

Behavioural Amendment Coversheet

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

1) Complete this coversheet. In the sections below provide information about this amendment for which you are requesting approval. This coversheet (form) 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 research proposal, identify the document below and describe the changes, once you have completed the amendment 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 Proposed changes to study

1.1.1 Briefly describe the nature of the proposed change(s). (e.g. change in PI)

* **1.1.2** Please explain the reason why you want to make the proposed change(s). (e.g. PI is on sabbatical and need to substitute new PI until end of study)

Explain how the amendment relates to the original research question(s) and approved procedures.

1.1.1. 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. Please note that a change in the Primary Contact does not require the submission of an amendment.

1.1.2 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.)

* 1.2 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, and if so, please explain what the increased risks are and why they are necessary.

1.2. Explain how the changes may or may affect participants or their potential willingness to continue in the study.

*** 1.3 Eligibility for delegated review**

Does your amendment qualify for delegated review? (Please pick "Yes" or "No" after reviewing the guidance notes on the right).

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 amendments do not involve any increase in risk to the participants beyond what was originally anticipated in the study, your 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 originally 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.

1.4 Progress of study

Describe briefly the status of the study and how far along you are in data collection and/or analysis.

*** 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.

Title

There are no items to display

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:

*** 1.6 Informed Consent**

Do the proposed changes to the study require any amendments to the consent process?

Yes
 No
 N/A
[Clear](#)

1.7 Summary of Changes

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

Revised or new documents:

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). If the current/submitting PI will continue to be involved in the study and will require online access you must add them to the list of co-investigators in question 1.3 of the application.

Ensure that any study materials (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 documents.

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: risupport@ors.ubc.ca; Ph: 604-878-RISE).

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 section 9.2 of the application.

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

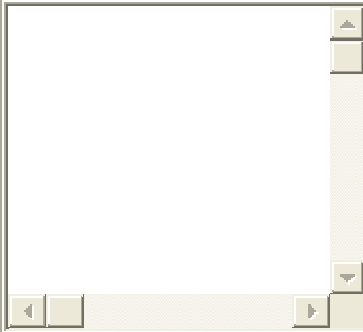
Are you submitting any of the following revised or new documents:

* 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 clearly identified in the revised document after completing this coversheet. E.g. changes to the ICF to replace old PI's name with new PI's name.



either using highlights or track changes.

[View Differences](#)

Click to view changes made in the body of the application