Annual Renewal with Amendments to the 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:**

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

*** 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 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 *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.* *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).* * **1.2.2** *Please explain the reason why you want to make the proposed change(s).*	Explain how the amendment relates to the original research question(s) and approved 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. 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.

* **1.4 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.
1.5 Participant recruitment **1.5.1** *Does this study involve the active recruitment of human participants?* ○ Yes ○ No *(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 ***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:* **1.5.5.** *Have there been any participant withdrawals?* ○ Yes ○ No *If so, please explain to the extent possible.*	**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.

* **1.6 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 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	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 **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 * *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 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)*	

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.