Annual Renewal 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

*** 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

Annual Renewal Coversheet

*Important Note: this form is for renewing your study. If you would like to make changes to your study, you should submit a **Renewal with Amendment** form unless you are submitting your post-approval activity to the Providence Health Care Board, in which case you should fill out a study amendment form as well as the annual renewal form.

* **1.1. Eligibility for delegated review** *Does this Annual Renewal qualify for delegated review? See guidance notes on the right for the criteria.* ○ Yes ○ No	Studies funded by the US funding agencies (e.g. DHHS, NCI) require full board review. All other studies are eligible for delegated review.
1.2. Participant Recruitment * **1.2.1.***Does this study involve the active recruitment of human participants?* ○ Yes ○ No *(If "Yes", please answer the following questions in 1.2. If "No", please proceed to question 1.3.)* **1.2.2.***Is recruitment ongoing?* ○ Yes ○ No ***Note:** Please complete the following even if data collection is complete.* **1.2.3.** *Please enter the number of participants taking part in the study covered by this Research Ethics Approval.* *Taken part to date:* *Goal:* **1.2.4.** *For multi-institution studies, please enter the number of participants taking part in the entire study (including centres outside of those applied for under this approval).* *Taken part to date:* *Goal:* **1.2.5. Have there been any participant withdrawals?** ○ Yes ○ No *If so, please explain to the extent possible.*	1.2.1. 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 1.3. 1.2.5. 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.

1.3. Progress of Study *Provide a brief summary of the 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.*	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.
1.4. Unanticipated Problems * **1.4.1.***After reading the definition of 'unanticipated problems' provided on the right, are there any unanticipated problems that you have experienced?* Yes No **1.4.2.** *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 war or insurrection in the area of the research might constitute an unanticipated problem.
1.5 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.*	
1.6. 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.*	
1.7. Additional Comments:	

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

1) When you click "Continue", 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.

2) Click "Continue" to work on this PAA coversheet at a later time.
This post approval activity will be in "Pre Submission" state. To work on this again, click the "Edit PAA Coversheet" button on the left side of the PAA home page.

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.