# 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.

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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
- ( ) 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

*** 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)

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**Commented [CREB1]: 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.

**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.

**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.

## 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.

**Commented [CREB2]:** 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? 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

**Commented [CREB3]:** "Studies sponsored by the United States Department of Health and Human Services (DHHS) (e.g. NIH and its related Institutes, US Center for Disease Control, etc.) may require Full Board Review under 45 CFR 46.109 (e) and 45 CFR 46.110 (Code of Federal Regulations), unless they fall into one of the 9 categories recognized as eligible for expedited review.

Generally, if a study is subject to these regulations, was initially reviewed by Full Board Review, the annual renewal must also be conducted by the Full Board unless the research meets the criteria outlined in category (8) or (9). For example, category (8) allows expedited review for research previously approved by the convened board as follows:

"(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; OR
(b) Where no subjects have been enrolled and no additional risks have been identified; OR
(c) Where the remaining research activities are limited to data analysis."

Category 9 in turn allows for expedited review of research previously approved by the convened board, where that research is not conducted under an investigational new drug application or investigational device exemption, and where exemptions outlined in categories (2)-(8) do not apply, if the REB has determined and documented at a full board meeting that the research involves no greater than minimal risk and no additional risks have been identified." Please read the UBC CREB Post Approval Activity guidance notes, Article 2, on Level of review found online here.

**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

**Commented [CREB4]:** Controls are people acting in a control capacity, including normal participants.

**Commented [CREB5]:** 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.

**Commented [CREB6]:** Complete if you received a waiver of consent for secondary use of data (such as a chart review, Popdata) or biological materials (such as left over samples 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 only.)

**4.2.Confirm the dates of the charts being reviewed.**

**Commented [CREB7]:** Dates of extracted charts/records should match those indicated in the initial application.

*** 5. Study Progress**

**5.1.** Summary: Provide a brief summary on the progress of the study.

**Commented [CREB8]:** The summary of progress to date should include information on whether participants are still participating in the research study.
**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.

*** 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)?

**Commented [CREB9]:** 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).

○Yes ○No

**6.2.** If "Yes", please explain.

*** 7. New Information**

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

**Commented [CREB10]:** 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.

**Commented [CREB11]: 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 contact your REB.**

**10. Additional Comments:**

**Commented [CREB12]:** 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.**

**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.