Annual Renewal with Amendments to the 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:**

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

Clinical Annual Renewal with Amendments Coversheet

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

1) Complete this coversheet. This coversheet is to provide an overview of the Renewal with Amendment for which you are requesting approval. The amendment 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. After you have completed the coversheet 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.

RENEWAL:

*** 1. Reason**

1.1. *Why is this renewal being requested, e.g. still recruiting or data collection is ongoing etc.? (Note that unless required by the study sponsor, studies that no longer require interaction with participants or access to their data generally no longer need research ethics approval. See guidance on the right.)*

1.2. *If this research has not started pleases explain why and indicate plans for moving forward. If the study is on hold, please explain and indicate the anticipated start date.*

Click here for more information pertaining to when a study qualifies for closure. Study closures must be submitted as a Post Approval Activity (PAA) on RISe.

If the study start date is changing, please revise the initial application accordingly.

*** 2. Participant Recruitment**

2.1. *Does this study involve direct interaction with human participants? (If no, skip to #3,* ***Participant Data: Chart Review and Sample Collection****. If yes, you must answer all of the questions in this section.)*

Yes No

2.2. *Is this study currently recruiting or will it be recruiting in the near future?*

Yes No

2.3. *How many participants (including controls and normals) are enrolled at institutions covered by this Research Ethics Approval?*

a. Enrolled to Date:

b. Enrollment Goal:

2.4. *For multi-institutional studies, how many participants (including controls and normals) are enrolled in the entire study across all sites?*

a. Enrolled to Date:

b. Enrollment Goal:

2.5. *How many participant withdrawals have there been at this site?*

2.6. *To your knowledge, did any participant withdraw as a result of study misconduct or complaints? If yes, please explain.*

2.3. Controls are people acting in a control capacity, including normal participants

2.5. WITHDRAWALS

Reference: ICH-GCP (E6) Guidance 4.3.4 states: Although a participant is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the participant's rights.

Note: Participants must not be required to give their withdrawal notice in writing; verbal notice must be accepted.

3. Chart Reviews and Sample Collection Studies **3.1. Participant Data: For Chart Review and/or Sample Collection Studies Only** *(This section should only be filled out if you are not required by the REB to consent individuals for the use of their data or tissues, e.g. you received a waiver of consent for secondary use of data (such as a chart review) or biological materials (such as left over tissue from diagnostic tests or surgeries) for part of or all of your study. If you are consenting participants for the use of their data or tissues, please fill out section 2, Participant Recruitment, only.)* *How many charts and/or samples have you included in this research?* *a. Included to Date* b. Inclusion Goal **3.2. Confirm the dates of the charts being reviewed.**	3.2. Dates of extracted charts should match those indicated in the initial application.
* **4. Unanticipated Problems** *Are there any outstanding actions that the REB, Data Safety Monitoring Board, and/or study sponsor has requested that you take with regard to an unanticipated problem (including any serious and unexpected adverse event or Safety Letter)?* ○ Yes ○ No *If Yes, please explain.*	The Principal Investigator is responsible for summarizing outstanding issues related to unanticipated problems, including serious and unexpected adverse events either observed throughout the study period or submitted to the Principal Investigator by the sponsor for other sites in multi-centre trials. If an item has been submitted to the REB, quote the post-approval activity number (i.e. PAA A006).
* **5. New Information not included in the Amendment portion of this Post Approval Activity (PAA)** **5.1.** *Provide the REB with any new information related to the study that is not included in this PAA. See definition on the right.* * **5.2.** *Has an amendment been approved or submitted in relation to this new information? If so, please provide the Post-Approval Activity number below. If not, please confirm that in your opinion, no changes need to be made to the protocol or the informed consent form as a result of all currently available new information.*	New information is any information that might adversely affect the safety or well-being of the study participants, the conduct of the trial or the participant's willingness to continue in a study. New information includes but is not limited to any relevant recent literature, interim findings, preliminary results of the study or of any other study (e.g. using the same drug), that has occurred or come to be known by the Investigator, since the last review.
6. 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.*	
7. Lapsed Studies *If the study has expired, please provide the following information:* *a) Provide an explanation for the late renewal;*	**FAILURE TO COMPLY WITH REQUIREMENT FOR ANNUAL RENEWAL** Prior to the expiration date of the study, either an annual renewal or a completion of study notification must be submitted to the REB using RISe. If either of these is not done, the REB may notify the investigator's Department Head or suspend or terminate the project, in which case

