

Continuing review process-

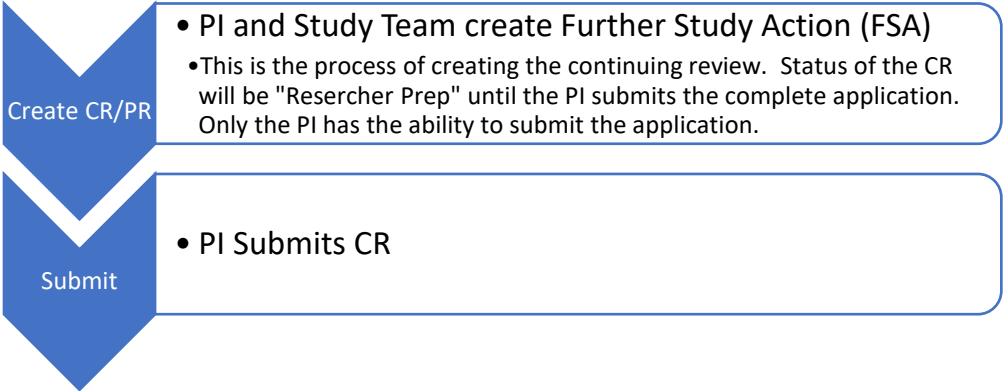
The frequency with which an active protocol must undergo continuing review is determined by the level of risk involved in the research. Research that is determined to be more than minimal risk and reviewed by a convened meeting of the IRB must undergo continuing review r.

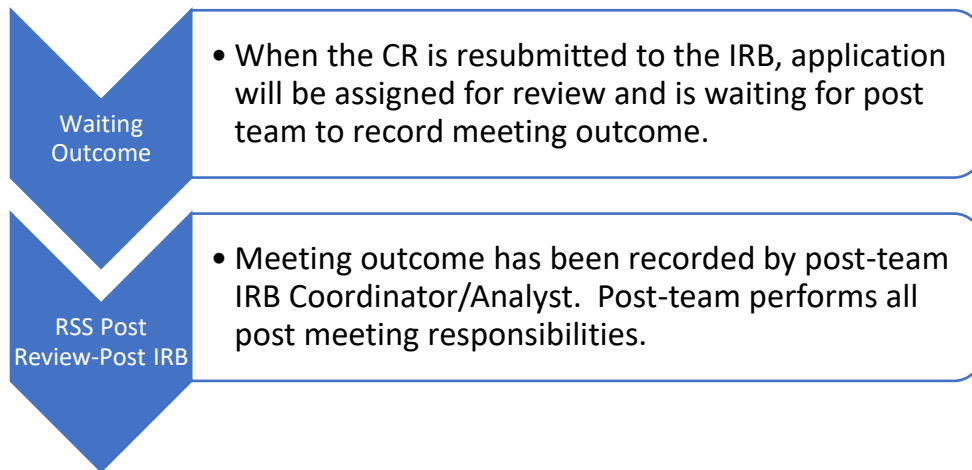
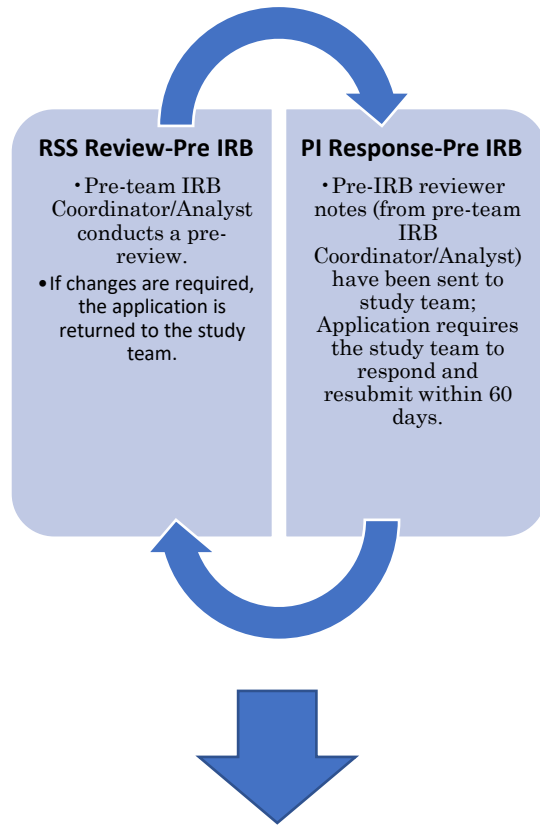
Research determined to be not more than minimal risk and was approved before January 20, 2019 must also receive continuing review . Research determined to be not more than minimal risk and was approved on or after January 20, 2019 may be determined not to require continuing review. Where continuing review is not required by regulation or a determination of the JHM IRB the JHM IRB may require submission of a progress report at periodic intervals or not require additional reporting on the study's progress. Please see Progress Report Process [insert page or doc] for more information.

