



Creating a Follow On Submission in RAS A Companion Guide: Protocol Closures

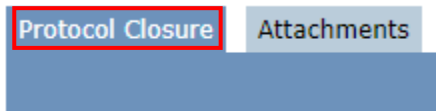
Follow on submissions include changes to study personnel, amendments (changes) to approved protocols, annual renewals, protocol closures, and reporting unanticipated issues and events (REB event).

TCPS2 (Art. 2.8) states that ethics review must continue throughout the study to ensure that all stages are ethically acceptable. This guide provides clarifications and helpful tips to ensure compliance with the requirements of continuing research ethics review within the RAS system. Not all questions in the Research Administration System (RAS) system are included as not all questions require further clarification. Please refer to this information as you craft your responses. The text in **black** is the question you will respond to. The direction in **green** clarifies what the Research Ethics Board (REB) is asking for.

NOTE: As you move through the tabs, you will see a number of “Yes” or “No” questions. Your responses may open additional tabs or text boxes which require your attention. If you change your answer to the “Yes” or “No” questions, these tabs or text boxes may disappear. Any responses you entered will not be saved.

As the system’s text boxes do not allow for formatting, we recommend using spacing and capital letters to create headings.

PROTOCOL CLOSURE



NOTE: When a study has concluded or when it has been terminated for any reason, PIs must submit a protocol closure form to the REB to indicate that continuing ethics review is no longer required. For more information on when to close a study, visit our [website](#).

- Is communication with participants complete (ex. recruitment, data collection, summary of findings, member checking)?
 - If ‘No’, please withdraw and submit a renewal request. Continuing ethics review is required when communication with participants is ongoing.
- Please provide a brief summary of the outcome of the study and progress in meeting the study objectives.
 - Describe your progress in the study and specify whether and how the study objectives have been met. Indicate whether and how study findings/results have been disseminated. If the study was terminated, provide specific details on why the study was terminated.
- Were there any problems encountered in this study?

- Answer 'No' if there were no problems encountered, no protocol deviations, and/or no adverse events.
 - Answer 'Yes' if there were any unanticipated problems, protocol deviations, and/or adverse events.
 - If 'Yes', a new box will open below. Describe in detail the unanticipated problem, deviation and/or adverse event, explain how you approached it, and discuss the outcomes.
- Were these previously reported to the REB?
 - If 'No', a new box will open below. Explain why the problems, protocol deviations, and/or adverse events were not reported to the REB.