Regulatory File Table of Contents
August 2017

Protocol #:		Protocol Name:		Site #:	

Document	TMF Artifact #	TMF Artifact Name
Sponsor/CRO		
Sponsor/CRO Contact Information	01.02.01	Trial Team Details
Sponsor/CRO Correspondence & Notes on Telephone Calls	File in Relevant Zone	Relevant Communications
Protocol		
Protocol Amendment Log	N/A	N/A
Signed Protocol, Current (or Protocol Signature Page and Location of Protocol)	05.02.02	Protocol Signature Page
Protocol Amendments, Current	05.02.03 02.01.04	Protocol Amendment Signature Page Protocol Amendment
Protocol, Previous Versions	02.01.02	Protocol
Protocol Deviation Log	05.04.06	Protocol Deviations
Protocol Deviation Reports	05.04.06	Protocol Deviations
Study-Pertinent Site SOPs	01.01.04	List of SOPs Current During Trial
FDA & Other Regulatory Authorities		
Signed FDA Form 1572 (drugs) Investigator Agreement (Devices)	05.02.08 05.02.19	Form FDA 1572 Investigator's Agreement (Device)
Signed Form FDA 1571 (if Investigator is also the Sponsor)	03.01.01	Regulatory Submission
FDA Documents, Correspondence and Logs	03.04.01	Relevant Correspondence
Site Personnel		
Investigator CVs and Statements of Experience	05.02.04	Principal Investigator Curriculum Vitae
Sub-Investigator CVs and Statements of Experience	05.02.05	Sub-Investigator Curriculum Vitae
Key Team Member CVs and Statements of Qualification	05.02.05	Sub-Investigator Curriculum Vitae
Professional Licenses	05.02.07	Site Staff Qualification Supporting Information
Financial Disclosure Forms (confidential) Location	05.02.10	Financial Disclosure Form
Training Logs / Attendance Sheets, Study-Specific	05.03.03	Site Evidence of Training
GCP & HSP Training Documentation	05.03.02	Site Training Material
Transport of Dangerous Goods Training Certificates	05.03.03	Site Evidence of Training
General		
Institutional Approval to Conduct Study	N/A	N/A
Investigator's Brochure / Package Insert (drugs) or Device Manual (devices), Current (or Location)	02.01.01	Investigator's Brochure

Study Manual, Current (or Location)	01.01.05	Operational Procedure Manual
Study Manual, Previous Versions (or Location)	01.01.05	Operational Procedure Manual
Delegation of Authority Log	05.02.18	Delegation of Authority Site Responsibility Log
Grant / Clinical Trial Agreement Location (Confidential)	05.02.12	Clinical Trial Agreement
Statement or Letter Added to Participant Health Records or Sent to Their Primary Care Physicians	N/A	N/A
Initiation Visit Letter, Agenda & Report	05.03.01	Trial Initiation Monitoring Report
Close-Out Visit Sponsor Letter, Agenda and Report	05.04.08	Final Trial Close Out Monitoring Report
Institutional Review Board		
Application, Initial	04.01.01	IRB or IEC Submission
IRB Approval Letters	04.01.02	IRB or IEC Approval
Progress Reports & Renewal Approvals	04.03.02	IRB or IEC Progress Report
Translation Certificates	04.01.01	IRB or IEC Submission
Other IRB Submissions and Attachments (or List of Documents and Location)	04.01.01 04.01.02 04.01.03	IRB or IEC Submission IRB or IEC Approval IRB or IEC Progress Report
IRB Correspondence & Notes on Telephone Calls	04.04.01	(IRB) Relevant Communications
IRB FWA #, Registration #, and Membership List	04.01.05 04.01.03	IRB or IEC Compliance Documentation IRB or IEC Composition
IRB Close-Out Letter and Confirmation of Receipt	04.03.03	IRB or IEC Notification of Trial Termination
Subject Recruiting		
Prescreening Log, Screening Log, & Enrollment Log	05.04.01 05.04.10	Subject Log (anonymous) Subject Identification Log (not anonymous)
Study Subject List Locations	N/A	N/A
Prescreening Form/Script, IRB Approved	02.02.06	Advertisements for Subject Recruitment
Screening Form/Script, IRB Approved	02.02.06	Advertisements for Subject Recruitment
Study Advertisements, Materials & Scripts, IRB Approved	02.02.06	Advertisements for Subject Recruitment
Handouts & Instructions, IRB Approved	02.02.04 02.02.05 02.02.07	Subject Information Sheet, Subject Participation Card, Other Information Given to Subjects
Informed Consent		
Informed Consent Log	N/A	N/A
Informed Consent Form, IRB-Approved, Current	04.04.01	Informed Consent Form
Informed Consent Form, Previous Versions	04.04.01	Informed Consent Form
IRB Informed Consent Approval Letters	04.04.02	Tracking Information
Location of Signed Informed Consent Forms	02.02.03	Informed Consent Form
Documentation Associated with Waivers, Legally Authorized	02.02.03	Informed Consent Form

