

HOW TO SUBMIT A FINAL PROJECT REPORT

The Final Project Report is part of the Continuing Review Application. On the first page of the Continuing Review Application, you will be asked questions regarding the status of the study (see below).

1. Status

* 1.1 Is the study permanently closed to the enrollment of new participants?

Yes No [Clear](#)

If yes, answer the following questions:

a. Are you continuing to or planning to perform interventions (e.g., tests, physical or psychological exams, administer medications or treatments) on subjects in order to gather data about them?

Yes No [Clear](#)

b. Are you continuing to or planning to interact with any subjects (e.g., letters, phone calls, interviews or re-contact participants) in order to gather data about them?

Yes No [Clear](#)

c. Are you continuing to or planning to gather any private identifiable information about subjects (e.g., chart reviews, receipt of information from health care entities)?

Yes No [Clear](#)

d. Does your study have a sponsor/monitor who still needs to conduct their official close-out visit and who may require access to patient's records or contact with a participant?

Yes No [Clear](#)

e. Are you continuing to or planning to analyze the data for this study?

Yes No [Clear](#)

If yes, does your study data contain participant identifiers or a link/code to identify study participants?

Select "no" if de-identified data has been sent to a sponsor, data coordinating center, or other entity for analysis and no additional analysis will occur at this site.

Yes No [Clear](#)

Based on the answers provided on this page, you will be directed to complete the full Continuing Review Application **OR** the Final Project Report. In order to be eligible to submit a Final Project Report, the study status must reflect the following:

1. The study is permanently closed to enrollment of new participants;
2. You are no longer continuing to or planning to perform interventions on subjects in order to gather data about them;
3. You are no longer continuing to or planning to interact with any subjects in order to gather data about them;
4. You are no longer continuing to or planning to gather any private identifiable information about subjects;

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5. If applicable, your sponsor/monitor has conducted the official close-out visit and will no longer require access to participant records or contact with the participants.
6. Data analysis is complete **OR** if you are continuing or planning to analyze data, the data does not contain participant identifiers or a link/code to identify study participants.

If these conditions do not apply to the study, the study should not be closed using a Final Project Report; the Continuing Review Application should be completed so that the study can be renewed for another year*.

*If the study was originally determined Exempt by the IRB, a Continuing Review Application does not need to be completed.

If the study is eligible to submit a Final Project Report, when you click "Continue" on the first page, the application will move to the next page (see below), allowing you to choose whether or not you would like to close the study.

Final Project Report

According to the responses provided, continuing review is no longer required and the study can be closed by way of final project report. **Be advised that if you would like to submit a final project report for the study, you would no longer be able to access patient data or records and would no longer be able to contact them for research purposes. If the study is closed, a New Study Application would be required to access patient data or records and to contact research participants.**

Would you like to submit a final project report and close this study?

Yes No [Clear](#)

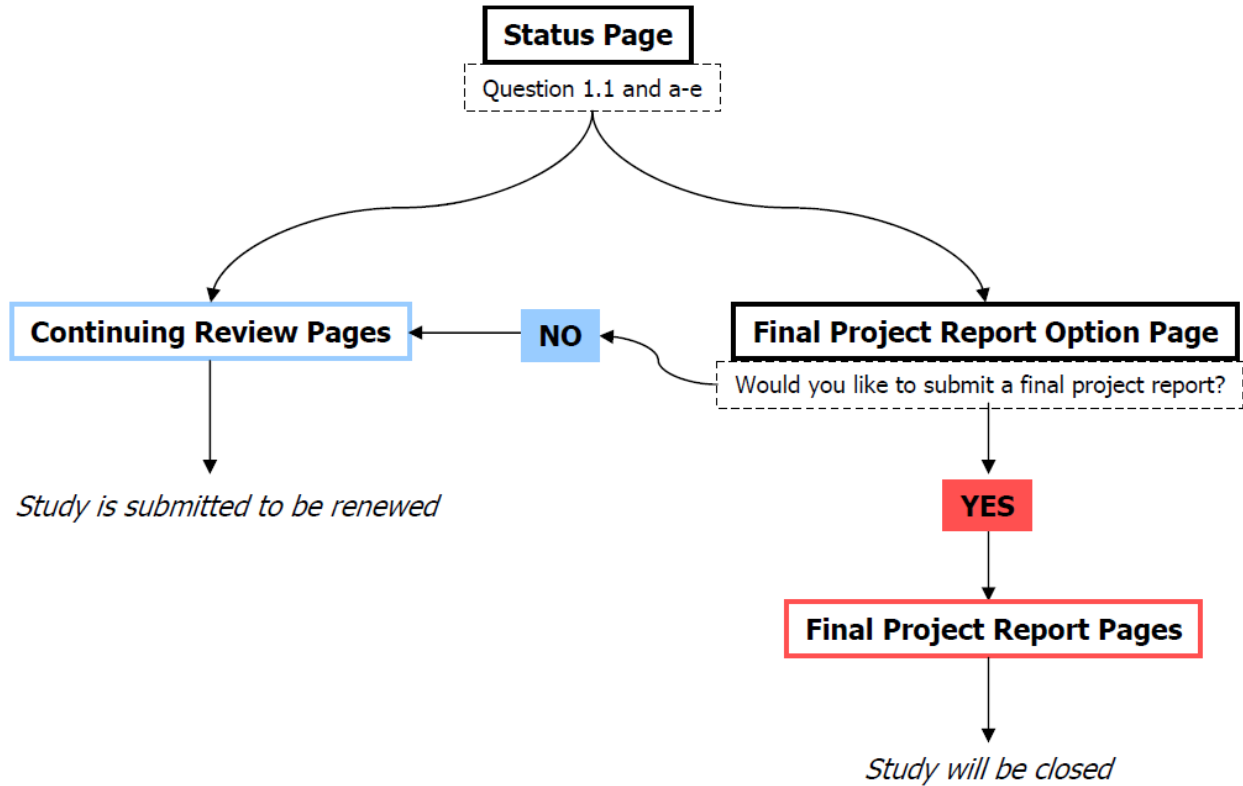
You are allowed to renew the study using the Continuing Review Application even if the study is eligible to be closed. If you select "no" on this page, you will automatically be taken to the Continuing Review Application when you click "Continue". Otherwise, the Final Project Report will follow.

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Workflow for the Continuing Review Application



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