LIST OF ATTACHMENTS

SOP #	SECTION/TITLE	ATTACHMENT NUMBER	ATTACHMENT TITLE
GA 100	**General Administration**		
GA 101	Sponsor Responsibility and Delegation of Responsibility	GA 101-A	Delegation of Responsibility Form
		GA 101-B	Form FDA 1571
		GA 101-C	Form FDA 1572
GA 102	Document Development and Change Control	GA 102-A	SOP Template
		GA 102-B	Document Control Form
		GA 102-C	Table of Modifications Form
		GA 102-D	Document Training Compliance Form
		GA 102-E	Study Training Form
GA 103	Sponsor Research Team Training	GA 103-A	Research Team Training Curriculum
		GA 103-B	Training Program Compliance Form
GA 104	Conflict of Interest Disclosure Requirements	GA 104-A	Form FDA 3454
		GA 104-B	Form FDA 3455
GA 105	Vendor Selection and Agreements	GA 105-A	Vendor Audit Report Form
		GA 105-B	Checklist: Vendor's Qualifications to Engage in Regulated Activities
		GA 105-C	(Sponsor's existing RFP template)
		GA 105-D	(Sponsor's existing vendor contract template)
		GA 105-E	Confidentiality Agreement Template
		GA 105-F	Investigator Contract Template
		GA 105-G	Transfer of Regulatory Obligations Form
RA 200	**Regulatory Affairs**		
RA 201	FDA Contacts and Meetings	RA 201-A	Telephone Contact Log
		RA 201-B	Accessing FDA Documents and Guidance Online
		RA 201-C	FDA Contact Information
RA 202	FDA Submissions	RA 202-A	IND Content and Format Checklist

		RA 202-B	IND Amendment Checklist
RA 203	FDA Reporting Requirements	RA 203-A	IND Annual Report Checklist
		RA 203-B	Reporting Requirements and Responsibilities Checklist
		RA 203-C	Form FDA 3500A
RA 204	Gene Transfer Research	RA 204-A	Contents of an NIH RAC Submission
		RA 204-B	Safety Reporting Requirements for Gene Transfer Research
		RA 204-C	AE Report Form for Gene Transfer Research
		RA 204-D	Other Reporting Requirements for Gene Transfer Research
PD 300	**Protocol Development**		
PD 301	Clinical Protocol Development	PD 301-A	Clinical Protocol Contents and Review Checklist
PD 302	Documents for Informing Investigators	PD 302-A	IB Development Checklist
		PD 302-B	IB Acknowledgement Form
SS 400	**Study Start-Up**		
SS 401	Investigator Selection and Qualification	SS 401-A	Investigator Feasibility Evaluation and Qualification Visit Report
		SS 401-B	Qualification Visit Checklist
SS 402	Initiation Visit and Site Training	SS 402-A	Initiation Visit Checklist
		SS 402-B	Investigator Delegation and Signature Log
		SS 402-C	Site Visit Log
		SS 402-D	Site Initiation Visit Agenda
		SS 402-E	Site Initiation Visit Confirmation Letter Template
		SS 402-F	Site Initiation Visit Report
		SS 402-G	Site Personnel Training Log
CO 500	**Clinical Operations and Project Management**		
CO 501	Communications		No Attachments
CO 502	Investigational Product Inventory Management	CO 502-A	Investigational Product Release Form
		CO 502-B	Subject Inventory Control Form
		CO 502-C	Investigational Product Accountability Form
CO 503	Documentation and Records Retention	CO 503-A	TMF Contents
		CO 503-B	Site Study File Contents
		CO 503-C	Table of ICH Essential Documents
CO 504		CO 504-A	Monitoring Visit Checklist

	Routine Monitoring Visits	CO 504-B	Monitoring Visit Report
		CO 504-C	Monitoring Plan Template
CO 505	Study Closeout Visit	CO 505-A	Site Closeout Visit Report Template
CO 506	Ensuring Investigator Compliance	CO 506-A	Report of Deviation from the Protocol
		CO 506-B	Determination of Actions to Ensure Investigator Compliance
		CO 506-C	Corrective and Preventative Action (CAPA) Plan Form
SM 600	**Subject Management**		
SM 601	Human Subject Protection	SM 601-A	IRB Submission Checklist
		SM 601-B	Informed Consent Form Template
		SM 601-C	Informed Consent Form Checklist
SM 602	Subject Recruitment Practices	SM 602-A	Guidelines for Recruitment and Advertising
SM 603	Subject Eligibility and Enrollment	SM 603-A	Subject Eligibility Checklist
		SM 603-B	Screening and Enrollment Log
SM 604	Specimen Management	SM 604-A	Specimen Shipping Log
SM 605	Adverse Event Recognition and Reporting	SM 605-A	Serious Adverse Event (SAE) Report Form
		SM 605-B	AE and Intercurrent Illness Log
		SM 605-C	Template Letter for Sending IND Safety Reports to IRBs
		SM-605-D	AE Reporting Decision Chart
SM 606	Protecting Confidentiality and Privacy	SM 606-A	Data Use Agreement
		SM 606-B	Checklist for Waiver of Authorization
		SM 606-C	Required Elements: Authorization
		SM 606-D	Authorization Template
DM 700	**Data Management**		
DM 701	Clinical Data Management	DM 701-A	Subject Data Clarification Form
		DM 701-B	Source Documentation Requirements
DM 702	Use of Electronic Data Management Systems	DM 702-A	Electronic Data Management Log
QA 800	**Quality Assurance**		
QA 801	Quality Assurance Audits	QA 801-A	Clinical Study Site Audit Checklist

QA 802	Inspections by Regulatory Authorities	QA 802-A	Checklist to Prepare the Site for an FDA Inspection
		QA 802-B	Checklist to Prepare for an FDA Inspection
		QA 802-C	Checklist of Procedures During an FDA Sponsor Inspection
IA 900	**Interim Analysis**		
IA 901	Assessing Need for a DMC	IA 901-A	Checklist of Considerations to Establish a DMC
IA 902	Establishing a DMC	IA 902-A	Roles and Responsibilities for Establishing a DMC
		IA 902-B	Responsibilities and Timeline for SOP Development
		IA-902-C	Contents of DMC SOPs