

## Quick Reference Guide for SAE's , Unanticipated Events, Investigator Brochures

This describes which submission method to use based on the state of the study (see column on right below). This also included some submission tips on page 2.

State of Study	Type of Report	Method of Submission	What to Include
<b>Study Not Yet Approved by REB</b>	<ul style="list-style-type: none"> <li>▪ SAEs (local or external) <i>that meet the criteria for individual reporting may be submitted</i> otherwise only the most recent Periodic (quarterly or six monthly) Safety Summary Report</li> <li>▪ Line Listings – only if accompanied by an interpretation of the pattern of SAEs and position statement as to whether a change was required.</li> <li>▪ Investigator Brochures (IB), IB updates or Product Monographs</li> <li>▪ Other Unanticipated Events</li> </ul>	<p>Submit using RISE in the Initial application or with a response to a proviso/deferral</p> <p>Attach to Section 9 of the RISE application.</p> <p>See <a href="#">tips on attaching documents</a> on page 2 of this document.</p>	<p>If submitting these with a response to proviso/deferral, indicate that “<b>Additional New Information</b>” is being submitted with the response and specify.</p>
<b>POST APPROVAL ACTIVITIES - Enter a "PAA nickname" in RISE to identify the item being submitted)</b>			
<b>Study Approved by REB</b>	<ul style="list-style-type: none"> <li>▪ SAE (local or external) <i>that meet the criteria for individual reporting may be submitted</i></li> <li>▪ Periodic (quarterly or six monthly) Safety Summary Report</li> <li>▪ Line Listings – only if accompanied by an interpretation of the pattern of SAEs and position statement as to whether a change was required.</li> </ul>	<b>Request for Acknowledgement in RISE</b>	<p>Provide information as requested in RISE e.g.,</p> <ul style="list-style-type: none"> <li>▪ Status of the study</li> <li>▪ Status of Subjects</li> <li>▪ Identify the information</li> <li>▪ Specify any action taken or proposed.</li> </ul> <p>If changes have been submitted on a previous or concurrent submission then provide the PAA number.</p>
	<p><b>Safety Reports such as CIOMS, Med Watch, etc.</b> should not be submitted unless the report <i>suggests that the research places the participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.</i> If the “greater risk of harm” doesn’t require some change then technically, it doesn’t qualify for submission to the REB. If a safety report is submitted at the request of the sponsor or investigator that does not meet the criteria, a rationale must be provided.</p>	<p><b>a) A Request for Acknowledgement (in RISE);</b> if an immediate action has been taken to eliminate a risk to subjects, or to immediately inform subjects about a risk, pending submission of a revised consent or protocol to be subsequently submitted as an amendment.</p> <p><b>b) An Amendment (in RISE)</b> with an explanation as to what is being changed and why, and to include the new or revised document (e.g., letter to subjects, addendum consent, revised consent, revised protocol), and a copy of the related report that supports the rationale for the change.</p>	Same as above
	<p><b>Other Unanticipated Events i.e.;</b></p> <ul style="list-style-type: none"> <li>▪ Protocol Deviations</li> <li>▪ Breach of Confidentiality</li> <li>▪ Study closed to accrual</li> <li>▪ Permanently or temporarily on hold</li> </ul>	<b>Request for Acknowledgement in RISE</b>	Same as above

	<p><b>Investigator Brochure (IB), Summary of changes to IB, Addendums to IB, Product Monographs</b></p> <p><b>Note: An IB or IB Update does not qualify as a substitute for a quarterly or six monthly periodic safety summary report.</b></p>	<p><b>Amendment in RISE</b></p> <p>(Eff. Oct 30, 2009, do not submit these for acknowledgment, they must be submitted as an amendment).</p>	<ul style="list-style-type: none"> <li>▪ Confirm whether any changes to the protocol or consent are required.</li> <li>▪ If changes have been submitted on a previous or concurrent submission provide the PAA number.</li> </ul>
<p><b>Study Completed (Terminated in RISE)</b></p>	<p>Safety Letters or any other such item that requires acknowledgment from the REB after the study is completed and terminated in RISE.</p>	<p><b>Request for Acknowledgement</b> in RISE. (The terminated study is located under the "Inactive" Tab in RISE.)</p>	

## Tips for attaching documents in RISE

### 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 and match the information contained within the document (i.e. version dates).

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 .pdf file containing several reports, only the "filename" of the .pdf file will appear on the certificate of approval, not the names of the individual reports contained within the .pdf file) if you require acknowledgment of each report then you will need to do one of the following;

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; or an Amendment,** there is no text box for you to enter an itemized list. Therefore, you will need to do the following;

- 1) Attach an itemized list (as a Word document)
- 2) Explain in the submission 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 by email to [reb@bccancer.bc.ca](mailto:reb@bccancer.bc.ca) or see [Contacts](#)