b) Confirm that NO study activities took place during the time over which there was no valid ethical approval; *c) Explain what strategies have been put in place so that this will not happen in the future.*	reactivation will require submission of a new application. If applicable, funding may be at risk of not being released. Any consent document signed during a period when there is no ethics approval is not valid. Reminder: The PI may designate one or two co-investigators with signing authority for the study. For instructions click here.
AMENDMENT:	
* **8. Proposed Changes to the Study** **8.1.** *Briefly describe the nature of the proposed change(s).* * **8.2.** *Please explain the reason for the proposed change(s).*	Briefly summarize (please do NOT cut and paste from the protocol). 8.1: 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.** 8.2: 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.
* **9. 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.* *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 View1, question 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 those documents that are being replaced. An updated Certificate of Approval will be issued to the newly designated Principal Investigator only.

New PI for this study:	**If you cannot find the name of the new PI in the list** have them added by contacting the applicable REBA. 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
* **10. Study Progress** **10.1.** *Summary: Provide a brief summary on the progress of the study. (See guidance on the right.)* **10.2.** *Monitoring and Summary Reports: Please attach a summary report if one is available by selecting "Add".* ***Clinical trials:*** *Please note that if you are conducting a clinical trial, a sponsor's summary report containing up-to-date information about the safety of participants is required. If a report is not being attached, please explain why in box 5.1 and whether or not any monitoring or interim analyses of this study took place. If so, indicate by whom and summarize the results.* Title	**10.1** The summary of progress to date should include information on whether participants are still participating in the research study. **10.2 Clinical trials:**Indicate if the trial is open or 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. If a safety summary report has been submitted to the REB within the last six months, quote the post-approval activity number (i.e. PAA A006). If this is a National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) or Canadian Cancer Society Research Institute (CCSRI) study, please attach a copy of the recent NCIC Clinical Trial Group Data Safety Monitoring Committee Report or provide an explanation as to why one is not available.
* **11. Risks to Participants** *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.*	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.
* **12. Level of Review** **12.1.** *Please review the guidance notes on the right and indicate whether this renewal with amendments PAA qualifies for Minimal Risk/Delegated Review. Note that if this amendment requires Health Canada approval it* ***does not*** *qualify for delegated review.* ***IMPORTANT NOTE: Both the renewal portion and the amendment portion of this PAA must qualify to be reviewed via delegated review in order to answer "yes" below.*** Yes No * **12.2.** *Is Health Canada Approval required for this amendment? (Please review the guidance notes to the right for further information.)* Yes No	12.1: Click here and scroll down to **Level of Review, for the criteria for Minimal Risk/Delegated Review of amendments**. 12.2: If this study required Health Canada approval when it was initially reviewed, your amendment may also require Health Canada approval. Click here for information on **Health Canada Criteria for Amendments Requiring Full Board Review** • Attach a copy of the NOL (No Objection Letter) for the amendment (if applicable) to View 9 of the application and enter the NOL control number in View 7.9. of the Application. **Note**: A Health Canada Acknowledgement of Notification is not an NOL.

Additional Comments:	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 annual renewal and amendment. At renewal, all studies qualify for delegated review **UNLESS** they are required to comply with U.S. regulations (see below), or full board review is required by the sponsor, or the REB Chair or delegate has requested renewals be reviewed at the full board. **Studies that must comply with U.S. regulations** must be submitted for full board review unless they meet the following criteria for minimal risk/delegated review: • The research is (i) permanently closed to the enrollment of new participants; and (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow up of participants; **OR** • Where no participants have been enrolled and no additional risks have been identified; **OR** • Where the remaining research activities are limited to only the analysis of already collected data. For Full Guidelines click here.
* **13. Changes to the Consent Form/Process** **13.1.** *Does this involve the recruitment of human participants? If yes, answer 13.2. and 13.3. below.* Yes No **13.2.** *Are the amendments such that participants still to be recruited to the study will receive an amended consent form?* Yes No **13.3.** *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:*	To attach the updated consent form, go to View 9.2 of the application. Click here for information on **Risks** and **re-consent**.
14. 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.**	14.1: List the revised or new documents being submitted and identify 'where' the change(s) are in each document i.e., reference the section page.

14.1. *Are you submitting any of the following revised or new documents?:* * *Revised Protocol:* 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 in the revised document and uploaded into the appropriate sections of the application form after completing this coversheet.* **14.2.** *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.*	Ensure that the changes in the documents are identifiable by either using highlights or track changes.
15. Additional Comments:	All changes described above must be entered in the appropriate sections of the Application or the submission will be returned as incomplete. **These changes can be made once you complete and exit this PAA coversheet.**

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.