRB Safety Report Cover Letter Template
		RA 203-C	Report of Deviation from the Protocol
RA 204	Conflict of Interest	RA 204-A	Conflict of Interest Assessment Checklist
		RA 204-B	Form FDA 3454
		RA 204-C	Form FDA 3455
		RA 204-D	Conflict of Interest Management Plan
PM 300	**Project Management**		
PM 301	Assessing Study Feasibility	PM 301-A	Study Review and Assessment Checklist
		PM 301-B	Study Effort and Cost Checklist
		PM 301-C	Salary Worksheet
		PM 301-D	Per Subject Cost Worksheet
		PM 301-E	Study Budget Worksheet
		PM 301-F	Pre-Study Qualification Visit Agenda
		PM 301-G	Pre-Study Qualification Visit Preparation Checklist
PM 302	Study Start-Up	PM 302-A	Initiation Visit Preparation Checklist
		PM 302-B	Initiation Visit Agenda
		PM 302-C	Initiation Visit Management Checklist
		PM 302-D	Staff Signature Log

PM 303	Investigational Product Management	PM 303-A	Investigational Product Receipt Form
		PM 303-B	Subject Inventory Control Form
		PM 303-C	Investigational Product Accountability Form
		PM 303-D	Temperature Logs
PM 304	Source Documentation	PM 304-A	Source Documentation Checklist
PM 305	Monitoring Visits	PM 305-A	Monitoring Visit Preparation Checklist
PM 306	Study Completion	PM 306-A	End-of-Study Documentation Checklist
PM 307	Protocol Compliance	PM 307-A	Request for Waiver/Report of Deviation From the Protocol
		PM 307-B	Summary of Deviations or Variances from the Protocol
SM 400	**Subject Management**		
SM 401	Recruitment	SM 401-A	Guideline for Recruitment and Advertising Practices
		SM 401-B	Model Screening Script
SM 402	Informed Consent	SM 402-A	Informed Consent Process
		SM 402-B	Informed Consent Form Template and Checklist
		SM 402-C	Informed Consent Form Elements Checklist
SM 403	Eligibility and Enrollment	SM 403-A	Subject Eligibility Checklist
		SM 403-B	Screening and Enrollment Log
SM 404	Protecting Confidential Information	SM 404-A	Guidelines for Safeguarding Confidential Information
		SM 404-B	Fax Log
SM 405	Subject Visits and Assessments	SM 405-A	Study Encounter Worksheet and Record – Screening
		SM 405-B	Study Encounter Worksheet and Record – Visit #
		SM 405-C	Study Encounter Record – Physical Exam – Visit #
		SM 405-D	Medical History – Screening
		SM 405-E	Intercurrent Medical History/Concomitant Therapy – Visit #
		SM 405-F	Specimen Shipping Log
SM 406	AE Management	SM 406-A	Criteria for Recognizing and Managing AEs

DM 500	**Data Management**		
DM 501	Clinical Data Management	N/A	
DM 502	Use of Electronic Data Management Systems	DM 502-A	Electronic Data Management Equipment Log
QA 600	**Quality Assurance**		
QA 601	Quality Assurance Audits	QA 601-A	Clinical Study Site Audit Checklist
QA 602	Inspections by Regulatory Authorities	QA 602-A	Checklist to Prepare for an FDA Inspection
		QA 602-B	Checklist of Procedures During an FDA Inspection