Post Approval Activities

* Select one of the following options to submit to the Research Ethics Board based on the guidelines (Click blue question mark for guidance): 🔵

Options
🔘 Amendments to Study

[Clear](#)

* Nickname

Enter a nickname for this PAA. What would you like this PAA to be known as to the Principal Investigator and study team?

(If you are notifying the REB of a protocol deviation or an unanticipated event or local serious adverse event please include the words "protocol deviation" or "unanticipated event" or "local SAE" as applicable in the nickname)

Behavioural Amendment Coversheet

Provide a summary of the changes to the Study (Application):

1) Complete this coversheet. This coversheet (form) is intended to provide an overview of the amendment for reviewers. Please briefly describe the changes in this coversheet. If your amendment includes new or updated documents, list by document name in Box 1.6.

2) Edit the application by recording the changes at the bottom of the appropriate boxes. To ensure a complete history of this project, do not overwrite previously approved text related to this project that has taken place with participants. If the activities never occurred, the information can be deleted. If changes are not recorded in the application, the amendment will be returned as incomplete.

3) Attach updated and new documents to page 9. Ensure the new version dates are the same as the dates entered on page 9.

4) Submit the Amendment. When the above steps are completed the PI or one of the designated Co-investigators with Signing Authority must then submit the amendment. When you have successfully submitted, the PAA status will change from "Pre Submission" to "REBA Screening."

* **1.1 Proposed changes to study**

1.1.1 Provide a brief summary of the proposed changes

* **1.1.2** Please explain why you want to make the proposed change(s)

* **1.2 Risks to participants**

Indicate whether or not the proposed changes will result in any increase in risk for the study participants beyond what was originally anticipated. If so, please explain what the increased risks are and why they are necessary. (If you submitted your application as a minimal risk study, please indicate whether the increased risks participants will be exposed to are beyond those they would encounter in their everyday lives.)

* **1.3 Eligibility for delegated review**

Is your amendment minimal risk?

○ Yes ○ No Clear

* 1.4 Progress of study

Provide a brief summary of the progress of the study. This can include information on whether the recruitment of participants, data collection, and/or fieldwork is going according to plan and any other details on whether the study implementation is meeting its timelines. It should also include the number of participants recruited thus far, if applicable.Please specify if data collection is complete.

* 1.5 Principal Investigator

Will the Principal Investigator (PI) be changed on the study?
○ Yes ○ No Clear

If "Yes", you must select here and complete the form with signatures then add the form below by clicking "Add".

Select "Add" to attach the signed letter for changing the Principal Investigator.
Add

Title

Select the new PI for the study. Once you hit "**...**", you can enter the PI's name, or enter the first few letters of his or her name and hit "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

New PI for this study:

1.6 Summary of Changes

Complete the questions below indicating whether any revisions or new documents are being submitted. For each section with a "Yes" response, provide a brief summary as to the changes being made.

Revised or new documents:

Are you submitting any of the following revised or new documents:

* Revised Proposal: ⬤ ○ Yes ○ No [Clear](#)

* Revised consent and/or assent documents: ○ Yes ○ No [Clear](#)

* Other "revised" or "new" document(s): ○ Yes ○ No [Clear](#)

[View Differences](#)

Click to view changes made in the body of the application