LSUHSC IRB Presents:

LUNCH & LEARN

REGULATORY BINDERS

APRIL 4, 2023

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Objectives

- To provide guidance for research investigators and study teams on organizing regulatory binders.

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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?
- ALL STUDIES SHOULD HAVE A REGULATORY BINDER, NOT JUST CLINICAL TRIALS

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Regulatory Binders 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

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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

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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

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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	

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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

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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

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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*

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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 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

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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	

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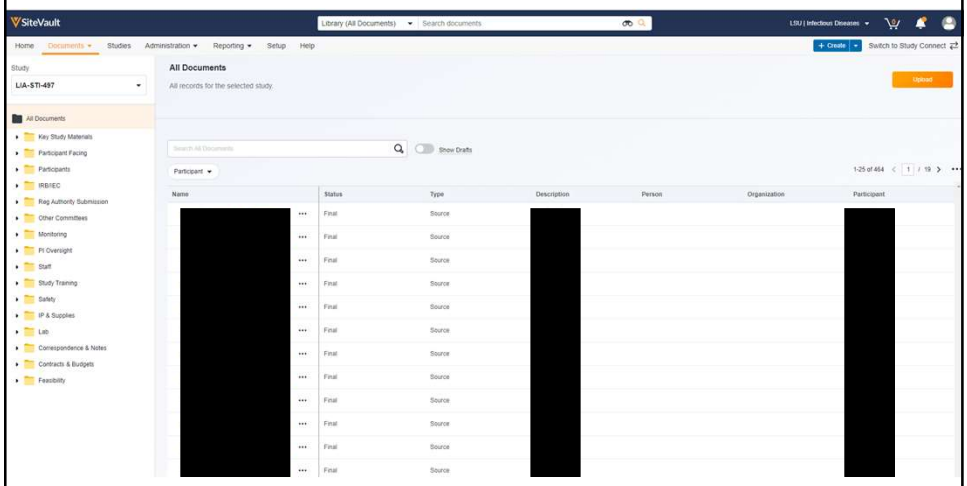

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Save the Date!

Date	Time	Topic
05/03/2023	12:00PM	Expanded Access Use of a Test Article
06/07/2023	12:00PM	Non-Human Subjects Research Determinations
07/05/2023	12:00PM	Reliance/Single IRB

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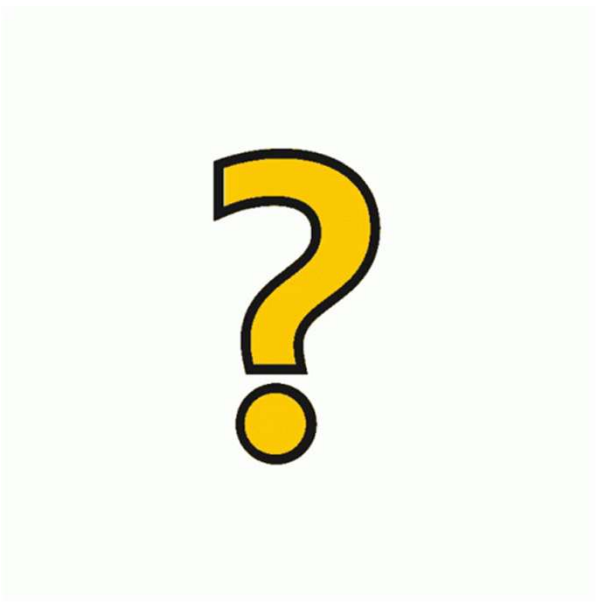

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