RISe Clinical application Post approval activity:

Renewal with Amendment

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
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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)

Version 2023-03-24

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 with Amendments Coversheet

1) Complete this coversheet.
Changes must be described in this coversheet. Provide an overview of the amendment.
2) Edit the Application. Changes must be entered into the appropriate sections of the application. If not done, the amendment will be returned as incomplete.
3) Submit the Amendment with Renewal. When the above steps are completed, the PI or one of the designated Co-investigators with Signing Authority must then submit the amendment.

RENEWAL:

*** 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)

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.

1.2. If this research has not started pleases explain why and indicate plans for moving forward. If the study is on hold, please explain and indicate the anticipated start date.

*** 2. Participant Recruitment**

2.1. Is participant consent obtained by researchers? (**If no, skip to question 3**. If yes, you must answer all of the questions in this section.)

○Yes ○No

2.2. Is this study currently recruiting or will it be recruiting in the near future?

○Yes ○No

2.3. How many participants (including controls and normals) are enrolled at institutions covered by this Research Ethics Approval?

a. Enrolled to Date:

b. Enrollment Goal:

2.4. 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:

2.5. How many participant withdrawals have there been at this site?

2.6. To your knowledge, did any participant withdraw as a result of study misconduct or complaints? If yes, please explain.

3. Chart Reviews and Sample Collection Studies

3.1. 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/or samples have you included in this research?

a. Included to Date

b. Inclusion Goal

3.2. Confirm the dates of the charts being reviewed.

Commented [CREB3]: Controls are people acting in a control capacity, including normal participants.

Commented [CREB4]: 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 [CREB5]: 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 2 only.)

Commented [CREB6]: Dates of extracted charts/records should match those indicated in the initial application.

* **4. Unanticipated Problems**

4.1. 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

4.2. If Yes, please explain.

* **5. New Information**

5.1. Provide the REB with any new information related to the study that is not included in this PAA.

* **5.2.** 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.

6. 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.

7. 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 [CREB7]: 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.

Commented [CREB8]: 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.

AMENDMENT:

*** 8. Proposed Changes to the Study**

8.1. Briefly describe the nature of the proposed change(s).

Commented [CREB9]: Briefly summarize (please do NOT cut and paste from the protocol).

Explain "what" the change(s) are, using the following categories:

a) Participant safety: changes to known risks, eligibility criteria, treatment, procedures, data monitoring etc. that affect participant safety.

b) Scientific Interpretability: changes to study objectives, endpoints, sample size, planned statistical analysis or interim analysis that affect the study design or scientific interpretability.

c) Administrative changes: changes in study personnel, project title, sponsor, start or end dates, specimen handling, or any other similar changes that do not affect safety or scientific interpretability.

*** 8.2.** Please explain the reason for the proposed change(s).

Commented [CREB10]: Briefly summarize (please do NOT cut and paste from the protocol).

Explain "why" each change was made. (For example, the previous PI has left the institution; interim data has resulted in a need to change the study objectives, etc.)

Ensure that the changes in the documents are identifiable by either using highlights or track changes.

*** 9. Changes in Principal Investigator**

9.1. Will the Principal Investigator (PI) be changed on the study?
○Yes ○No

If "Yes", you must select here and complete the form with signatures then add the form below by clicking "Upload".

9.2. Select "Upload" to attach the signed letter for changing the Principal Investigator.
[Add Document]

Select the new PI for the study. Once you hit "**...**", you can enter the PI's name, or enter the first few letters of his or her name and hit "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

9.3. New PI for this study:

Commented [CREB11]: Do not change the submitting PI's name on this application or you will not be able to continue to submit the application (the REB will do this when they approve this amendment). However, if the submitting PI will continue to require online access to this study, you must add them to the list of co-investigators in View1, question 1.3 of the application.

Ensure that any study materials (e.g. consent or assent forms) are revised to reflect the new Principal Investigator. Attach the revised study documents to View 9 of the application and delete only those documents that are being replaced. An updated Certificate of Approval will be issued to the newly designated Principal Investigator only.

If you cannot find the name of the new PI in the list please ensure that they are registered RISe users. Please click here.

* **10. Study Progress**

10.1. Summary: Provide a brief summary on the progress of the study. (See guidance on the right.)

Commented [CREB12]: 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.

* **10.2.A** Is your study Health Canada / US FDA regulated or funded by a for-profit entity?
○Yes ○No

Please attach following reports if available:
10.2B Summary/Study newsletter:
[Add Document]

10.2C Monitoring report:
[Add Document]

10.2D 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.

10.2.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:

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

* **11. Risks to Participants**

Indicate whether or not this amendment will result in any increase in risk or discomfort for the study participant. If so, please explain what these are and why they are required.

Commented [CREB13]: Explain 'how' the change(s) may (or may not) affect a participant's safety or their willingness to continue to participate. If already enrolled participants will NOT be re-consented, please provide an explanation.

* **12. Level of Review**

12.1. Please review the guidance notes in the blue question mark, and indicate whether this renewal with amendments PAA qualifies for Minimal Risk/Delegated Review. Note that if this amendment requires Health Canada approval it **does not** qualify for delegated review.

IMPORTANT NOTE: Both the renewal portion and the amendment portion of this PAA must qualify to be reviewed via delegated review in order to answer "yes" below.

○Yes ○No

Commented [CREB14]: Amendment: To determine appropriate level of review, please see Study Amendments, Article 2 here.

Renewal: 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.

* **12.2.** Is Health Canada Approval required for this amendment?
○Yes ○No

12.3. Additional Comments:

* **13. Recruitment and Consent Process**

13.1. Does this involve the recruitment of human participants? If yes, answer 13.2. and 13.3. below.

○Yes ○No

13.2. Are the amendments such that participants still to be recruited to the study will receive an amended consent form?

○Yes ○No

13.3. Will already enrolled participants be updated with any new information included in this amendment? Please provide your rationale below, including details of how and when participants will be re-consented, if applicable.

○Yes ○No

13.4. Details:

Commented [CREB15]: If this study required Health Canada approval when it was initially reviewed, this amendment may also require Health Canada approval. Click here for information on **Health Canada Criteria for Amendments Requiring Full Board Review**.

- Attach a copy of the NOL (No Objection Letter) for this amendment (if applicable) to View 9 of the Application and enter the NOL control number in Box 7.9 of the Application.

Note: A Health Canada Acknowledgement of Notification is not an NOL.
Amendments may be submitted for REB review while the Health Canada approval for it is pending. The Health Canada approval document will however, be required prior to the REB issuing the certificate of approval for the amendment.

14. Documentation: Complete each section below to provide an overview of the changes for which you are seeking approval. **Upon completion of this coversheet, these changes must also be entered into the appropriate sections of the application.**

Are you submitting any of the following revised or new documents?:

* **14.1.** Revised Protocol: ○Yes ○No

* **14.2.** Revised consent and/or assent forms: ○Yes ○No

* **14.3.** Other "revised" or "new" document(s): ○Yes ○No

14.4. If "Yes", list each document(s) name and provide a brief summary describing the changes being made to that document.

15. Additional Comments:

Commented [CREB16]: List the revised or new documents being submitted and identify 'where' the change(s) are in each document i.e., reference the section page.

Ensure that the changes in the documents are identifiable by either using highlights or track changes.

Commented [CREB17]: 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.