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Continuing Reviews

The IRB is required to conduct substantive and meaningful continuing review not less than once per year. For research requiring review by convened IRB (full board continuing review), the IRB approval period may extend no more than 365 days after the convened meeting at which the research was last approved. For research within the categories appropriate for expedited review (expedited continuing review), the IRB approval period may extend no more than 365 days after the expedited review at which the research was last approved. The regulations permit no grace period and no exceptions to the one year requirement. Research that continues after the approval period expires is research conducted without IRB approval. GU’s designated IRBs will automatically suspend the enrollment of new subjects in any ongoing research that does not receive continuing review and approval prior to the end of the stipulated approval period. Previously enrolled subjects may continue their involvement in suspended research only where the IRB determines that continued involvement is in the best interest of the subjects.

You should begin preparing your application for continuing review before IRB approval for your study ends. If the study is currently approved in the paper system (i.e. pre-eRIC system), you will need to fill in the study application in the eRIC system prior to submission of your continuing review.
The image below is an example of the Continuing Review workspace:
Creating and Submitting a New Continuing Review

The table below outlines the essential steps for creating and submitting a new continuing review to the IRB.

In the approved study's workspace, click the *New Continuing Review* button to start the application for a new continuing review submission.
After selecting **New Continuing Review**, you are directed to the first screen in the form, which directs you to indicate the status of your study. Please select the status of your study and click “Continue” to move forward.

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Fill out the continuing review form. In addition to completing the form, **please remember to submit an amendment in addition to your continuing review** if you need to increase your local accrual numbers, extend the duration of the study, or make any modifications to your protocol, Informed Consent/Assent documents, or any other items pertaining to the study.
Each “investigator” must submit a Georgetown University Study Specific Disclosure Form as part of the continuing review submission. “Investigator” includes the principal investigator and any other person who is responsible for the design, conduct, or reporting of research. The SSDF form can be accessed from the continuing review workspace by clicking on the Create SSDF button.

Click “Request SSDF” to send out an email notification to those individuals who are required to fill out the SSDF.
Once you have completed your SSDF and filled in the continuing review form, click on the Submit Continuing Review button to submit your continuing review to the IRB for review.

**NOTE:** If there is a new Department or Equivalent Reviewer since the previous IRB review, the continuing review will first be routed to him/her for approval, prior to submission to the IRB. Please allow sufficient time for Department or Equivalent Reviewer approval, if applicable.

If an error is received, click Cancel and address the issues that remain. The example here shows the error that appears if all required Study Specific Disclosure Forms (SSDFs) are not submitted before attempting to submit.
Complete the “Submit Continuing Review” form. Once you click “OK” you will no longer be able to modify the continuing review.

Once submitted successfully, the Current State will change, a log in the history will be made, and the submission will disappear from the study team’s eRIC Inbox.
Continuing Reviews submitted by the study team can be located under the *Continuing Reviews* tab in the main study workspace.