

## Creating a Follow On Submission in RAS A Companion Guide: Renewals

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. Text in **red** denotes things you should not do.

<u>NOTE:</u> 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.

## Renewal Request Attachments Submit

NOTE: As per Article 6.14 of the TCPS 2, protocols are approved for <u>one year only</u>. The protocol expiry date can be found on the Protocol Approval letter. Any protocols that will continue beyond that date must be renewed. It is the responsibility of the researcher to ensure that they do not continue the study without an active ethics protocol.

Undertaking research with human participants without an active approval is a breach of the TCPS2, the University's Ethics of Research Involving Human's Policy, and the University's Responsible Conduct of Research Policy.

To initiate a renewal, a Renewal Request must be submitted in RAS. We recommend submitting the request within the final <u>month</u> of the protocol date's expiry. Once approved, a Renewal Approval letter will be issued. A researcher a cannot continue their research activities until the Renewal Approval letter has been received.

NOTE: New or revised documents should not be uploaded during the renewal review.

- Have there been changes to the protocol design that have not been approved by the REB?
  - If 'Yes', a new question will appear asking if an amendment has already been submitted. If the answer is 'No', you must also submit an amendment with your requested changes. Do NOT include information on your protocol changes in the renewal request.
- Provide a brief summary of the progress of the study.
  - Describe what research activities have taken place so far and what activities are still ongoing or need to be completed.
- Provide a brief justification for the renewal request.
  - o In one or two sentences, describe why you need a renewal. Do NOT include personal health information about yourself or team members.