Annual Renewal 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

*** 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 Coversheet

* **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 please explain why and indicate your plan 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 study start date is changing, please revise the initial application accordingly.
* **2. Level of Review** *Does this Annual Renewal qualify for Minimal Risk/Delegated Review? See guidance notes on the right for the criteria.* ○ Yes ○ No	All studies qualify for delegated review at annual renewal **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.
* **3. Participant Recruitment** **3.1.** *Does this study involve direct interaction with human participants? (If no, skip to question 4, **Participant Data: Chart Review and Sample Collection**. If yes, you must answer all of the questions in this section.)* ○ Yes ○ No **3.2.** *Is this study currently recruiting or will it be recruiting in the near future?* ○ Yes ○ No	**3.3.** Controls are people acting in a control capacity, including normal participants. **3.5. 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.

3.3. *How many participants (including controls and normals) are enrolled at institutions covered by this Research Ethics Approval?* *a. Enrolled to Date:* *b. Enrollment Goal:* **3.4.** *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:* **3.5.** *How many participant withdrawals have there been at this site?* **3.6.** *To your knowledge, did any participant withdraw as a result of study misconduct or complaints? If yes, please explain.* ***Current Approved Consent and/or Assent Form(s), Protocol****If data is currently being collected from participants or will be collected in the future, and the current approved version of the consent and/or assent form(s) are not already in View 9 of the RISe application form, or if the current approved version of the protocol is not already in View 9 (regardless of the status of the study) please attach a copy below by selecting the "Add" button. (Please DO NOT attach revised documents that have not been approved by the REB; revised documents must be submitted as amendments).* Title	
4. Chart Reviews and Sample Collection Studies **4.1.** ***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 reviews) 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 3,* ***Participant Recruitment****, only.)* *How many charts and/or samples have you included in this research?* *a. Included to Date* *b. Inclusion Goal*	4.2. Dates of extracted charts should match those indicated in the initial application.

4.2. ***Confirm the dates of the charts being reviewed.***	
* **5. Study Progress** **5.1.** *Summary: Provide a brief summary on the progress of the study. (See guidance on the right.)* **5.2.** *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	**5.1** The summary of progress to date should include information on whether participants are still participating in the research study. **5.2 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 enrolment, 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.
* **6. 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).
* **7. New Information** **7.1.** *Provide the REB with any new information related to the study. See Definition on the right.* * **7.2.** *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.
8. 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.*	

9. Lapsed Studies *If the study has expired, please provide the following information:* *a) Provide an explanation for the late renewal;* *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.*	**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 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.**
10. 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.