

Quick Reference Guide - Safety Letters, SAE's (local and external) and Unanticipated Events, Investigator Brochures

(This describes which submission process to use and tips for attaching files. This does not include timelines or specific policies)

State of Study	Type of Report	Type of Submission	What to Include in REB Submission	REB Certificate
Not Yet Approved by REB	Safety Letters, Line Listings, Quarterly Reports, Six Monthly Reports, Investigator Brochures (IB), Addendums to IB, Product Monographs, Unanticipated Events	Attach to Section 9 of the initial application in RISE or with response to proviso/deferral.	See tips on attaching multiple letters If in response to proviso/deferral, indicate as "Additional Information"	These will be included on initial Approval Certificate
	SAE	Same as above	Same as above	Same as above
POST APPROVAL ACTIVITIES (in RISE enter a " PAA nickname " to identify the item being submitted)				
Approved by REB but NOT YET Activated	SAE	Request for Acknowledgement	<ul style="list-style-type: none"> Include a statement that the study is NOT yet activated. PAA Nickname required 	Acknowledgment
Approved by REB <u>and</u> Activated (even if no subjects have been enrolled.)	SAE: (See exception below)	BCCA REB SAE Dbase	If received in RISE, the REBA will return the PAA to PI to submit via the REB SAE database.	The SAE dbase provides a trial-specific REB Acknowledgment
	SAE: No access to the SAE Dbase (Researcher who are declared "exempt" by the REB from using the SAE dbase.)	Request for Acknowledgement	<ul style="list-style-type: none"> Must include this statement: "This submission is for an SAE report for a study that is exempt from the BCCA REB SAE database." PAA Nickname required 	Acknowledgment in RISE
Approved by REB (whether activated or not)	Safety Reports, Line Listings, Quarterly Reports, Six Monthly Reports, Unanticipated Events i.e; -Protocol Deviations -Dear Doctor Letters -Breach of Confidentiality -Study closed to accrual -Permanently or temporarily on hold due to safety issue.	Request for Acknowledgement	<ul style="list-style-type: none"> Status of the study (<i>open to accrual or other</i>) Number & Status of Subjects (<i>On treatment, on follow-up</i>) Identify the new information Specify any action that has been taken or proposed to be taken in response to the new information. If required changes have been completed on a previous or concurrent amendment provide the PAA number. PAA Nickname required 	Acknowledgment
	New Investigator Brochure (IB), Summary of changes to IB, Addendums to IB, Product Monographs	Request for Acknowledgement	<ul style="list-style-type: none"> Confirm that no changes to the protocol or consent are required. If required changes have been completed on a previous or concurrent amendment provide the PAA number. If changes are required, then submit as an amendment (attach to section 9) with the revised documents and appropriate changes to the RISE application PAA Nickname required 	Acknowledgment
Terminated (Study Completed)	Safety Reports, SAEs or any other such item that requires acknowledgment from the REB.	Request for Acknowledgement	<p>No amendments can be submitted. No study activity should occur on a completed study and this should be confirmed in the submission.</p> <ul style="list-style-type: none"> PAA Nickname required 	Acknowledgment of an item received on a completed study.
Errors in SAE reporting (i.e.: large quantities of missed SAEs for late submission) Errors or malfunctioning of the SAE Dbase Requests for SAE fee waiver.			Contact the BCCA REB describing the situation by email to reb@bccancer.bc.ca	

How to Determine Whether a Document is a SAE or Safety Report

1) Serious Adverse Event Reports are primary documents that describe either the original and/or follow up report of the single (local or external) serious adverse event.

SAE reports (primary documents) should be added to the SAE database once the study is approved and activated, whether they require a change to the current protocol or consent or not, and whether or not any subjects have actually been enrolled since the study was activated. Before entering the SAE report in the database, check to ensure that the report has not already been entered.

2) Safety Reports; Line Listings, Quarterly Reports, Six Monthly Reports, summaries of SAEs (e.g. CIOMS, SUSARs or other variations), are considered to be secondary documents that represent an interim update of either the most recent edition of the Investigator's Brochure or an interpretation of an SAE with instructions concerning how the safety issue affects the continued conduct of the trial. When a new edition of the IB is issued it incorporates the information from all Safety Reports that have accumulated since the previous edition of the IB. In the interim, this secondary document may require acknowledgment from the REB.