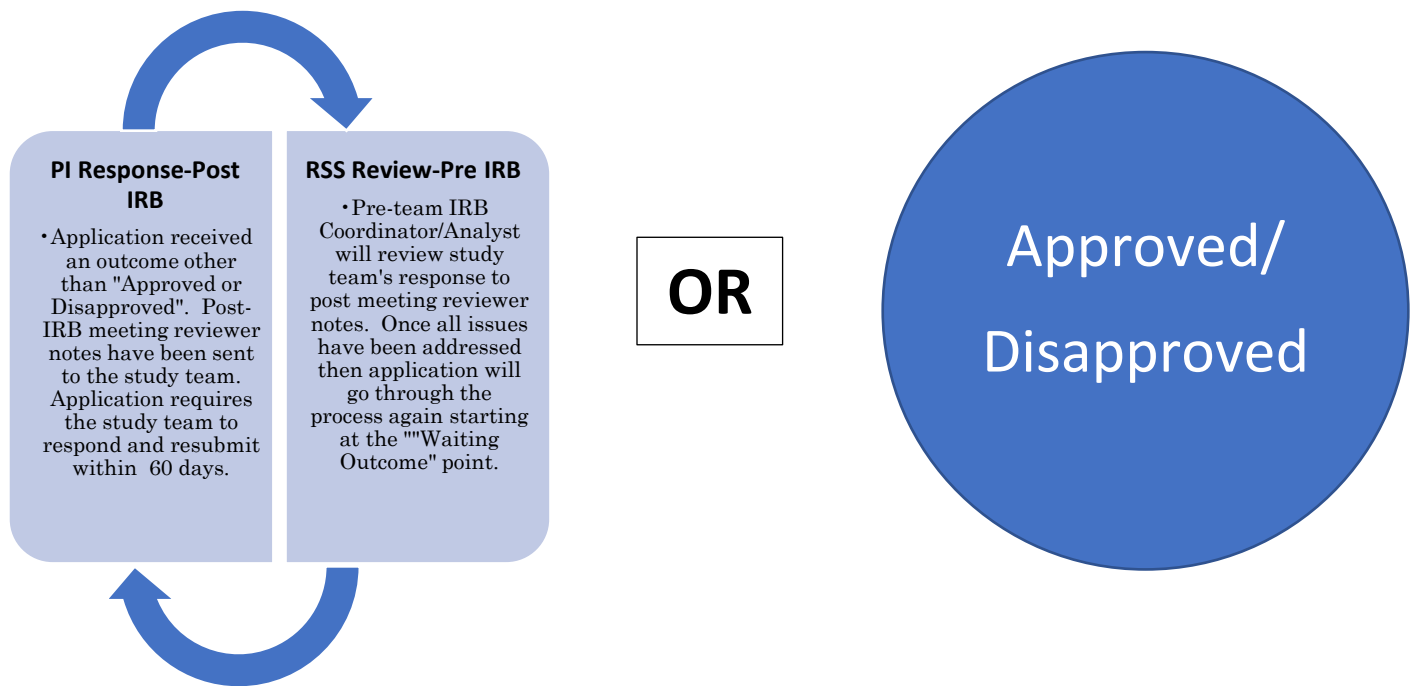
The frequency with which continuing review must be conducted will be indicated in the initial approval letter and in each continuing review approval letter.

The IRB electronic submission system, eIRB, is programmed to send notification to study teams prior to the protocol expiration date as a reminder that a CR must be submitted. Reminders are generated at 60 days, 30 days and 24 hours prior to expiration. If a CR is not submitted prior to expiration, all research-related activity, including data analysis, must stop. If the PI wishes to continue the research, an appeal can be made to reinstate the application so a CR can be submitted. If the CR is submitted but not approved prior to expiration, the application moves to a lapsed state and all research-related activity, including data analysis, must stop until the application is approved. If it is in the best interest of participants to continue research-related activities while a protocol is in the lapsed state, the PI may submit a written request to continue them on the study. This request must be approved by the committee Chair.

eIRB notifies the study team at 60 days, 30 days and 24 hours prior to the expiration date that the PI must request to extend the research for another 3 years using the Extend Approval activity in eIRB. If the PI does not request the extension, the protocol moves to an expired state. If the PI wishes to continue the research, an appeal can be made to reinstate the application so the PI can extend the research.







It is important to submit the CR 6-8 weeks before the study expiration. This allows the Board time to complete the review prior to the expiration date.

Lapsed vs Expired-

If a CR has been submitted but not approved before the study's expiration date, the study will move to a lapsed state and no research activities, including data analysis, may continue until approval has been granted.

If CR review has not been submitted before the study's expiration date, the study will move to an expired state, all research activity, including data analysis, must stop and a new application needs to be submitted to continue the research. A request to reinstate the application so the CR can be submitted via email to the IRB Help Desk, jhmeirb@jhmi.edu. From there a determination will be made whether or not to reinstate the application to allow a CR to be submitted.