Regulatory Binders provide a framework for organizing essential study documents. A regulatory binder can be paper or electronic. It is the responsibility of a study team member, usually the Coordinator, to establish the regulatory binder location. Maintaining a regulatory binder ensures compliance with Good Clinical Practices (GCP). This guidance can be used as a template for organizing a regulatory binder and/or electronic file. A sponsor may provide a specific order for the regulatory binder.

Documents should be stored in the binder in reverse chronological order.

The Basic Regulatory Binder and the Study Subject Information Binder should be separate. If paper, the binders should be stored in different locations with the Study Subject information binder stored in a secure location. If stored electronically, the Study subject information should be in a password-protected folder.

The binders should be maintained for a period of 3 years, or longer if dictated by the sponsor or law, after the study has ended.

Basic Regulatory Document Sections:

1. Personnel
2. IRB Approvals & Correspondence
3. Sponsor Documents
4. Monitoring Records
5. Laboratory Documents
6. Reportable Events
7. Drug/Device Information
8. Other Documentation

Study Subject Information Sections:

1. General Subject Information
2. Individual Subject Files

BASIC REGULATORY DOCUMENTS

PERSONNEL

Documentation	Additional Information
Curriculum Vitae (CV)	• Required for PI and Sub-investigators • Signed and dated • Updated every 2 years
Current license and/or certifications	• Required for all professional study staff • Dental, medical, pharmacology, etc.
FDA 1572, *as applicable*	
CITI Training Completion Certificates	• Required for all study team members • Biomedical Research • GCP Drug or Device Development, *for clinical trials*
Delegation Log	*Documents the signatures and initials for all staff that collect and record study data, and lists the study-related procedures each staff member has been delegated by the PI*

IRB APPROVALS & CORRESPONDENCE

Documentation	Additional Information
Submission Forms	• Initial Submission • All Amendment Submissions • All Renewal Submissions • All Renew/Amend Submissions • Closure Form
Outcome Letters	• Approvals of initial, amendment, renewal, and renew/amend submissions • MRSA Letters • Deferral Letters
Other IRB Correspondence	
Protocol	• All IRB-approved versions
Consent and/or assent forms, *as applicable*	• All IRB-approved versions
HIPAA Authorization, as applicable	• All IRB-approved versions
Blank Study Instruments, *as applicable*	• Data collection forms • Questionnaires • Case Report Forms (CRFs) • Other instruments

IRB-approved Recruitment Materials, *as applicable*	• Emails • Flyers • Other materials
IRB-approved Educational Materials or other study information designed for subjects	• Brochures • Powerpoint Slides • Study-Specific Instructions • Other materials

SPONSOR DOCUMENTS *(as applicable)*

Documentation	Additional Information
Award Documents	• Grant application • Notice of Grant Award (NGA) or clinical trial agreement (CTA) • Progress reports
Sponsor Correspondence	

MONITORING RECORDS *(as applicable)*

Documentation	Additional Information
Monitoring Log	*Document any study-related activity performed to monitor the progress of the study or the accuracy/completeness of study records*
Data & Safety Monitoring Board (DSMB) reports	
Sponsor Monitoring Correspondence	• Emails • Monitor report
Audit Reports	• Internal audit reports • External audit reports

LABORATORY DOCUMENTS *(as applicable)*

Documentation	Additional Information
Copies of laboratory certifications	*Must be up-to-date*
CV for Laboratory Director	
Laboratory Policies & Procedures	
Normal lab values	*For reference*

REPORTABLE EVENTS

Documentation	Additional Information
Event Tracking log	Should document: • Protocol deviations (PD) • Related Adverse Events (AE)

	• Unrelated AEs • Unanticipated Problems (UP) • Off-site PDs, AEs, UPs
RNI Submission Forms	• Initial Forms • Outcome Information

DRUG/DEVICE INFORMATION *(as applicable)*

Documentation	Additional Information
Investigator Brochures & Safety Update Letters	• All versions
Policies and Procedures	• Dispensing of study drug/device • Security of study drug/device • Storage of study drug/device
IND/IDE Application(s)	
Drug/Device Shipment and Receipt records	*May be maintained by Pharmacy*
Drug/Device Accountability Log	*May be maintained by Pharmacy*
Drug/Device Disposal records	*May be maintained by Pharmacy*
Temperature Logs for Drug/Device Storage	*May be maintained by Pharmacy*
FDA Correspondence	• Email, mail communications • Annual report

OTHER DOCUMENTATION *(as applicable)*

Documentation	Additional Information
Other Regulatory Review Documents	• IBC • Radiation Safety • Other IRB approval letters
Other Documentation	*Anything not outlined above that the study team wants to maintain with the rest of the study files*

STUDY SUBJECT INFORMATION

GENERAL SUBJECT INFORMATION

Documentation	Additional Information
Screening Log	*Capture all potential study subjects who may be qualified for participation in the research*
Enrollment/Randomization Log	*Capture all subjects who have been consented & randomized, as applicable*
Subject Compensation Documentation	*Accounting of all funds paid to subjects*

INDIVIDUAL SUBJECT FILES

Documentation	Additional Information
Eligibility Checklist	• Signed & dated by staff confirming eligibility • Lists specific inclusion/exclusion criteria
Consent Form(s), HIPAA Authorization(s), and Notice of Privacy Practice	• Signed & dated • All versions
Individual Case Report Forms	
Completed Study Instruments	
Visit Schedule Log	