LSUHSC IRB Presents:

LUNCH & LEARN

STUDY TEAM REGULATORY RESPONSIBILITIES

August 2, 2023

Objectives

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

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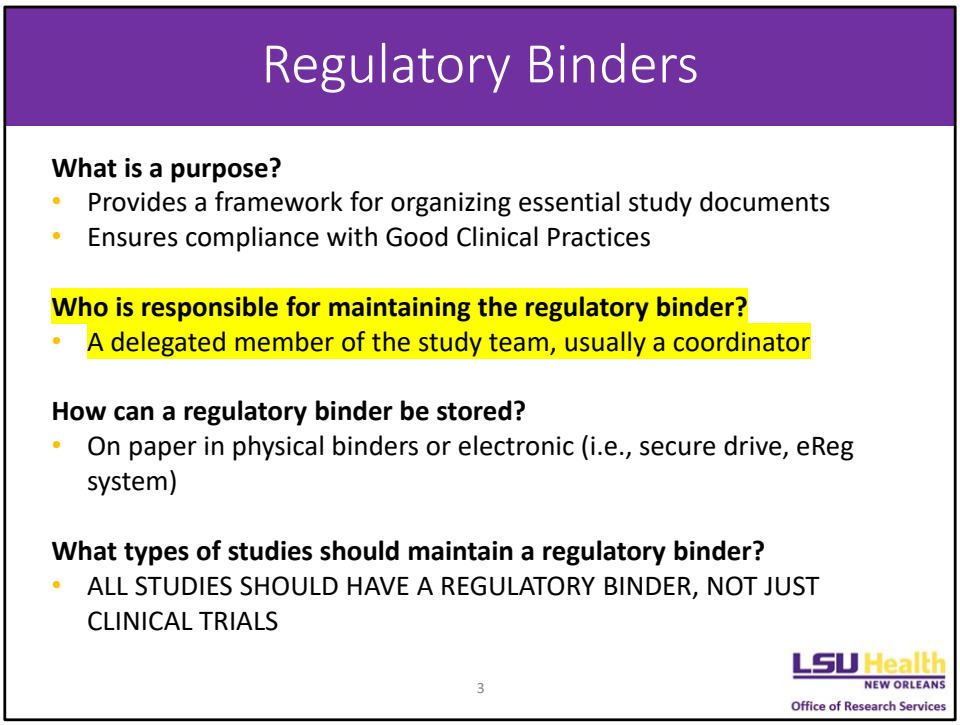

Back in April, we had a lunch and learn diving into the weeds of regulatory binders. As a refresher, the binder is a framework for organizing study documents. While the IRB maintains our own records per the federal regulations, it is also the responsibility of the study team to maintain their own files. 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

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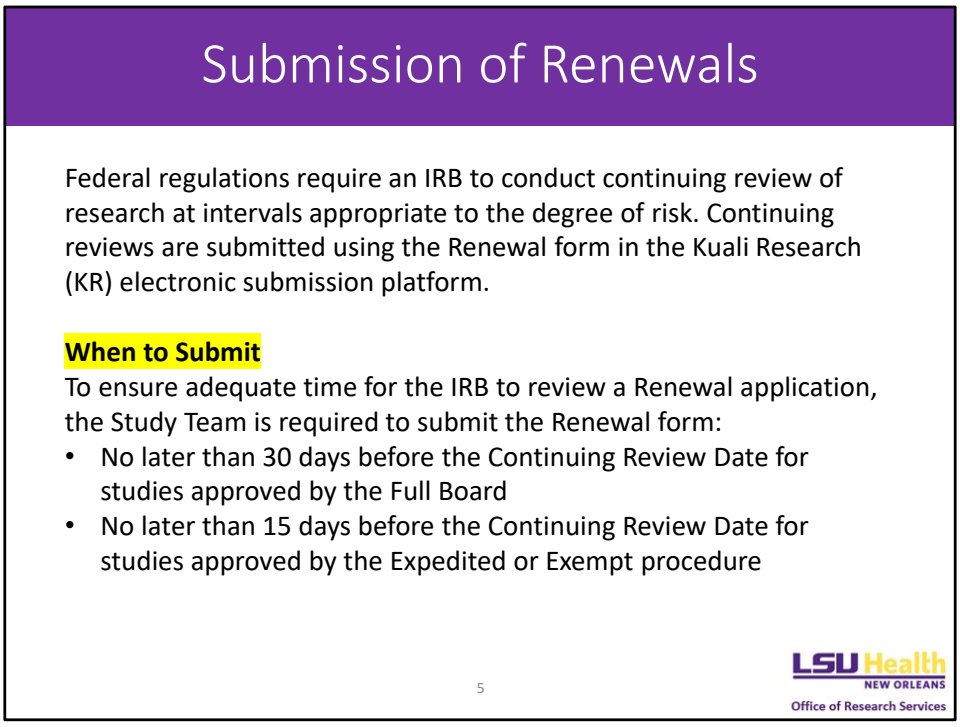

In our March Lunch & Learn, we dove into the details of Renewals (aka Continuing reviews). Federal regulations require regular review of the research to ensure continued compliance with the study as it was approved and with the regulations.

