



**STUDY TEAM REGULATORY  
RESPONSIBILITIES**

August 2, 2023

## Objectives

- To inform Study Teams of the regulatory responsibilities they have when conducting research

# 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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Back in April, we had a lunch and learn diving into the weeds of regulatory binders. As a refresher, the binder is a framework for organizing study documents. While the IRB maintains our own records per the federal regulations, it is also the responsibility of the study team to maintain their own files. This task is usually delegated to one member of the team but everyone is ultimately responsible for ensuring compliance with this requirement.

# Personnel Training

Each study team member is responsible for keeping their own training up to date.

Training	Frequency	Training Provider	Required for...
Biomedical Research	Every 3 Years	CITI	Personnel conducting biomedical or clinical research
Social & Behavioral Research	Every 3 Years	CITI	Personnel conducting social or behavioral research
Good Clinical Practice	Every 3 Years	CITI	Personnel conducting clinical trials
Conflicts of Interest in Research	Every 4 Years	CATS	All personnel
HIPAA Privacy in Research	Annual	CATS	All personnel
Bloodborne Pathogens – High Risk	Annual	CATS	All personnel
Shipping Biological Materials	Every 2 Years	CATS	Personnel shipping biospecimens
Annual COI Disclosure	Annual	Kuali	All personnel

## Submission of Renewals

Federal regulations require an IRB to conduct continuing review of research at intervals appropriate to the degree of risk. Continuing reviews are submitted using the Renewal form in the Kualu Research (KR) electronic submission platform.

### **When to Submit**

To ensure adequate time for the IRB to review a Renewal application, the Study Team is required to submit the Renewal form:

- No later than 30 days before the Continuing Review Date for studies approved by the Full Board
- No later than 15 days before the Continuing Review Date for studies approved by the Expedited or Exempt procedure

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In our March Lunch & Learn, we dove into the details of Renewals (aka Continuing reviews). Federal regulations require regular review of the research to ensure continued compliance with the study as it was approved and with the regulations.

As a courtesy, the Kualu system sends out email reminders of continuing review 60, 45, 30, 15, 7, and 1 day prior to IRB approval lapse; however, it is ultimately the study team's responsibility to ensure that the renewal application is submitted timely.

## Halting Research Activities

If IRB approval lapses, all research activities must stop immediately, except when the investigator judges it to be in the best interest of current participants to continue, in which case s/he must notify the IRB Office promptly.

### **How to Resume the Study**

The Study Team may resume research activity once a Renewal application has been reviewed AND approved by the IRB.

## Submission of Amendments

Federal regulations require an IRB to conduct review of all proposed modifications to a research study **prior to** those modifications being implemented. Modifications to research are submitted using the Amendment form in the Quali Research (KR) electronic submission platform.

### **When to Submit**

The study team should submit any proposed changes to the research prior to implementing those changes. They should be submitted as soon as possible to avoid any delays in planned implementation.

# Reportable New Information

Any new information that may impact on the conduct of an IRB-approved research study or the safety and welfare of the participants in that study must be documented by the Study Team in the appropriate manner.

## **PROMPT REPORTING**

**Time Frame:** 5 business days of becoming aware

**Method:** Reportable Event Application

### **RNIs that Require Prompt Reporting**

- Serious AEs
- Unanticipated Adverse Device Effect
- Serious or Continuing Non-Compliance
- Major or Continuing Consent/HIPAA Issues
- Major Protocol Deviations
- Emergency Deviations
- Incarceration of Study Participant
- Breach of Privacy/Confidentiality
- Hold/Suspension/Termination
- Results of Audit/Inspection by Government
- New FDA Black Box Warning
- Significant/Unresolved Subject Complaint
- State Medical Board Hospital Staff Action

## **NON-PROMPT REPORTING**

**Time Frame:** Next Renewal or Closure

**Method:** Event Tracking Log

### **RNIs that Do Not Require Prompt Reporting**

- Unexpected & related/possibly related AEs
- Minor Non-Compliance
- Minor Consent/HIPAA Issues
- Minor Protocol Deviations
- AEs and UPs that DO NOT occur locally

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In our December Lunch & Learn, we discussed reportable new information and the reporting requirements set forth by Federal regulations and the institution. It is the study team's responsibility to report RNIs accordingly in order to keep the study in good standing.



## Contact the IRB with Questions

Staff Member	Title	Contact
<a href="#">Lynn Arnold</a> , MBA	Manager, Research Compliance	<a href="mailto:larnol@lsuhsc.edu">larnol@lsuhsc.edu</a> or (504) 568-3779
<a href="#">Noel Cal</a> , MA	IRB Analyst II	<a href="mailto:ncal@lsuhsc.edu">ncal@lsuhsc.edu</a> or (504) 568-2491
<a href="#">Mark James</a> , PhD	IRB Analyst I	<a href="mailto:mjam20@lsuhsc.edu">mjam20@lsuhsc.edu</a> or (504) 568-1285
<a href="#">Mya Sherman</a> , MS, MA	IRB Analyst II	<a href="mailto:msherm@lsuhsc.edu">msherm@lsuhsc.edu</a> or (504) 568-1668
	Central Office	<a href="mailto:IRBOffice@lsuhsc.edu">IRBOffice@lsuhsc.edu</a> or (504) 568-4970

*In regulatory, it is not better to beg for forgiveness than ask for permission.*

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We are all familiar with the old adage its easier to beg for forgiveness than ask permission. That is not the case in the regulatory world.

# Save the Date!

Date	Time	Topic
09/06/2023	12:00PM	FDA's IRB Inspection: A Post-Mortem

