DEVICE TRIAL REGULATORY BINDER INDEX
STUDY NAME (Pro000)
PI NAME

1	**PROTOCOL**	• Clinical Trial Protocol / Protocol Signature Page • Device Manual (IB, IFU) / Signature Page • FDA Letters • DSMB Reports
2	**AGREEMENTS / STUDY TEAM**	• Investigator Agreement(s) • Financial Disclosure Agreement(s) • Curricula Vitae, Medical Licenses, Credentialing Certificates (*Filed Electronically*)
3	**INFORMED CONSENT FORMS**	• Informed Consent(s)
4	**IRB CORRESPONDENCE**	• Initial Submission and Approval • Amendments – Submission(s) and Approval(s) • Continuing Reviews – Submission(s) and Approval(s) • Reportable Events – Submission(s) and Approval(s) • IRB Membership Roster and IRB Statement of Assurance
5	**LABORATORY**	• CAP & CLIA Laboratory Certificates, Reference Ranges • Director's CV and License (*Filed Electronically*)
6	**STUDY LOGS**	• Site Visit Log • Delegation of Authority Log • Training Log / Documents • Protocol Deviation/Violation Log
7	**SPONSOR CORRESPONDENCE**	• Site Initiation Visit / Site Monitoring Reports • Study Related Correspondence Between Site, Sponsor, Etc. (Emails, Newsletters, Progress Reports)
8	**SERIOUS ADVERSE EVENTS (SAE)**	• SAE Forms and Completed Serious Adverse Event Reports
9	**Unanticipated Events/Note to File**	• Any unanticipated events • Note to File
10	**DEVICE INVENTORY**	• Device Accountability Logs / Shipment receipts / Supply Forms (*With Coordinator*) • Screening/Patient logs (*With Coordinator*)

10	**MISCELLANEOUS**	• CRFs and Worksheets • Miscellaneous (questionnaires, patient recruitment materials, etc.) • Hospital Resources Clinical Research Checklist