

## 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

- Annual Renewal with Amendments to the Study (UBC CREB and C&W REB studies only)

[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 Annual Renewal with Amendments Coversheet

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

**1) Complete this coversheet (form).** In the sections below provide information about this amendment for which you are requesting approval. This coversheet is to provide an overview of the amendment. The changes must be described in this coversheet and **the changes must then be entered into the appropriate sections of the application.**

**2) Edit the application.** If this is not done the amendment will be returned as incomplete. (e.g.: if submitting an amended protocol, identify the document below and describe the changes, once you have completed the coversheet then edit the applicable sections of the application form.) This is to ensure that, once approved, the application form will contain the current information for your study.

**3) 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. For **instructions on how to designate a Co-Investigator with signing authority** contact your REB.

### 1.1. 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 "Upload".

Select "Upload" to attach the signed letter for changing the Principal Investigator.  
[Upload](#)

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:

### \* 1.2. Proposed changes to study

**1.2.1.** Briefly describe the nature of the proposed change(s). 

\* **1.2.2.** Please explain the reason why you want to make the proposed change(s). 

\* **1.3. 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.) 

\* **1.4. Eligibility for delegated review.** Is your amendment minimal risk? 

Yes  No [Clear](#)

\* **1.5. Participant Recruitment**

**1.5.1.** What stage of recruitment is your study? 

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Ongoing

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Complete

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Paused

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Not Applicable

[Clear](#)

Please provide further details around the stage of your recruitment:

**1.5.2.** Does your study involve secondary use of data or observations without direct interaction with participants? 

Please provide further details if you selected Yes above:

**1.5.3.** Please enter the total number of participants who have been involved in the study:

Goal (total number of participants):

**1.5.4.** Have there been any participant withdrawals? 

Yes  No [Clear](#)

If so, please explain to the extent possible.

## **1.6. 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. 

Add

**Title**

## **1.7. Unanticipated problems**

**1.7.1.** After reading the definition of 'unanticipated problems' provided in the guidance "?", are there any unanticipated problems that you have experienced and have not already been reported via a Request of Acknowledgement? 

Yes  No [Clear](#)

**1.7.2.** If "Yes", explain

## **1.8. Summary of changes**

Complete each section below to provide an overview of the changes for which you are seeking approval. **Upon completion of this coversheet, these changes must also be entered into the appropriate sections of the application.**

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](#)

If "Yes", list each document(s) name and provide a brief summary describing the changes being made to that document. These changes must also be entered into the appropriate sections of the application form and highlighted in the revised document after completing this coversheet.

### **1.9. Changes in Conflict of Interest**

Please provide details of any changes in relation to conflict of interest status of the Principal Investigator and/or other members of the study team.

### **1.10. Lapsed studies**

**1.10.1.** If the study has expired please provide a written explanation for the late renewal:

**1.10.2.** Have any research-related activities been conducted since the study expired? If yes, please describe:

**1.10.3.** Please describe the procedures that have been put in place to ensure timely submission in the future:

**1.11. Additional Comments:** (If any)

[View Differences](#)

Click to view changes made in the body of the application