

# RISe Clinical application Post approval activity:

## Amendment

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### 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
- 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 Amendment Coversheet

**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).



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



## \* 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. 

**\* 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

**5.2.** Is Health Canada Approval required for this amendment? 

Yes     No

**5.2.B.** Additional Comments:

**\* 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

**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:



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Edit: Human-Post Approval Activities - H11-00001-A006

**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