

TABLE OF CONTENTS

	INTRODUCTION		6
	LIST OF ABBREVIATIONS		7
	GLOSSARY		8
	LIST OF ATTACHMENTS		20
I	GA	100	GENERAL ADMINISTRATION
		101	Sponsor Responsibility and Delegation of Responsibility 23
		A	Fulfilling Regulatory Obligations 24
		B	Delegation of Responsibility 27
		C	Transfer of Responsibility to Contractors 28
		102	Document Development and Change Control 29
		A	Document Initiation and Approval Procedures 30
		B	Document Change Procedures 31
		C	Document Implementation 32
		103	Sponsor Research Team Training 33
		A	Training Plan 34
		B	Documentation of Training 35
		104	Conflict of Interest Disclosure Requirements 36
		A	Financial Disclosure for Sponsors and Investigators 37
		B	FDA Reporting Requirements 38
		105	Vendor Selection and Agreements 39
		A	Institutional Vendor Requirements 40
		B	Regulatory Aspects 40
		C	Vendor Audits 41
II	RA	200	REGULATORY AFFAIRS
		201	FDA Contacts and Meetings 42
		A	Oral and Written Correspondence with FDA 43
		B	Meetings with FDA 43
		202	FDA Submissions 45
		A	IDE Development and Submission 46
		203	FDA Reporting Requirements 49
		A	Preparation of Reports 50
		B	Device Study Reporting 51
III	PD	300	PROTOCOL DEVELOPMENT
		301	Clinical Protocol Development 54
		A	Writing the Clinical Protocol 55
		B	Protocol Review and Approval 56
		C	Protocol Amendments 57
		D	Case Report Forms 58
		302	Documents for Informing Investigators 59
		A	Preparing the Investigational Plan 60
		B	Report of Prior Investigations 61

IV	SS	400	STUDY START-UP	
		401	Investigator Selection and Qualification	62
		A	Investigator Qualification	63
		B	Investigator Agreements	64
		C	Disqualified Investigators	65
		402	Initiation Visit and Site Training	66
		A	Initiation Visit Preparation	67
		B	Investigative Site Training	68
		C	Documenting the Initiation Visit	69
V	PM	500	PROJECT MANAGEMENT	
		501	Communications	70
		A	General Communications	71
		B	Communications with IRB	71
		C	Communications with Investigators and Site Staff	72
		D	Communications Records	72
		502	Investigational Product Inventory Management	74
		A	Labeling and Release of Investigational Product	75
		B	Investigational Product Receipt, Storage and Issue	76
		C	Final Product Accountability Verification	77
		503	Documentation and Records Retention	79
		A	Creating the RMF	80
		B	Maintenance of the RMF	80
		504	Routine Monitoring Visits	82
		A	Scheduling/Frequency of Visits	83
		B	Preparation for a Monitoring Visit	84
		C	Conducting a Monitoring Visit	84
		505	Study Closeout Visit	88
		A	Site Closeout for Completion of Enrollment	89
		B	Suspension for Inadequate Enrollment	90
			Suspension of Study by FDA or the IRB	91
		506	Ensuring Investigator Compliance	92
		A	Managing Protocol Deviations	93
		B	Termination for Protocol Violations	94
VI	SM	600	SUBJECT MANAGEMENT	
		601	Human Subject Protection	95
		A	IRB Submissions and Review	96
		B	Informed Consent Process	97
		C	Emergency or Other Unique Research	98
		602	Subject Recruitment Practices	100
		A	Sponsor-Produced Materials	101
		B	Investigator-Produced Materials	101
		603	Subject Eligibility and Enrollment	102
		A	Subject Eligibility Documentation	103
		B	Conduct of Screening Activities at the Site	103
		604	Specimen Management	104

		A	Assessing Site's Specimen Management	105
		B	Specimen Handling and Retention Requirements	105
		605	ADE Recognition and Reporting	107
		A	Identifying ADEs	108
		B	Clinical Management and Documentation of ADEs	109
		C	Reporting Procedures for ADEs	109
		606	Protected Health Information	112
		A	General Sponsor Activities	113
		B	Determining Covered Entity Status	114
		C	Working with Covered Entities as Clinical Trial Sites	114
		D	Authorization and Informed Consent	115
		E	Subject Recruitment	116
		F	Subject Access to Source Documents	116
VII	DM	700	DATA MANAGEMENT	
		701	Clinical Data Management	118
		A	Data Collection and Transcription	119
		B	Data Management and Retention	119
		702	Use of Electronic Data Management Systems	121
		A	Electronic Systems Set-up	122
		B	Electronic Data Collection and Management	123
VIII	QA	800	QUALITY ASSURANCE	
		801	Quality Assurance Audits	125
		A	Internal Audits	126
		B	Audits by Third Parties	126
		C	Auditing the Investigative Site	127
		802	FDA Inspections	130
		A	Preparing for an Inspection	131
		B	Conducting the Inspection	131
IX	AT	900	ATTACHMENTS	A 1-113