As a courtesy, the Kuali 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.

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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 Kuali 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.

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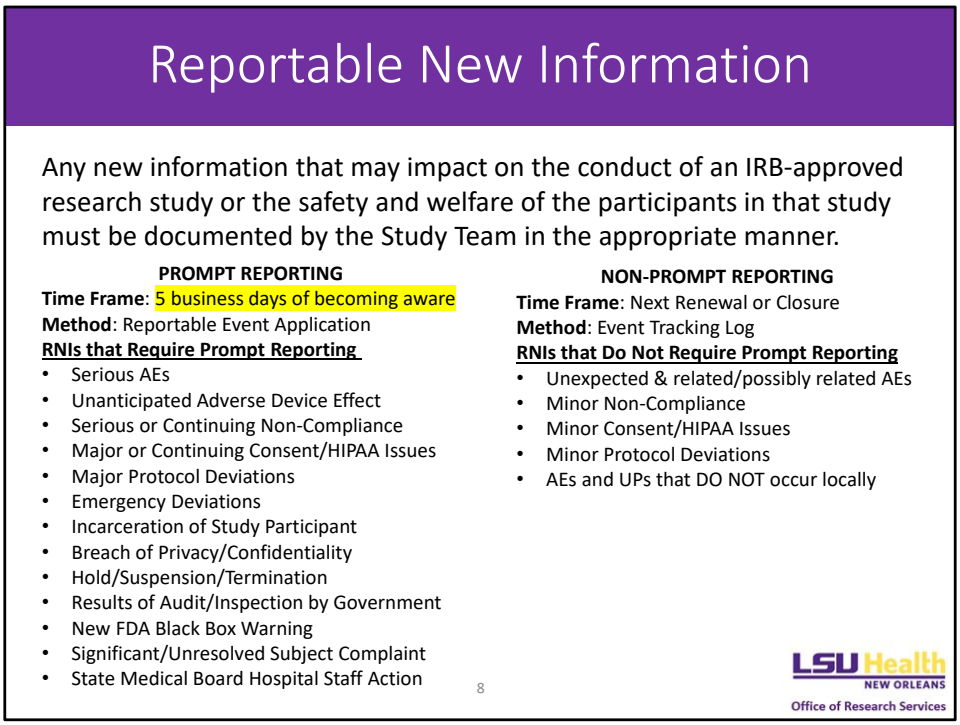
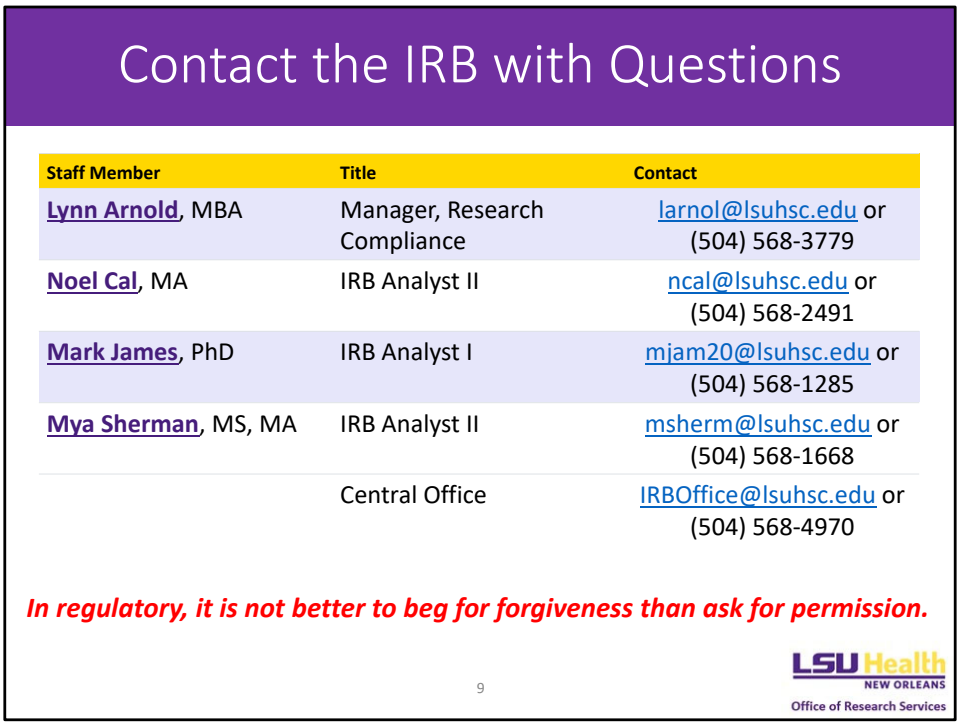


In our December Lunch & Learn, we discussed reportable new information and the reporting requirements set forth by Federal regulations and the institution. It is the study team's responsibility to report RNIs accordingly in order to keep the study in good standing.



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

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