RISe Clinical application Post approval activity:

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.

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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)

Clinical Amendment Coversheet

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.

Provide a summary of the changes to the Study (Application):

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. When the above steps are completed, the PI or one of the designated Co-investigators with Signing Authority must then submit the amendment.

*** 1.1 Proposed changes to study**

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

Commented [CREB2]: 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.

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

Commented [CREB3]: 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.

* 2. Changes in Principal Investigator

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

2.2. If "Yes", you must complete, sign and upload the Change Principal Investigator form here.
[Add Document]

Select the new PI for the study.
New PI for this study:

* 3. Study Progress

3.1. Is this study currently open to enrollment (accrual) of human participants? If No, please explain below in 3.2.

○Yes ○No

3.2. Describe the study progress, e.g. are there participants on treatment or follow-up only etc.

* 4. 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 [CREB4]: 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.

Commented [CREB5]: The summary of progress to date should include information on whether participants are still participating in the research study. Especially in the case of clinical trials, the summary should indicate if the trial is 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 enrollment, remarks about the ability to recruit participants are also appropriate as is any information about the results from any interim analyses.

Commented [CREB6]: 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.

*** 5. Level of Review**

5.1. Please click blue ? at the end of this question to review the guidance notes and indicate whether this amendment qualifies for Minimal Risk/Delegated Review. Note that if this amendment requires Health Canada approval it does not qualify for delegated review.

○Yes ○No

Commented [CREB7]: To determine appropriate level of review, please see Study Amendments, Article 2 here.

5.2. Is Health Canada Approval required for this amendment?

○Yes ○No

5.2.B. Additional Comments:

Commented [CREB8]: 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.

*** 6. Recruitment and Consent Process**

6.1. Does this study involve the recruitment of human participants? If yes, answer 6.2. and 6.3. below.

○Yes ○No

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

○Yes ○No

Commented [CREB9]: To attach the updated consent form, go to View 9.2 of the application.
Click here for information on **Risks** and **re-consent**.

6.3.A. 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

6.3.B. Details:

7. 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.

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

* **7.1.A.** Revised Proposal: ○Yes ○No
* **7.1.B.** Revised consent and/or assent forms: ○Yes ○No
* **7.1.C.** Other "revised" or "new" document(s): ○Yes ○No

7.1.D. If "Yes", Please
1) list each document(s) name
2) provide a brief summary describing the changes being made to that document. These changes must be highlighted /track changed in the revised document and uploaded into the appropriate sections of the application form after completing this coversheet.

Comments:

Commented [CREB10]: 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.

You have reached the end of the Post Approval Activity (PAA) Coversheet. Please follow the steps below.

1) Click "Continue" to enter the amendment changes in the application (this must be completed before the PAA can be submitted by the PI).

If this is not the initial completion of the coversheet, you will be taken directly to the PAA home page where you can edit the application or coversheet.

2) Submit the PAA for review.
When the application amendments have been completed, click "Save" then "Exit". 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 contact your REB.

note: to update your own personal profile (appointments, email address, etc.), click here