Example of Regulatory Binder Sections

Tab	Documents (all versions) to be maintained in this Section
Current IRB approved protocol	
Current IRB approved ICF	
Signed ICFs	
Institutional Review Board	• **<u>IRB Submissions</u>** **Initial/Ongoing** **Continuing** **Revision** **Amendment** **Termination** • **<u>Including all versions of the following:</u>** **Protocol with signature page** **ICF** **Recruitment materials** **Blank CRFs** **Participant educational/study informational materials** **Reportable events (protocol deviations/ unanticipated problems/ SAEs/New information)** **Data Safety Monitoring Board Reports/Other Sponsor reports** **Correspondence with the IRB** **<u>Including:</u>** **Approval letters** **Proviso letters** **PI responses to IRB** **IRB notices of upcoming expiration dates** **Request for corrected IRB letter** **IRB stamped approved documents** **IRB Membership Roster (Maintain from date of first submission to close out of the study (all 4 boards if UTHSC)** **IRB FWA**
Study Team Credentials	• **Curriculum vitae (CVs)/resume/bio sketch for the Principal Investigator/ sub-or co-investigator(s) and key study personnel (KSP) for the study** • **Financial Disclosure Forms** • **Clinical professional licensure/certification (dental, medical, nursing, pharmacy, etc.) for all KSP**

Example of Regulatory Binder Sections

Training Documents	• **Human Subject Protection** • **ICH GCP E6 (R2)** • **FDA regulations** • **45CFR46** • **Declaration of Helsinki** • **Nuremburg Code** • **Institution specific training** • **Protocol/procedures/IP** • **In-services** • **Study related meetings** • **IATA** • **SOPs/MOPs** • **Site Initiation Visit**
Delegation Log	
Subject Logs	• Master log • Screening/Enrollment log
Case Report Forms, Blank	
Case Report Forms, Completed	
Source Documents	
Investigational Product	• **Current Investigational brochure, package insert, or device manual, all versions** • **Investigational brochure, package insert, or device manual, all versions** • **Sample of product label** • **Documentation of study product shipment/receipt/dispensing/return/disposal** • **Current Investigational brochure, package insert, or device manual, all versions** • **Investigational brochure, package insert, or device manual, all versions** • **Sample of product label** • **Documentation of study product shipment/receipt/dispensing/return/disposal** • **Instructions for IP handling** • **Temperature log, when applicable** • **Storage/maintenance instructions** • **Unblinding procedures, as applicable**

Example of Regulatory Binder Sections

	• **IP Accountability Log/Dispense record to subject**
Laboratory	• **Copy of laboratory certification and accreditations** • **Laboratory normal reference ranges/values for procedures included in the protocol** • **Certification of analysis/reliability of tests performed, when requested** • **Copy of Laboratory Director's license and CV (current within 2 years)**
Specimens	• **Shipping/Receipt documentation** • **Storage temperature logs**
Adverse Events	
Protocol Deviations	• **Maintain a protocol deviation log** • **Corrective Action Preventive Action (CAPA), as applicable for each deviation**
Monitoring	• **Monitoring reports/letters** • **Monitoring Log**
Correspondence	**Significant e-mails/faxes/letters/electronic documents, meeting notes, phone calls from the following:** • **Sponsor** • **Contract Research Organization (CROs)** • **Monitor** • **IRB (prefer to keep this correspondence with the IRB section)** • **Study Team**
Legal /Financial Documents	• **FDA** • **Contracts** • **Budgets** • **Subject payments** • **Letter of Understanding/Confidentiality Agreement** • **Data Sharing Agreement** • **Material transfer Agreement** • **Signed agreements between parties (i.e., sponsor/CRO/Institution investigators)**
Note to Files	