

How To Create and Submit an Amendment for Submission to BCCA REB Using RISE

An amendment in RISE is a "post-approval activity (**PAA**)".

- On your RISE homepage, click on the "**Human Ethics**" tab.
- In the **top section**, open the study (do not create a PAA from a PAA in the bottom section).
- On the study homepage, on the left hand side, click on "**I want to create...a post approval activity...Human Ethics**"
- Select the type of Post-Approval Activity (**click on Amendment**).
- An "**Amendment coversheet**" will appear. Be sure to complete all sections.
- **Coversheet Question 1.6, Please summarize all items being submitted.** If an amended protocol is being submitted the protocol changes must be summarized so as to identify administrative changes from changes those that affect subject safety. If submitting personnel changes, please list them so we can note them on the certificate. (see other tips below)
- **After completing the coversheet**, the application will become "unlocked" so you can "**edit the application**" in any section that is applicable and if you are attaching a revised document follow the instructions at the top of View 9 (delete **ONLY** the document you are replacing), once it is approved View 9 of the application should always contain your current approved documents for the study.
- **When you have finished editing the application, save and exit**, you will now be in the "**PAA Homepage**" and the PAA is assigned a number "A001" or "A002" etc. (you can tell when you are in a PAA homepage by looking at the study number at the top it will have the red letters "PAA" and the PAA number. Example: **(PAA) H06-00123-A001**)
- On the left side of the PAA Homepage, **click on "submit"**

When you see the "**status**" on the top left change to **REBA Screening**...you know the amendment has been submitted.

Track the status of the PAA; click on the Human Ethics tab and open the study and click on the "Post approval activities" tab...all post approval activities for the study are listed there and you can see the status.

Additional Tips:

PI's may Designate 2 Co-investigators with Signing Authority.

Once a study is initially approved a PI may designate up to 2 "**Co-'investigators with signing authority**" who can also submit post approval activities (except for responses to deferrals). This is quick to do and does not require submission to REB for approval. Follow the instructions in **Help Document #4 "How to Designate Co-investigator(s) with Signing Authority"**:
<http://www.bccancer.bc.ca/RES/REB/rise.htm#help>

Amendment Coversheet Question 1.5: If the "amendment" is one that it requires Health Canada approval, it must be submitted for full board review and the applicable Health Canada NOL must be attached to View 9 of the application form (you can submit the application without the NOL if it is pending, the REB will review but not release the certificate of approval until the NOL is received).

If you are changing your own name from the primary contact in the application but still need to see the study then in the application form be sure to add yourself **first** to 1.4, then change the primary contact name (or you can't access the application).

To save or send a copy of the certificate, in order to keep the logos and signatures intact (until RISE produces a pdf file) you must first save it to your hard drive by clicking on File>Save As> and select "Web Archive" as the file format. You can then attach it to an email from your hard drive.