Completion of Clinical Study PAA – 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:**

Completion of Clinical 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

Completion of Clinical Study Coversheet

*** 1. Date of Completion** *Enter the effective date of completion.*	
*** 2. Confirmation of Completion of Data Collection** *After reviewing the guidelines on the right, confirm that participant data collection has been completed.* ○ Yes ○ No	Select here for the definition of study closure for studies involving human participant recruitment and studies that do not involve direct human participation (e.g. chart reviews and data registries). A study is considered complete where there has been either an official "close-out" visit by a Sponsor or there is no further requirement to submit data to the Sponsor. Studies being monitored by some sponsors are not complete until the centre is notified by the sponsor that the study is complete. Studies that are grant funded may be completed when there is no active grant that requires ethics approval.
3. Number of Participants, Charts or Samples ***3.1.*** *Enter the number of research participants enrolled at the sites/institutions covered by this ethics approval.* **3.2.** *Enter the number of charts reviewed or samples collected (See guidance note on right)*	**Question 3.2** should be answered only if you were 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 (such as chart reviews) or biological materials (such as tissue from diagnostic tests or surgeries) for part or all of your study. If you consented individuals for the use of their data, please complete 3.1
*** 4. Final Date / Notice** *Enter the date of the study monitor's final visit or notice, if applicable. If not applicable please select "not applicable" below.* *Not Applicable* ☐	
*** 5. Data/ Biospecimen Storage/ Destruction** **5.1.** *Describe plans for the final disposition of the data/biospecimens. Include, as applicable, how long the study data/biospecimens will be retained and where, and what plans there are for future use of the data/biospecimens (if any) including who will have access to the data/ biospecimens in the future and for what purpose. Please note that under UBC Policy #85, the PI must ensure that all study data is retained for at least 5 years within a UBC-affiliated facility. For Clinical Trials, in accordance with Health Canada the retention period is at least 25 years.* ***The applicable retention period must be confirmed in the response to 5.1.*** **5.2.** *If the data/biospecimens will be destroyed, indicate the planned method for erasure/destruction of the data/biospecimens, including when they will be destroyed.*	Please include the following information: • Final disposition/storage of all research-related study documents. According to UBC Policy 85, study data should be kept for a minimum of 5 years after publication. Clinical trials data must abide by Health Canada's regulations regarding data retention and generally must be kept for 25 years. Click here for more information concerning Health Canada requirements. • The procedure that will be followed in response to additional requests for access to the study data/ biospecimens (after the study has been completed and analyzed). • Plans for the final disposition of any electronic data or if applicable, the final disposition of any biospecimens.

* **6. Reason for Completion** *Please provide the reason for the completion of this study (i.e. did the study run its course, or if it ended early, explain why; if the study involved enrollment of participants, comment about enrollment and whether enrollment goals were achieved.) Include any other information required by the study sponsor to be submitted to the Research Ethics Board.*	
7. Reported Results and Sponsor close-out Title **Please note:** *Once the Completion of Study form is reviewed, the REB will issue an Acknowledgement and the study will automatically be listed in RISe as "Terminated" and will show under your "Inactive" tab. The ONLY activity available from that point on is a Request for Acknowledgement if needed. The study cannot be amended or reactivated.*	List publications that have reported results from this study. If the final report from this study has not yet been published indicate your plans for such publication. Attach any supporting documents for the Research Ethics Board by selecting "Add". Please include the official "close-out letter" from the Sponsor, if applicable. **Note: The REB requires at a minimum, an end-of-study report for all studies at study completion.**

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.