RISe Clinical application Post approval activity:

Renewal

Legend
Text in Comments boxes on the right, are guidance notes/instructions to researchers.
Grey shaded questions will show/hide depending on previous answer.

The University of British Columbia
a place of mind

New: Human-Post Approval Activities

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):**

- (•) Annual Renewal
- ( ) Amendments to Study
- ( ) Completion of Clinical Study
- ( ) Request for Acknowledgement

* **Nickname**

Enter a nickname for this PAA.
(If applicable to your PAA, include descriptive words such as "IB update" or "protocol deviation" or "unanticipated event" or "local SAE" in the nickname)

Clinical Annual Renewal Coversheet

*** 1. Reason**

1.1. Why is this renewal being requested, e.g. still recruiting or data collection is ongoing etc.? (Unless required by the study sponsor, studies that no longer require interaction with participants or access to their data generally can be completed. Please click blue question mark)

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.

*** 2. Level of Review**

Does this Annual Renewal qualify for Minimal Risk/Delegated Review? Click blue question mark for the criteria.

○Yes ○No

*** 3. Participant Recruitment**

3.1. Is participant consent obtained by researchers? (**If no, skip to question 4**. 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. 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.

4. Chart Reviews, Database Records and Sample Collection Studies

4.1. Complete section **only if** you are **not** required by the REB to consent individuals for the use of their data or biospecimen.

How many charts/records and/or samples have you included in this research?

a. Included to Date

b. Inclusion Goal

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.

* **5.2.A** Is your study Health Canada / US FDA regulated or funded by a for-profit entity?

○Yes ○No

Please attach following reports if available:
5.2B Summary/Study newsletter:
[Add Document]

5.2C Monitoring report:
[Add Document]

5.2D Data Safety Monitoring Board:
[Add Document]

If you are conducting a clinical trial, a sponsor's summary report containing up-to-date information about the safety of participants is required.

5.2.E If there are no reports attached above, please explain why below and whether or not any monitoring or interim analyses of this study took place. If so, indicate by whom and summarize the result:

5.3 Please attach summary report (if available):
[Add Document]

* 6. Unanticipated Problems

6.1. 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

6.2. If "Yes", please explain.

* 7. New Information

7.1. Provide the REB with any new information related to the study.

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.

10. Additional Comments:

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.