LSU HEALTH COORDINATOR COMPETENCIES

X

DOCUMENTATION & DOCUMENT MANAGEMENT

Study Documentation

Objectives

- Outline required components of study documentation for all clinical research
- Define standard documentation terminology

Regulatory Binders

What is a purpose?

- Provides a framework for organizing essential study documents
- Ensures compliance with Good Clinical Practices

Who is responsible for maintaining the regulatory binder?

- A delegated member of the study team, usually a coordinator

How can a regulatory binder be stored?

- On paper in physical binders or electronic (i.e., secure drive, eReg system)

What types of studies should maintain a regulatory binder?

- Best practice is for all studies to have one. It is required for clinical trials.

Regulatory Binder Tips

- Documents should be stored in reverse chronological order
- The basic regulatory binder and the study subject binder should be separate
- Study subject binders should be stored securely
  - If paper, in a locked office
  - If electronic, in a password-protected folder
- Binders should be maintained for the life of the study plus 10 years, or more if dictated by a sponsor

Regulatory Binder Sections

LSU Health NEW ORLEANS
Office of Research Services

Personnel
IRB
Sponsor
Monitoring
Lab
RNIs
Drug/Device
Other

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	• Signed and dated

Personnel
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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

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IRB Approvals & Correspondence

Documentation	Additional Information
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 • Emails • Flyers • Other materials
IRB-approved Educational Materials or other study information designed for subjects	• Brochures • PowerPoint Slides • Study-Specific Instructions • Other materials

Personnel
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Sponsor Documents

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

Personnel
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Monitoring Records

Documentation	Additional Information
Monitoring Log	
Data & Safety Monitoring Board (DSMB) Reports	
Sponsor Monitoring Correspondence	• Emails • Monitor report
Audit Reports	• Internal audit reports • External audit reports

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Laboratory Documents

Documentation	Additional Information
Copies of Laboratory Certifications	• Up-to-date
CV for Lab Director	
Lab Policies & Procedures	
Normal Lab Values	• For Reference

Personnel
IRB
Sponsor
Monitoring
Lab
RNIs
Drug/Device
Other

Reportable New Information

Documentation	Additional Information
Event Tracking Log	• Protocol deviations (PD) • Related Adverse Events (AE) • Unrelated AEs • Unanticipated Problems (UP) • Off-site PDs, AEs, UPs
Reportable Event Form	• Initial Forms • Outcome Information

Personnel
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Drug/Device
Other

Drug/Device Information

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*

Personnel
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Drug/Device
Other

Drug/Device Information

Documentation	Additional Information
Temperature Logs for Drug/Device Storage	*May be maintained by Pharmacy*
FDA Correspondence	• Email, mail communications • Annual report

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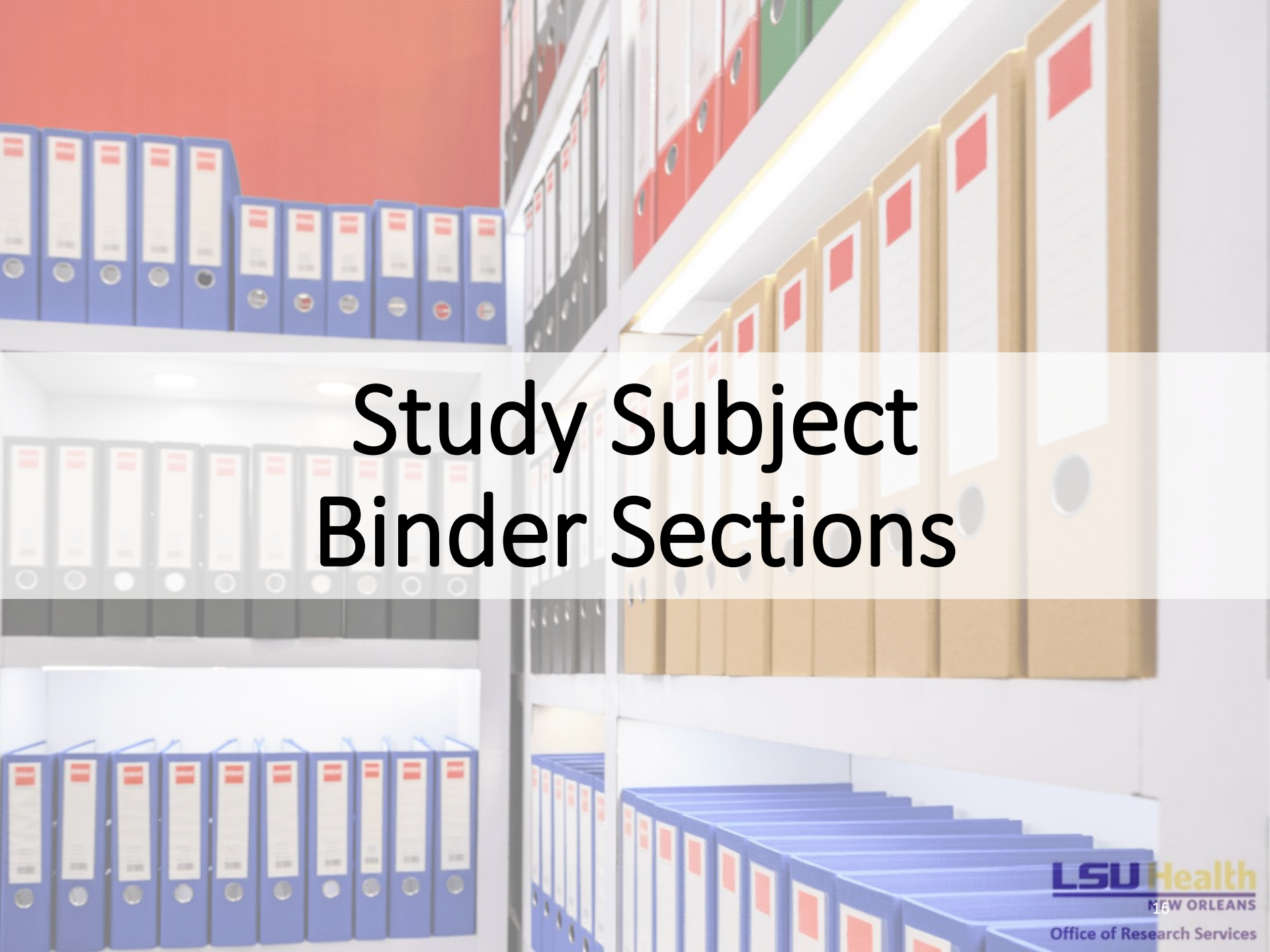
Other

Other Documentation

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 Binder Sections

Subject Logs

Eligibility

ICF, HIPAA, NPP

Subject CRFs

Instruments

Schedule

Individual Study Subject Information

Documentation	Additional Information
Logs	• Screening • Enrollment/ Randomization • Compensation
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	

LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ✓ Protocol Compliance
- ✓ Informed Consent
- ✓ Patient Recruitment & Retention
- ✓ Management of Patients
- ✓ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development