

## LIST OF ATTACHMENTS

<b>GA 100</b>	<b>GENERAL ADMINISTRATION</b>		
<b>GA 101</b>	<b>SPONSOR RESPONSIBILITY AND DELEGATION OF RESPONSIBILITY</b>	GA 101-A	DELEGATION OF RESPONSIBILITY FORM
		GA 101-B	FORM FDA 1571
		GA 101-C	FORM FDA 1572
<b>GA 102</b>	<b>DOCUMENT DEVELOPMENT AND CHANGE CONTROL</b>	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
<b>GA 103</b>	<b>SPONSOR RESEARCH TEAM TRAINING</b>	GA 103-A	RESEARCH TEAM TRAINING CURRICULUM
		GA 103-B	TRAINING PROGRAM COMPLIANCE FORM
<b>GA 104</b>	<b>CONFLICT OF INTEREST DISCLOSURE REQUIREMENTS</b>	GA 104-A	FORM FDA 3454
		GA 104-B	FORM FDA 3455
<b>GA 105</b>	<b>VENDOR SELECTION AND AGREEMENTS</b>	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
<b>RA 200</b>	<b>REGULATORY AFFAIRS</b>		
<b>RA 201</b>	<b>FDA CONTACTS AND MEETINGS</b>	RA 201-A	TELEPHONE CONTACT LOG
		RA 201-B	ACCESSING FDA DOCUMENTS AND GUIDANCE ONLINE
		RA 201-C	FDA CONTACT INFORMATION

<b>RA 202</b>	<b>FDA SUBMISSIONS</b>	RA 202-A	IND CONTENT AND FORMAT CHECKLIST
		RA 202-B	IND AMENDMENT CHECKLIST
<b>RA 203</b>	<b>FDA REPORTING REQUIREMENTS</b>	RA 203-A	IND ANNUAL REPORT CHECKLIST
		RA 203-B	REPORTING REQUIREMENTS AND RESPONSIBILITIES CHECKLIST
		RA 203-C	FORM FDA 3500A
<b>RA 204</b>	<b>GENE TRANSFER RESEARCH</b>	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
<b>PD 300</b>	<b>PROTOCOL DEVELOPMENT</b>		
<b>PD 301</b>	<b>CLINICAL PROTOCOL DEVELOPMENT</b>	PD 301-A	CLINICAL PROTOCOL CONTENTS AND REVIEW CHECKLIST
<b>PD 302</b>	<b>DOCUMENTS FOR INFORMING INVESTIGATORS</b>	PD 302-A	IB DEVELOPMENT CHECKLIST
		PD 302-B	IB ACKNOWLEDGEMENT FORM
<b>SS 400</b>	<b>STUDY START-UP</b>		
<b>SS 401</b>	<b>INVESTIGATOR SELECTION AND QUALIFICATION</b>	SS 401-A	INVESTIGATOR FEASIBILITY EVALUATION AND VISIT REPORT
		SS 401-B	QUALIFICATION VISIT CHECKLIST
<b>SS 402</b>	<b>INITIATION VISIT AND SITE TRAINING</b>	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

<b>CO 500</b>	<b>CLINICAL OPERATIONS AND PROJECT MANAGEMENT</b>		
<b>CO 501</b>	<b>COMMUNICATIONS</b>		NO ATTACHMENTS
<b>CO 502</b>	<b>INVESTIGATIONAL PRODUCT INVENTORY MANAGEMENT</b>	CO 502-A	INVESTIGATIONAL PRODUCT RELEASE FORM
		CO 502-B	SUBJECT INVENTORY CONTROL FORM
		CO 502-C	INVESTIGATIONAL PRODUCT ACCOUNTABILITY FORM
<b>CO 503</b>	<b>DOCUMENTATION AND RECORDS RETENTION</b>	CO 503-A	TMF CONTENTS
		CO 503-B	SITE STUDY FILE CONTENTS
		CO 503-C	TABLE OF ICH ESSENTIAL DOCUMENTS
<b>CO 504</b>	<b>ROUTINE MONITORING VISITS</b>	CO 504-A	MONITORING VISIT CHECKLIST
		CO 504-B	MONITORING VISIT REPORT
		CO 504-C	MONITORING PLAN TEMPLATE
<b>CO 505</b>	<b>STUDY CLOSEOUT VISIT</b>	CO 505-A	SITE CLOSEOUT VISIT REPORT TEMPLATE
<b>CO 506</b>	<b>ENSURING INVESTIGATOR COMPLIANCE</b>	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
<b>SM 600</b>	<b>SUBJECT MANAGEMENT</b>		
<b>SM 601</b>	<b>HUMAN SUBJECT PROTECTION</b>	SM 601-A	IRB SUBMISSION CHECKLIST
		SM 601-B	INFORMED CONSENT FORM TEMPLATE
		SM 601-C	INFORMED CONSENT FORM CHECKLIST
<b>SM 602</b>	<b>SUBJECT RECRUITMENT PRACTICES</b>	SM 602-A	GUIDELINES FOR RECRUITMENT AND ADVERTISING
<b>SM 603</b>	<b>SUBJECT ELIGIBILITY AND ENROLLMENT</b>	SM 603-A	SUBJECT ELIGIBILITY CHECKLIST
		SM 603-B	SCREENING AND ENROLLMENT LOG
<b>SM 604</b>	<b>SPECIMEN MANAGEMENT</b>	SM 604-A	SPECIMEN SHIPPING LOG

<b>SM 605</b>	<b>ADVERSE EVENT RECOGNITION AND REPORTING</b>	CO	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
<b>SM 606</b>	<b>PROTECTING CONFIDENTIALITY AND PRIVACY</b>	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
<b>DM 700</b>	<b>DATA MANAGEMENT</b>		
<b>DM 701</b>	<b>CLINICAL DATA MANAGEMENT</b>	DM 701-A	SUBJECT DATA CLARIFICATION FORM
		DM 701-B	SOURCE DOCUMENTATION REQUIREMENTS
<b>DM 702</b>	<b>USE OF ELECTRONIC DATA MANAGEMENT SYSTEMS</b>	DM 702-A	ELECTRONIC DATA MANAGEMENT LOG
<b>QA 800</b>	<b>QUALITY ASSURANCE</b>		
<b>QA 801</b>	<b>QUALITY ASSURANCE AUDITS</b>	QA 801-A	CLINICAL STUDY SITE AUDIT CHECKLIST
<b>QA 802</b>	<b>INSPECTIONS BY REGULATORY AUTHORITIES</b>	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
<b>IA 900</b>	<b>INTERIM ANALYSIS</b>		
<b>IA 901</b>	<b>ASSESSING NEED FOR A DMC</b>	IA 901-A	CHECKLIST OF CONSIDERATIONS TO ESTABLISH A DMC
<b>IA 902</b>	<b>ESTABLISHING A DMC</b>	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