Comment [u1]: Text in Comments boxes are guidance notes/instructions to researchers.

Post Approval Activities

*** Select one of the following options to submit to the Research Ethics Board based on the guidelines (Click blue question mark for guidance):**

	Options
○	Annual Renewal
○	Annual Renewal with Amendments to the Study (UBC BREB, UBC CREB and C&W REB studies only)
○	Amendments to Study
○	Completion of Clinical Study
○	Request for Acknowledgement

Clear

Comment [u2]: Annual Renewals
For Clinical studies click here for information on annual renewals. If this is an annual renewal of a for-profit (industry or pharmaceutical) sponsored study, a renewal fee is required. For more details about fee payment please consult the applicable REB administration or their website.
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 clinical 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.

*** 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)

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 Clear

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

*** 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

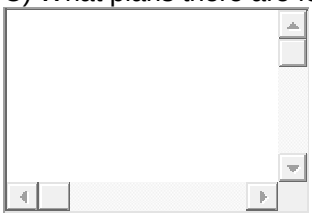
Comment [u3]: Click here for the definition of study closure for studies involving participant recruitment and studies that do not involve direct human participation (e.g. chart reviews and data registries).

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.

Comment [u4]: **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.

* 5. Data/ Biospecimen Storage/ Destruction

5.1. Please describe:
A) How long the study data/biospecimens will be retained and where
B) Who will have access to the data/ biospecimens in the future and for what purpose.
C) What plans there are for future use of the data/biospecimens (if any)



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.

Comment [u5]: Please include the following information:

- Final disposition/storage of all research-related study documents. For studies reviewed by a UBC REB: According to UBC Policy SC6 (formerly 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. Submission of study results to ClinicalTrials.gov

Is this a study registered with ClinicalTrials.gov?

○ Yes ○ No Clear

Comment [u6]: **Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) (PDF)** requires Responsible Parties to register and submit summary results of clinical trials with ClinicalTrials.gov.

For more information about this requirement, please refer to Clinical Trials Registration on the Office of Research Services website.

If yes, please confirm that a summary of study results has been submitted to ClinicalTrials.gov. Details should include the name of the individual responsible for submitting results, as well as the date of submission.

8. Reported Results and Sponsor close-out

Add

Title
There are no items to display

9. If this study required Health Authority Operational Approval, confirm that the Health Authority has been notified separately of the study's completion.

Yes No Clear

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.

Comment [u7]: 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.

This is the end of the Post Approval Activity (PAA) Coversheet.

1) Clicking "Continue" will bring you to the PAA homepage.

2) To work on this again, click the "Edit PAA Coversheet" button on the left side of the PAA homepage.

3) ONLY the Principal Investigator or a Co-Investigator with full signing authority will be able to "Submit PAA" from the PAA homepage for the initial submission.