Behavioural Annual Renewal with Amendments Coversheet

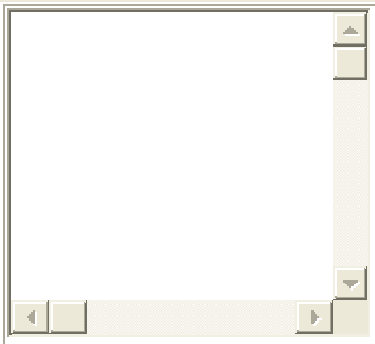
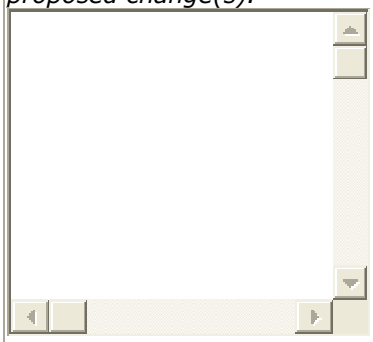
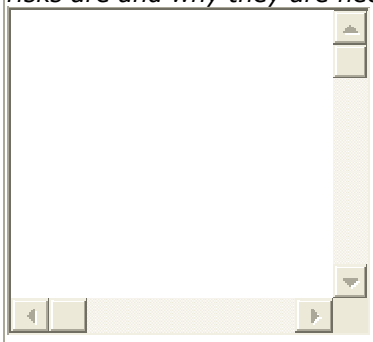
Provide a summary of the changes to the Study (Application):

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** select here.

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 "Add".* *Select "Add" to attach the signed letter for changing the Principal Investigator.* [None] *Select the new PI for the study. Once you hit "Select", 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:*	Do not change the current/ **submitting** PI's name on this application or you will not be able to continue to submit the application (the REB will do this when they approve this amendment). However, if the current / submitting PI will continue to be involved in the study and will require on line access you must add them to the list of co-investigators in question 1.3 of the application. Ensure that any study documents (e.g. consent or assent documents) are updated and attached to reflect the new Principal Investigator. To attach the new study documents go to page 9 of the application and amend the appropriate questions. An updated Certificate of Approval will be issued to the newly designated Principal Investigator only. **If you cannot find the name of the new PI in the list** have them added or inform them to add themselves by contacting the RISe helpdesk (email: risesupport@ors.ubc.ca; Ph: 604-878-**RISE**).
* **1.2 Proposed changes to study** **1.2.1** *Briefly describe the nature of the proposed change(s).*	Explain how the amendment relates to the original research question(s) and approved

 * **1.2.2** *Please explain the reason why you want to make the proposed change(s).* 	procedures. **1.2.1.** Explain what the change(s) are, using the following categories; • **Study design**: changes to study objectives and procedures. • **Administrative changes**: changes in study personnel, project title, sponsor, start or end dates, or any other similar changes. **1.2.2.** Explain why each change was made (e.g. the previous PI has left the institution; interim results indicate a need to change the study objectives, etc.)
* **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, and if so, please explain what the increased risks are and why they are necessary.* 	Explain *how* the changes may or may not affect participants or their potential willingness to continue in the study.
* **1.4 Eligibility for delegated review** *Please review the guidance notes on the right and indicate whether this renewal with amendment qualifies for Delegated Review.* Yes No Clear	Renewals and amendments to studies funded by the US funding agencies (e.g. DHHS, NCI) require full board review. If your study is not funded by one of these agencies and the annual renewal with amendment does not involve any increase in risk to the participants beyond what was originally anticipated in the study, your annual renewal with

	amendment qualifies for delegated review, regardless of whether the study was originally submitted as a full board or minimal risk application. If the amendment does involve a slight increase in risk beyond what was initially anticipated but the overall risks to participants fall within the minimal risk category, your amendment also qualifies for delegated review. Click here for further information on the definition of minimal risk.
1.5 Participant recruitment **1.5.1** *Does this study involve the active recruitment of human participants?* Yes No Clear *(If "yes", please answer the following questions in 1.5. If "no", please proceed to question 1.6.)* **1.5.2** *Is recruitment ongoing?* Yes No Clear ***Note:*** *Please complete the following even if data collection is complete.* **1.5.3** *Please enter the number of participants taking part in the study covered by this Research Ethics Approval. Taken part to date:* *Goal:* **1.5.4** *For multi-institution studies, participants taking part in the entire study (including centres outside of those applied for under this approval).Taken part to date:* *Goal:*	**1.5.1.** If your study is limited to an existing data set or naturalistic observation where no active recruitment is involved, your response here would be "no" and you may proceed to question 1.6. **1.5.5.** Participants are entitled to withdraw and are not required to give written notification, or to explain their reasons for such withdrawal. If, however, there have been any participant withdrawals and you are aware of the circumstances / the reasons please indicate them here.

1.5.5. *Have there been any participant withdrawals?*

Yes No Clear

If so, please explain to the extent possible.

* **1.6 Informed consent** *Do the proposed changes to the study require any amendments to the consent process?* Yes No N/A Clear	The N/A category would apply to studies involving no consent process (e.g. some types of secondary use of data or naturalistic observation). To attach the updated consent documents go to question 9.2 in the application form.
1.7 Progress of study *Provide a brief summary of the overall progress of the study. This can include information on whether the recruitment of participants and/or fieldwork is going according to plan and any other details on whether the study implementation is meeting its timelines. If data collection is ongoing please provide details below.* Title There are no items to display	The summary of progress to date should include information on whether participants are still being recruited in the research study or whether fieldwork is still being conducted (in the case of naturalistic observation and participant observation studies). For ongoing studies, remarks about the ability to recruit participants are also appropriate, as is any information about the results from any interim analyses.

1.8 Unanticipated problems **1.8.1** *After reading the definition of 'unanticipated problems' provided on the right, are there any unanticipated problems that you have experienced?* Yes No Clear **1.8.2** *If "Yes", explain*	An unanticipated problem is any incident, experience, or outcome that meets **all** of the following criteria: • Unexpected (in terms of nature, severity, or frequency); • Related or possibly related to participation in the research; • Suggests that the research places research participants or others at a greater risk of harm than was previously known or recognized. For example, the theft of a laptop containing confidential information about participants would constitute an unanticipated problem; an outbreak of war or insurrection in the area of the research might constitute an unanticipated problem.
1.9 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. List the revised or new documents being submitted and identify where the change(s) are in each document i.e., reference the section page. Ensure that the changes in the documents are identifiable by either using highlights or track changes.

1.10 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.*	
1.11 Lapsed studies *If the study has expired and the renewal is being completed with the permission of the REB Chair or Manager, please provide a written explanation for the late renewal and confirmation that NO study related actions took place during the time over which there was no valid ethical approval, and explain what strategies have been put in place so that this will not happen in the future.*	
1.12 Additional Comments: *(If any)*	

View Differences
Click to view changes made in the body of the application