What is an eIRB Continuing Review?

In eIRB, your study file consists of 1) the study application, 2) all the attached documents in the application (i.e., consent forms, flyers, protocol), and 3) the history log, reflecting all the correspondence and action letters. Federal regulations require that all research be reviewed at no less than annual intervals and that studies involving high risk may require more frequent review.

The purpose of this process is to review an entire study and determine that the anticipated risks and benefits are reflected in the actual experience of subjects and that the safeguards in place at the time of original approval are, in fact, adequate to ensure the safety of subjects.

Click on “New Continuing Review” in the study workspace to create the Continuing Review. Answer the questions in the Continuing Review Smart Form. The Smart Form will guide you through the necessary questions for you to complete the report.

The migration of studies that currently exist and are approved as paper studies is as follows:
1. The IRB will create a “Shell” record with minimum information in eIRB, then notify the study staff
2. The Study Staff will create and complete the Continuing Review Smart Form
3. The Study Staff will create and complete an Amendment answering ALL applicable questions, based on the type of research being conducted, in the study Smart Form
4. On the Amendment, note that the Amendment is associated with a Continuing Review and note if the Amendment reflects any changes to the study as currently approved.

Items of note:
1. Continuing Reviews cannot be accepted by the IRB for process more than 45 days prior to expiration
2. To ensure time to address any committee concerns, Continuing Reviews should be submitted at least 30 days prior to expiration
3. Continuing Reviews are requests to continue the research study “As Currently Approved”. If there are changes to the currently approved study, they must be submitted as Amendments to the study. These are two separate items even if submitted simultaneously.
4. If subjects were enrolled during the previous approval period, a copy of the most recent signed consent must be uploaded with the Continuing Review request.
What are the parts to an eIRB Continuing Review?

**The Continuing Review Application:** Serves as the cover letter providing information on the previous approval period. To edit the Continuing Review application, click the *Edit Continuing Review* icon on the left.

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**NOTE:** Like a new study submission, any member of the study team can create a Continuing Review, but only the Principal Investigator can submit a Continuing Review to the IRB.