

LSUHSC IRB Presents:
LUNCH
& **LEARN**

CONTINUING REVIEW / RENEWALS

MARCH 1, 2023

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Objectives

- To provide guidance for research investigators and study teams on continuing review required for their IRB protocols.
- To provide guidance to investigators and study teams on what information should be submitted as part of the IRB renewal.

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Continuing Review

Continuing Review = Process; Renewal = Application

- Federal regulations require an IRB to conduct continuing review of research at intervals appropriate to the degree of risk.
- This review allows the IRB to monitor the progress of the study and ensures that the study continues to meet the requirements for approval.
- Continuing Review is required until the Principal Investigator has completed all research-related interactions and interventions with participants or when the collection and analysis of identifiable private information, as described in the IRB-approved research protocol, has been completed.

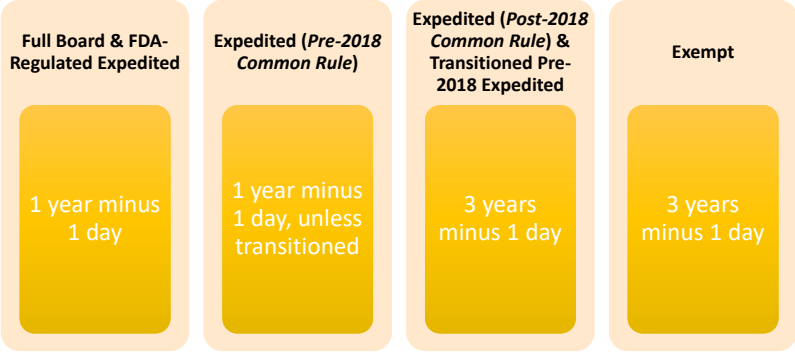
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Continuing Review Schedule

Although the revised Common Rule does not require continuing review of Exempt and Expedited research, the LSUHSC IRB has elected to require regular reporting on all research approved by our IRB.



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Continuing Review Date vs Expiration Date


Kuali lists two dates related to continuing review of a study:

CR Date

- X years minus 1 day from last approval
- If the renewal is not approved by this date, the IRB approval is considered lapsed, and all study activities must stop

Expiration Date

- 60 days after the CR Date
- If a renewal is not approved by this date, the study will be closed permanently


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Continuing Review Reminders

Reminders for the study team to submit continuing review are sent out in the following intervals:

Before CR Date	After Lapse
60 days	1 day
45 days	7 days
30 days	15 days
15 days	30 days
7 days	45 days
1 day	59 days

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Submitting a Renewal

How to Submit

Continuing reviews are submitted using the Renewal form in the Quali Research (KR) electronic submission platform.

When to Submit

To ensure adequate time for the IRB to review a Renewal application, the Principal Investigator 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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If Approval Lapses...

If IRB approval lapses, all research activities must stop, 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

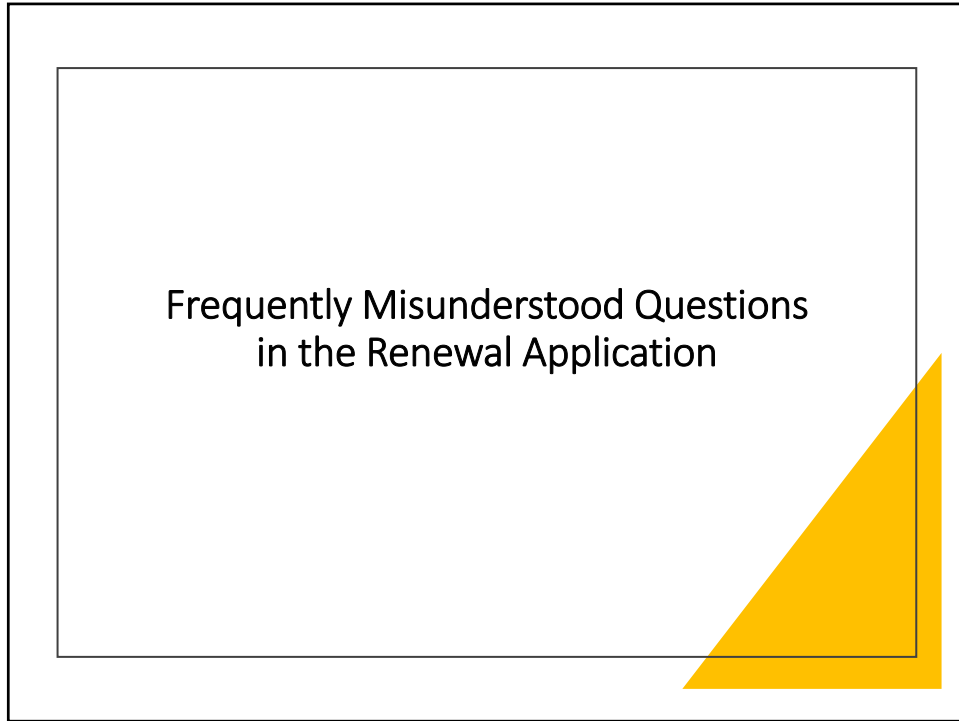
The investigator may resume research activity once a Renewal application has been reviewed AND approved by the IRB.