Representatives, etc.		
PHI, Biospecimens & HIPAA		
Location of HIPAA Authorizations	N/A	N/A
PHI Disclosure Log	N/A	N/A
Biospecimen Transfer Log	N/A	N/A
Current HIPAA Form (if not in Consent Form)	N/A	N/A
Previous Versions of HIPAA Form (if not in Consent Form)	N/A	N/A
Study Drug/Device		
Drug/Device Accountability Log	06.01.05	IP Accountability Documentation
Drug/Device Accountability Records (Receiving, Dispensing, Destruction, Shipping)	06.01.05 06.01.11	IP Accountability Documentation IP Certificate of Destruction
Dispensing/Pharmacy/Storage Instructions	06.01.02	IP Instructions for Handling
Unblinding/Decoding Procedure & Location of Codes	06.03.02	IP Unblinding Plan
Randomization Instructions (normally in protocol)	N/A	N/A
Master Randomization Log	06.03.01	IP Treatment Allocation Documentation
Temperature Logs	06.01.01	IP Supply Plan
Certificates of Analysis / Material Safety Data Sheets	06.02.04	Certificate of Analysis
Clinical Laboratory		
Lab Certifications (CLIA, CAP)	08.01.01	Certificate or Accreditation
Lab Director's CV & License	08.01.07	Head of Facility Curriculum Vitae
Lab Normal Values/Ranges (with Updates)	08.01.04	Normal Ranges
Lab Manual	08.01.05	Manual
Lab Correspondence & Notes on Telephone Calls	08.03.01	Relevant Communications
Study Kit Inventory	N/A	N/A
Study Kit Accountability Records	N/A	N/A
Safety / Serious Adverse Events		
Sponsor Instructions	07.01.01	Safety Management Plan
SAE Log	07.01.02	Pharmacovigilance Database Line Listing
SAE Reports & Confirmations of Receipt	07.02.02 07.03.02	SAE Report Tracking Information
SAE Correspondence & Notes on Telephone Calls	07.03.01	Relevant Communications
Adverse Event Log	04.03.01 07.01.02	Notification to IRB or IEC of Safety Information Pharmacovigilance Database Line Listing
IND Safety Reports	07.02.01	Expedited Safety Report
Data & Safety Monitoring Board Reports	01.03.03	Committee Output

Data Entry & Queries		
Data Entry Instructions	10.02.01	CRF Completion Requirements
Source Documents, Blank	N/A	N/A
Case Report Forms, Blank	02.01.07	Sample Case Report Form
Subject Diary, Blank	02.02.01	Subject Diary
CRF/EDC Log	N/A	N/A
Data Queries and Related Correspondence & Notes on Telephone Calls	10.05.01	Relevant Communications
Documentation of Data Corrections	10.02.04	Documentation of Corrections to be Entered Data
Site Monitoring & Improvement		
Site Monitoring Visit Log	05.04.04	Visit Log
Remote Monitoring Log	05.04.05	Additional Monitoring Activity
Site Monitoring Reports and Related Correspondence & Notes on Telephone Calls	05.04.03 05.04.12 05.05.01	Monitoring Visit Report Monitoring Visit Follow-up Documentation Relevant Communications
Third-Party Documentation & Correspondence		
Third-Party Contact Information	01.02.01	Trial Team Details
Third-Party Documentation	09.03.03	Meeting Material
Third-Party Correspondence & Notes on Telephone Calls	09.03.01	Relevant Communications
Other		
Clinical Study Report	02.03.01	Clinical Study Report