

## 1. Status

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

Yes  No [Clear](#)

If yes, answer the following four 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](#)

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Above is the new first page of the Continuing Review Application (formerly known as the Renewal Application). Based on your answers on this page, you will be directed to complete the rest of the Continuing Review Application **OR** the Final Project Report. In order to be eligible to submit a Final Project Report, you must answer the questions on this page as shown above: the study must be closed to enrollment (question 1.1) and questions a-d must be answered "no". If these conditions do not apply to your study, the study should not be closed using a Final Project Report and the Continuing Review Application should be completed so that your study can be renewed for another year.

If you are eligible to submit a Final Project Report, when you click "Continue" the application will move to the next page (below), allowing you to choose whether or not you would like to close the study. You are allowed to renew the study using the Continuing Review Application even if your 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.

## 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](#)

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## Flow for the Continuing Review Application

