

Amendments to Study PAA - Clinical – 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

Clinical 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 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. (For example, 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 Proposed changes to study

1.1. Briefly describe the nature of the proposed change(s).

* 1.2. Please explain the reason for the proposed change(s).

Briefly summarize (please do NOT cut and paste from the protocol).

1.1: Explain 'what' the change(s) are, using the following categories:

a) Participant safety: changes to known risks, eligibility criteria, treatment, procedures, data monitoring etc. that affect participant safety.

b) Scientific Interpretability: changes to study objectives, endpoints, sample size, planned statistical analysis or interim analysis that affect the study design or scientific interpretability.

c) Administrative changes: changes in study personnel, project title, sponsor, start or end dates, specimen handling, or any other similar changes that do not affect safety or scientific interpretability.

1.2: Explain 'why' each change was made. (For example, the previous PI has left the institution; interim data has resulted in a need to change the study objectives, etc.)

Ensure that the changes in the documents are identifiable by either using highlights or track changes.

* 2. Changes in 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.

Do not change the 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 submitting PI will continue to require online access to this study, you must add them to the list of co-investigators in View 1.3 of the application.

Ensure that any study materials (e.g. consent or assent forms) are revised to reflect the new Principal Investigator. Attach the revised study documents to View 9 of the application and delete only the documents that are being replaced.

An updated Certificate of Approval will be issued to the newly designated Principal Investigator only.

<p><i>New PI for this study:</i></p>	<p>If you cannot find the name of the new PI in the list have them added by contacting the applicable REBA.</p> <p>Select the name of the applicable UBC ethics board to contact the REBA: BC Cancer Agency Research Ethics Board Providence Health Care Research Ethics Board Clinical Research Ethics Board Children's and Women's Research Ethics Board</p>
<p>* 3. Study Progress</p> <p><i>Describe the study progress, e.g. are there participants on treatment or follow-up only etc.</i></p>	<p>The summary of progress to date should include information on whether participants are still participating in the research study. Especially in the case of clinical trials, the summary should indicate if the trial is closed to enrollment and the status of enrolled participants, i.e., if on study treatment or if all are now on long term follow up only. For studies open to enrollment, remarks about the ability to recruit participants are also appropriate as is any information about the results from any interim analyses.</p>
<p>* 4. Risks to Participants</p> <p><i>Indicate whether or not this amendment will result in any increase in risk or discomfort for the study participant. If so, please explain what these are and why they are required.</i></p>	<p>Explain 'how' the change(s) may (or may not) affect a participant's safety or their willingness to continue to participate. If already enrolled participants will NOT be re-consented, please provide an explanation.</p>
<p>* 5. Level of Review</p> <p>5.1. <i>Please review the guidance notes on the right and indicate whether this amendment qualifies for Minimal Risk/Delegated Review. Note that if this amendment requires Health Canada approval it does not qualify for delegated review.</i></p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>5.2. <i>Is Health Canada Approval required for this amendment? (Please review the guidance notes to the right for further information.)</i></p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p><i>Additional Comments:</i></p>	<p>5.1: Click here and scroll down to Level of Review for the criteria for Minimal Risk/Delegated Review of amendments.</p> <p>5.2: If this study required Health Canada approval when it was initially reviewed, this amendment may also require Health Canada approval. Click here for information on Health Canada Criteria for Amendments Requiring Full Board Review.</p> <ul style="list-style-type: none"> • Attach a copy of the NOL (No Objection Letter) for this amendment (if applicable) to View 9 of the Application and enter the NOL control number in View 7.9 of the Application. <p>Note: A Health Canada Acknowledgement of Notification is not an NOL.</p> <p>Amendments may be submitted for REB review while the Health Canada approval for it is pending. The Health Canada approval document will however, be required prior to the REB issuing the certificate of approval for the amendment.</p>
<p>* 6. Changes to the Consent Form/Process</p> <p>6.1. <i>Does this study involve the recruitment of human participants? If yes, answer 6.2. and 6.3. below.</i></p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>6.2. <i>Are the amendments such that participants still to be recruited to the study will receive an amended consent form?</i></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>	<p>To attach the updated consent form, go to View 9.2 of the application.</p> <p>Click here for information on Risks and re-consent.</p>

6.3. Will already enrolled participants be updated with any new information included in this amendment? Please provide your rationale below, including details of how and when participants will be re-consented, if applicable.

Yes No

Details:

7. Documentation: 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.

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

* Revised Proposal: Yes No

* Revised consent and/or assent forms: 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 be highlighted /track changed in the revised document and uploaded into the appropriate sections of the application form after completing this coversheet.

7.2. Are you adding any documents that have already been approved by the REB in order to bring your application up to date? If yes, list these documents below, clearly indicating the document name, version, and the PAA number during which it was approved.

7.1: 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.