Secondary documents should be submitted as attachments to a Request for Acknowledgement using RISE. The Request for Acknowledgement will be acknowledged and reviewed by the REB. If the secondary report from the sponsor describes a "local SAE", that occurred at BCCA, please ensure that the local event has already been entered in the SAE database, before submitting the secondary report in RISE for acknowledgment. *Note: SAE reports noted in line listings do NOT need to be entered into the BCCA REB SAE database.*

When to start using the REB SAE Database

Prior to REB Approval: Submit both SAEs (primary documents) and Safety Reports (secondary documents) in RISE either with the initial application or with a response to proviso/deferral.

After the REB Approval but pending activation: Continue to submit both SAEs (primary documents) and Safety Reports (secondary documents) in RISE as a Post-Approval Activity (PAA) "Request for Acknowledgement" until the study is activated.

After the REB Approval and the date of activation: Submit SAE (primary documents) original and/or follow-up SAE reports for local or external events, whether or not subjects have been enrolled), using the BCCA REB SAE Database reporting system. Submit the secondary documents as a PAA "Request for acknowledgment" using RISE.

Exceptions:

1. Researchers outside of PHSA network (see below).
2. If a change is required to the protocol or consent, then it should be submitted in RISE as an amendment with a summary of the required changes and applicable revised documents.

Researchers Outside of the PHSA/BCCA network

Researchers who are outside of the PHSA network and do not have access to the BCCA REB SAE database should contact the BCCA REB to request an exemption from the SAE database and for instructions on how to submit SAEs to the REB once their study is both approved and activated.

Contact the BCCA REB by email: reb@bccancer.bc.ca or call (604) 877-6283

Tips for attaching multiple safety letters or SAEs in RISE

Although there is no file size limit for RISE, there are a few things to consider.

Uploading a 90mb document (which is about 1,165 pages) will take RISE approximately 30 -45 minutes to upload.

If you are able to, we recommend scanning up to 100 pages at a time and uploading each 100 page file. This would take less time, so for example if you have 1,000 pages and scan about 10 files containing 100 pages each, then each file will take less time to upload in RISE. To save even more time, you don't have to attach each file one at a time, you can attach a "zip file" that contains all 10 files and this may not take as long to upload. (*Also see "filenames" below.*)

Instructions for creating and attaching a "zip file"

- Go to the drive where your files are kept and highlight the documents you want to attach (limit to 15 or 20 files per batch)
- right click, and select "send to" (it doesn't actually send anywhere),
- In the bottom of the dialogue box that appears select "compressed folder" and a "compressed folder" is automatically created for you on your PC that contains the files you highlighted.
- Then you can go to RISE to section 9.8 and click on "Add" and select the "zipped folder" from your hard drive. It will attach to RISE as one file.

Note: Zip files may only be used for multiple safety letters or SAE's (all other types of study documents must be attached individually).

Filenames

The information and filenames you enter in RISE when you attach documents will appear "as entered" in the Acknowledgment or Certificate from the REB. Due to the security features of RISE, the REB cannot edit your entries in RISE, please ensure your entries are accurate.

You may choose any identifiers you wish in the filename however; the filename should include the information for which your sponsor requires acknowledgment. If the filenames you enter cannot adequately provide this (i.e.: If you are attaching a zip file, or a .pdf file containing several reports, only the "filename" of the zip file or .pdf file will appear on the certificate of approval, not the names of the individual files contained within the zip or .pdf file) then you will need to do one of the following;

If you are submitting these in a Request for Acknowledgment; some sponsors will provide you with an itemized list from which you can copy and paste into the request for acknowledgment text box. Both the contents of the text box and the filename of each attachment will be appear "as is" in the Acknowledgment from the REB.

If you are attaching these in a new submission or in a response to proviso/deferral for the initial submission; the same method can be used as noted above, with one exception; there is no text box for you to enter an itemized list of the attached files if needed. Therefore, if you need a list to appear on the certificate you will need to do the following;

- 1) Attach an itemized list (as a Word document)
- 2) Explain in the PAA Coversheet that the items in the list need to appear on the certificate of approval
- 3) Ensure the list is accurate, as it will be entered "as is" into the certificate of approval.

If you have any questions, please contact the REB at reb@bccancer.bc.ca or see [Contacts](#)