Study Expiration and Administrative Closure

A lapsed study that has not obtained Renewal approval by the Expiration Date will be administratively and permanently closed. Once permanently closed, the study cannot be re-activated. Continuation of research that is administratively closed will require submission, review and approval of a new protocol in KR.

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Study Type & Status: Renewal Option

Which renewal option did you select when initiating this submission?

Renew

Renew & Amend

TIPS:

- *Study Team response should match the submission type.*

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LSU Health
NEW ORLEANS
Office of Research Services

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Data Protection

Does this study involve the collection and storage of protected health information/HIPAA identifiers as defined here?

- Yes
 No

TIPS:

- *If the study team is collecting a HIPAA Authorization, then the response to this question should be “Yes”.*

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Study Personnel & Modifications: Approved Modifications

List and briefly summarize each IRB-approved modification to the study (to funding, personnel, procedures, key documents, etc.) during the most recent approval period.

TIPS:

- *Only amendments approved since the last renewal should be listed*
- *If the study team is submitting a Renew/Amend application, do not list the amendments being requested here.*

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Research Participants

Does this research involve the collection and analysis of data from medical records (i.e., chart review study)? *If yes...*

- Total number of charts approved for review
- Number of charts reviewed/searched since the last review
- Number of charts used for data collection since the last review
- Number of charts reviewed but not included in the data collection since the last review

TIPS:

- *Only answer yes if a chart review is a primary component of your research design (i.e., not used just for screening)*
- *Total number of charts approved should match what is in the IRB application*

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Research Participants

Does this research involve the collection and analysis of data from medical records (i.e., chart review study)? *If yes...*

- Total number of participants approved for enrollment
- Number of participants enrolled since the last review
- Total number of participants enrolled since the start of the study
- Total number of participants withdrawn since the start of the study
- Number of participants withdrawn since the last review

TIPS:

- *Total number of charts approved should match what is in the IRB application*
- *Total numbers of enrolled and withdrawn should be based on last year's reported numbers plus any new subjects enrolled/withdrawn during the past approval period*

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Reportable Events: Promptly Reported Events

Have ALL EVENTS REQUIRING PROMPT REPORTING that have occurred since the last review of the study been reported to the IRB?

- Yes
 No
 N/A; no such RNIs have occurred

TIPS:

- *If there are no events in the Reportable Events tab, then the study team should respond "N/A"*

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Reportable Events: Not Promptly Reported Events

Have there been any events since the last review of the study that DID NOT REQUIRE PROMPT REPORTING to the IRB?

- Yes
 No

TIPS:

- *If "Yes," be sure to attach the Event Tracking Log*
- *If any issues are identified during the continuing review and the IRB requests documentation of the RNI, then be sure the ETL is updated and attached here*

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Renewal Supporting Documents

Attach ALL relevant supporting documents not previously attached to the table below.

- The most recent version of the approved protocol (*legacy only*)
- The most recent version of the approved consent form or information sheet (*legacy only*)
- Two redacted copies each of the signed consent, HIPAA and Notice of Privacy Practice forms (*if applicable*)
- Current Investigator Brochure (*for FDA-regulated research*)
- DSMB/DMC reports released since the last review (*if applicable*)

TIPS:

- *Make sure all pages of the consent, HIPAA, and NPP are scanned*
- *Names, DOBs, and signatures of the subjects should be redacted; please leave dates visible.*

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Save the Date!

Date	Time	Topic
04/05/2023	12:00PM	Regulatory Binders
05/03/2023	12:00PM	Expanded Access Use of a Test Article
06/07/2023	12:00PM	Non-Human Subjects Research Determinations

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