

Amendments to Study PAA – Behavioural – SAMPLE FORM

Post Approval Activities

*** Select one of the following options to submit to the Research Ethics Board based on the guidelines listed on the right:**

Amendments to Study

*** 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)

• Annual Renewals

For Clinical studies click [here](#) for information on annual renewals. Reminder: If this is an annual renewal of a for-profit (industry or pharmaceutical) sponsored study, an annual renewal fee is required. For more details about fee criteria, exemptions and methods of payment please consult the applicable REB administration or their web-site. For Behavioural studies click [here](#) for more details on annual renewals.

• Amendments to Study

Amendments are changes to an ongoing study. If you are changing any part of the study (e.g. co-investigators, title, agency, documentation) you must submit an amendment. Click [here](#) for more information on amending behavioural studies.

• Completion of Clinical Study

For Clinical studies click [here](#) for criteria on study completion.

• Completion of Behavioural Study

The researcher will have no further contact with subjects for the purpose of data collection, follow up, or research. Click [here](#) for more information on completion criteria.

• Request for Acknowledgement

Protocol deviations, unanticipated problems, new information, safety letters, local serious adverse events, studies on hold, off hold, closed to accrual/enrollment, or miscellaneous information (PI, Sponsor or REB requires acknowledgement). Click [here](#) for more information on Request for Acknowledgement criteria. Any other changes to an ongoing study must be submitted through an amendment.

• Response to Request for Information (RFI)

The Research Ethics Board has issued a Request for Information (RFI) regarding your research study and requires a response. Use this option to respond to the REB.

Note: Investigator Brochures must be submitted as an amendment

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. 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.)

Click [here](#) for further information on the definition of minimal risk.

* 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

If your study 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.

Renewals and amendments to studies funded by the US funding agencies (e.g. DHHS, NCI) require full board review. You should answer "no" to this question, if this is the case.

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

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

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

*** 1.6 Informed Consent**

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

Yes

No

N/A

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.

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:

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

* Revised Proposal: Yes No

* Revised consent and/or assent documents: Yes No

* Other "revised" or "new" document(s): Yes No

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.

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.

You have reached the end of the Post Approval Activity (PAA) Coversheet. Please follow the steps below.

1) Click "Continue" to enter the amendment changes in the application (this must be completed before the PAA can be submitted by the PI).

If this is not the initial completion of the coversheet, you will be taken directly to the PAA home page where you can edit the application or coversheet.

2) Submit the PAA for review.

When the application amendments have been completed, click "Save" then "Exit". You will be brought to the PAA home page where **ONLY** the Principal Investigator or a Co-Investigator with full signing authority will be able to "Submit PAA" for review. For instructions on how to designate a Co-Investigator with signing authority select [here](#).

note: to update your own personal profile (appointments, email address, etc.) select the link to your name in the top right corner of your homepage.