

FAQ

Why is the IRB renaming the Renewal Application as the Continuing Review Application?

Renaming the Renewal Application is a part of the IRB's continuing efforts to increase consistency with the terminology that is being used throughout the federal regulations and the IRB community.

Why is the IRB combining the Continuing Review Application with the Final Project Report?

By combining the two processes, it will help ensure that studies that need to remain open undergo a Continuing Review and studies that can be closed complete a Final Report. Combining the applications acts as a tool to assist the study team in determining what the appropriate course of action is for their study. It also helps to prevent studies from being closed prematurely or renewed unnecessarily.

How do I submit a Final Project Report to close my study using the new application?

You access the Final Project Report via the Continuing Reviewing Application. The Continuing Review Application has been designed to allow for the Final Project Report to be submitted if necessary. The initial page of the Continuing Review Application asks questions that will help the study team determine if closing the study is appropriate and if a Final Project Report can be submitted instead. The Continuing Review Application assesses the answers given by the study team and automatically directs the team toward the Final Report or Continuing Review. Even if the system determines that a Final Project can be submitted, the study team can still opt to proceed with the Continuing Review instead.

I want to close my study, but the application won't take me to the Final Project Report pages. What should I do?

If the Continuing Review Application does not direct you to the Final Project Report pages, it is most likely because you have answered one of the initial questions in such a way that it is unlikely your study should be closed. If you are confident your study can be closed, it is possible you misinterpreted one of the initial questions or have a special situation that needs to be addressed. If this is the case, feel free to contact our office and speak with an IRB representative who can help assess the appropriate course of action for your study.

The Continuing Review Application says that I can close by study, but I would like to keep it open. How do I renew my study?

After you have answered the initial questions about your study, the Continuing Review Application may determine that your study can be closed. However, closing your study is not compulsory. You will be given the option in the application to proceed with the Continuing Review even if it is determined that the study could be closed.

Can I look at patient records after I have submitted a Final Project Report to close my study?

No. Once a Final Project Report has been submitted, the study team cannot access patient records and cannot obtain any new patient data. Once a study is closed, the study team is only allowed to analyze data that was collected while the study was open. If you would like to re-access patient records after the study has been closed, you will need to submit a New Study Application.

Can I contact study participants after I have submitted a Final Project Report to close my study?

No. Once a study is closed, the study team cannot contact former study participants in any way (including follow-up phone calls, emails, letters, etc.). If you would like to contact former study participants after the study has been closed, you will need to submit a New Study Application.

Should I submit a Final Project Report to close my study if the sponsor needs to do the close-out visit?

No. If your study has a sponsor and the close-out visit is pending, you should not close the study. There is always the possibility that the sponsor may require that patient records be re-accessed or that new patient information be obtained. If the study has been closed, however, the study team would need to submit an entirely new study application and have it approved before the sponsor's request could be fulfilled.

Where do I find all of my previously submitted renewals?

On the main page of the study in ERICA, there is a series of gray tabs. Under the tab labeled "Continuing Review", you will find a list of all previously submitted renewals/continuing reviews.

Where do I find a Final Project Report that was already submitted before the update?

On the main page of the study in ERICA, there is a series of gray tabs. Under the tab labeled "Continuing Review", you will find a subsection titled "Final Reports" in which the Final Report for the study will be located.

Do I need to withdraw my Continuing Review Application if I later decide to submit a Final Project Report to close the study?

If the Continuing Review Application has yet to be approved, this application can be modified and a Final Project Report can be submitted to close the study. If the Continuing Review Application has been approved already, a new Continuing Review Application will need to be started in order to access the Final Project Report.