Regulatory Binder Checklist Guidance

A regulatory binder refers to the regulatory documentation related to the conduct of your research study. It is the compilation of materials that you will use, or refer to, as your study progresses. Most documents are not subject specific but refer to the overall conduct of the study. This may be organized in a binder or may be kept in an electronic file format, whichever is preferred by the PI and accessible to the study team, regulatory authorities, human research protection program (HRPP) staff, and Institutional Review Board (IRB) members.

Documentation should be maintained in a well-organized fashion, providing a complete and thorough history from protocol development to study completion. Maintaining a regulatory binder allows the research team to readily reference information, and provides access to essential documents by IRB or regulatory authorities.

This document clarifies the standard content of a study's regulatory binder. It serves as a template and may be modified for study-specific needs/requirements. It adheres to the requirements of:

- Good Clinical Practice (GCP, E6)
- Health and Human Services (HHS) policy for protection of subjects, 45 CFR Part 46
- Food and Drug Administration (FDA) policy for the protection of human subjects, 21 CFR Parts 50 and 56

Tips:

- Label the binder with the following information:
  - IRB Study Number
  - Study Title
  - PI Name
  - Sponsor Name
  - Institution and Location
  - Binder Number (if there are multiple binders)
- Store items in reverse chronological order, with the newest items within a section placed at the front of the section.
- Keep documents within in the binder up to date
- Store in a readily accessible, secure location

Regulatory Binder Checklist	
Study Title:	
Protocol Number:	
Principal Investigator:	
NCT Number:	

Regulatory Binder Essentials		N/A
Protocol GCP 8.2.2; 8.3.2	• Maintain all IRB approved versions (include version number/date) • Protocol Signature Page, if applicable	
CV's, Licensure, Training Certificates GCP 4.1.1; 8.2.10; 8.3.5	• CV's must be current, signed and dated within 2 years. If a study is NIH funded then an investigators NIH BioSketch may be filed • Proof of valid licenses and current professional certification should be on file for all study staff • Documentation of all training and study specific training certificates	
HRPP/IRB Documentation GCP 8.2.7; 8.2.9; 8.3.2-8.3.4	• IRB Approval Letters • QA/QI Progress Reviews • Translation Certifications • Any correspondence from foreign ethics committees (for research occurring outside of the US) • HIPAA Waiver	
Study Logs FDA: Guidance for Sponsors, Clinical Trial Investigators, and IRBs- Data Retention when Subjects Withdraw from FDA-Regulatory Clinical Trials 2008; FDA info sheet guidance for IRBs and Clinical Investigators Recruiting Study Subjects GCP: 8.3.20; 8.3.21	• Delegation of Authority Log • Study Specific Training Log • Screening/Enrollment Log • Termination Log Note: These items are needed for non-FDA regulated research.	
Consent Forms HHS: 45 CFR 46.116; 46 CFR 46.117 FDA: 21 CFR 50; 21 CFR 56 GCP: 8.2.3; 8.2.7; 8.3.2; 8.3.12	• All IRB approved versions of the consent form • All IRB approved versions of the Parental Permission Form • All IRB approved versions of Assent Forms • All IRB approved HIPAA Release Forms • IRB Approved Media Release Form • Signed copies of above forms should be kept in a separate secure location with limited access.	
Data Collection Tools FDA 21 CFR 312.53; 312.62 GCP: 8.3.14; 8.3.15; 4.9.3	• Copy of all IRB approved data collection tools (i.e., surveys, case report forms, etc.) ○ These should be blank forms	
Recruitment Materials	• Maintain all IRB approved Recruitment Materials	
Other Documentation	• Certificates of Confidentiality	

FDA -Regulated Research		N/A
Investigator Brochure, Package Insert, or Device Manual FDA: 21 CFR 312.55; 312.57; 312.62; 812.140 GCP: 8.2.1; 8.3.1	• Most recent version of the Investigator Brochure (IB), package insert, or sample label • Device Manual of Report of Prior Investigations (ROPI) for investigational Devices • Investigator Brochure Signature Page	
Drug/Device Related Information FDA: 21 CFR 312.55; 312.57; 312.62; 812.140 GCP: 8.2.1; 8.3.1	• IND/IDE- Include all versions. • Unmasking procedures for blinded trials	

FDA Documentation
FDA: 21 CFR 54; 312.30; 312.32; 312.33; 812.150(b)(1); 812.150 (b)(5); 812.43 (c)
GCP: 4.11; 5.16.2; 5.17;8.3.16;8.3.18; 8.3.19
	• Include copies of all reports sent to the FDA
	• Correspondence with the FDA.
	• FDA 1571- All signed and dated versions
	• FDA 1572 (Drug Study Only)- All signed and dated versions.
	• FDA Safety Reports
	  ○ Include all reports and related correspondence.
	  ○ FDA Forms 3500 and 3500A	

Sponsor Correspondence/ Documentation GCP 8.3.20- 8.3.25	• Site Visit Log (Monitoring Log) • Copies of All External Monitoring/ Auditing Reports • Documentation of Site Initiation • For DoD funded research, include medical monitor communication and documentation	
Logs	• Screening/Enrollment • AE/SAE/Protocol Deviations • Monitoring/Site Visits • Investigational Product Dispensation/Accountability	
IRB Roster/FWA	• Copy of the IRB roster • Federalwide Assurance (FWA) number	
If the research involves Labs		N/A
CLIA/CAP Certifications GCP: 8.2.11; 8.2.12; 8.2.14; 8.3.6; 8.3.7	• Lab certifications and Updates to certification over lifetime of study.	
Current/Past Lab Normal Ranges GCP: 8.2.11; 8.2.12; 8.2.14; 8.3.6; 8.3.7		
Copy of CV for Lab Manager GCP: 8.2.11; 8.2.12; 8.2.14; 8.3.6; 8.3.7		
Biospecimen Log		

Additional Sections as Applicable		N/A
NIH Documentation	• Notice of Award • Progress Reports • Correspondence	
External IRB Documentation	• Local context reviews • Correspondence • Reliance agreements	
Ethics Committee/ Community Advisory Board Documentation	• Non-regulatory reviews • Non-regulatory correspondence	
Scientific Review	• Documentation or reports of any scientific reviews	
Detailed Data Protection Plan GCP 8.2.2; 8.3.2	• Data Safety Monitoring Plan (DSMP) ○ This may be described in the protocol • Reports from DSMB	
Financial Disclosures for each Investigator	• NIH and other sponsors require signed financial disclosure forms to be maintained and submitted, as required, on each study team member.	
Public Registration of Research Study	• All research studies that are applicable clinical trials must be registered at ClinicalTrials.gov and assigned an NCT# as per ICJME, FDAAA, and local institutional policy.	