



Closing a Study

There is no separate closure form in ESTR. A study is closed when the Investigator selects the 4 closed research milestones on the Continuing Review SmartForm (Enrollment closed, subjects completed all research activities, collection of info is complete, analysis is complete).

If a Continuing Review/Closure is submitted:

1. Complete the “Submit Pre-Review” activity.
2. Complete the “Submit Non-Committee Review” activity.
NOTE: On the Non-Committee Review activity form, if it is appropriate to close the study, select “Approved / Exemption Granted” and leave question 3 (regarding review level) blank.
3. Generate the letter and be careful to use the “closed” template.
4. Complete the “send letter” activity.
5. Go to the main study workspace and complete the “close” activity.
6. The study will transition to “closed.”
7. Look at the “follow on submissions” tab and ensure no follow on submissions remain in pre-submission or IRB review.
NOTE: If any follow on submissions are in pre-submission or IRB review, transition those submissions to an appropriate end-state for that submission (such as ‘withdrawn’).

To complete a closure without a submitted Continuing Review/Closure application:

1. Go to the main study workspace and complete the “close” activity.
2. Make any needed context notes on the “close” activity.
3. The study will transition to “closed.”
4. Attach any correspondence or additional notes regarding the closure without a CR application or review via public or private comment.
5. Look at the “follow on submissions” tab and ensure no follow on submissions remain in pre-submission or IRB review.
NOTE: If any follow on submissions are in pre-submission or IRB review, transition those submissions to an appropriate end-state for that submission (such as ‘withdrawn’).