



IMPORTANT UPDATES

Date: June 12, 2009

To: Researchers and research staff who submit applications to the BCCA Research Ethics Board

From: George Browman, M.D., Chair, UBC BCCA Research Ethics Board

1. Ongoing Changes to RISe Application Forms

Numerous changes to the RISe research ethics forms and guidelines have been and will continue to be implemented over the next couple of months. The forms and guidance notes have only had minor revisions since the implementation of the electronic system, and a thorough revision and update is necessary to ensure that we continue to keep up with current standards and requirements. The UBC Office of Research Services that provides oversight for all UBC affiliated REB's and the RISe programmers are working together to update the RISe application forms. For those using the behavioural application form, we anticipate that many of the post-approval activity forms will need to be changed so that there are separate, more appropriate forms for those who conduct behavioural research. Due to the broad scope of RISe and prioritizing program changes, it is not possible to provide advance notice however, your feedback is important and welcome.

Of note, due to the technical features of RISe, changes (such as newly added items) appear not only in newly created submissions of the application or coversheets but also retrospectively (in previous and current pending versions). Therefore, it may appear that in a previous submission approved by the REB, that a question was not answered, when in fact it simply did not exist at that time. If the REB approved a submission, it was done so with sufficient information provided at that time. If you require a copy of the originally approved RISe application or final approved version of subsequent amendment(s) they can be retrieved in RISe by going to the study homepage, click on the "Application Changes" tab and scroll to the bottom, these are available in a "read only", printer-friendly version. *(In some cases, the "originally approved version" of the initial application is also located under the "Post Approval Activities" tab.)*

Summary of Changes to RISe application May 4, 2009– see [Appendix 1](#)

2. BCCA Abbotsford Centre now available on the RISe application.

The BCCA Abbotsford Centre can now be selected in Section 4.2A as a participating centre and a lead PI can be identified in Section 11. You may now also enter this into your RISe profile if this is your main work location.

3. Post Approval Activity (PAA) "Nickname" required.

When creating a new Post-Approval Activity (PAA) in RISe, enter a "PAA nickname" to identify the content of the amendment or acknowledgment. *(This is separate from the "study nickname")*. The PAA nickname should be entered in the text box that appears on the opening page of the PAA (under the type of PAA to select). It is particularly important if you are reporting a protocol deviation, unanticipated event, or an updated Investigator Brochure, to identify this within the PAA nickname. The system will identify whether it is an Amendment or Annual renewal or Request for Acknowledgment. The nickname should differentiate similar types of submissions as shown below:

Examples:

- Protocol Deviation #1 – Drug Dosage Missed
- Protocol Deviation #2 – Drug Dosage Decrease & Safety Letter Jan 1, 2009
- IB Version #4 dated October 2009
- Protocol Amendment #4 and Revised Consent
- Change of PI and Primary Contact

The PAA nickname will appear in RISe and will facilitate audits as well as the REB and yourself by being able to view the list under the "Post Approval Activities (PAAs)" tab for a study and readily locate an item without needing to open each PAA. In the future, the REB may return a PAA to you if a nickname is not provided.

This is located on our REB webpage [RISe Tips and Help](#) - *RISe Help Document #8*
or click on this link: [Post Approval Activity \(PAA\) Nickname](#)

4. Updated Investigator Brochure (IB)

Once a study is approved, updated Investigator Brochures, addendums to the IB and/or Product Monographs may now be submitted as a Request for Acknowledgment *provided that*,

- the PAA nickname identifies the item
- no changes are required to the protocol or informed consent form.

If changes are required, an Amendment must be submitted which should include the updated IB, summary of changes to the IB and/or Product Monograph, revised documents (i.e., consent) and edits to the RISe application.

5. Submission Process for SAEs, Safety Letters and Investigator Brochures.

A "Quick Reference Guide" is attached to assist those who submit this document to the REB to determine which submission process applies to SAEs, Safety Letters and Investigator Brochures.

This is located on our REB webpage [RISe Tips and Help](#) – *Rise Help Document #9*
or click on this link [Quick Reference Guide – SAEs Safety Letters & IBs](#)

6. Updates to the BCCA REB web pages

Changes to the BCCA REB web pages will take place over the next few months to update REB information and improve navigation. The BCCA REB web pages are located at:

<http://www.bccancer.bc.ca/RES/REB.htm>

7. Contacting the BCCA REB

Please use our generic REB email address: reb@bccancer.bc.ca quoting your REB number (i.e., H0x-xxxxx) Contacts: <http://www.bccancer.bc.ca/RES/REB/Contacts.htm>

8. QUESTIONS

If you have questions or concerns about this notice, please contact Bonnie Shields, Manager, UBC BCCA REB e-mail: reb@bccancer.bc.ca or phone (604-877-6284)

Thank you for your attention,
George Browman, MD
Chair, UBC BCCA REB

Summary of Changes to RISE Application Forms effective May 4, 2009

Guidance Notes

The Guidance Notes in RISE have been updated. In particular, the reference to registration for publication requirements of the ICMJE has been updated to include the "new definition" of what constitutes a clinical trial, and also which registration sites ICMJE recognizes, and an updated link.

New Questions in the Application Forms on RISE

New questions have been added, others clarified and new guidance notes added. All questions in RISE applications should be completed (even with a "not applicable"). This will alleviate the REB having to return the application to ask for all questions to be answered so that the Board has all the information needed for review.

Clinical Research new project application:

1. New question 4.3.C – previous rejection of study by a research ethics
2. New question 6.6.A – justification for alteration of waiver or consent form
3. New question 5.1A – Short lay language summary of project
4. New question 5.6 – Use of existing records to identify research subjects
5. Clarification for question 7.1 – studies at multiple centres
6. New question 7.1 – submission to other BC or Canadian Ethics Boards
7. Reconfiguration and clarification of question 7.8 – Health Regulatory Approvals
8. Clarification of question 7.9 – Regulatory Agency and certificate of approval control number
9. New question 7.12A – FDA IND or IDE Number
10. New question 8.4.A – personal identifiers and health information
11. Clarification question 8.5 – access to data
12. New questions 8.5 A, B, and C – storage of data and safeguards of data
13. Clarification question 8.6 What will happen at end of study?
14. New question 8.7 – data sent to external institutions
15. New question 8.8 – receiving data form other institutions
16. New questions 9.1 A and B – attached Health Canada Regulatory approval certificate and FDA IND/IDE letters

Post Approval Activity (PAA) Nickname - can now be entered on the PAA selection page – [PAA Nickname](#)

Amendment PAA Coversheet

Questions 1.5 to 1.7 have been modified, some questions are new and guidance notes have been updated.

1. question 1.5.1 – asks to describe the nature of the changes
2. question 1.5.2 – new - asks to explain the reason for the changes
3. question 1.5.3 – new - explain if the changes will result in any increased risk or discomfort to subjects.
4. question 1.6.1 – no change, just re-numbered – used to be 1.5.1
5. question 1.6.2 - no change, just re-numbered – used to be 1.5.2
6. question 1.6.3 – no change, just re-numbered – used to be 1.5.3

Annual Renewal PAA Coversheet

The Annual Renewal PAA Coversheet has an added new questions asking the researcher to advise / elaborate on any new information that he/she may have come across, concerning the trial. The guidance notes clarify that the REB wants to know of any interim findings, preliminary results, and recent literature concerning the study drug, particularly anything that may change or affect the safety of subjects or the scientific or ethical validity of the study since the last review.

1. question 1.2.7 indicate number of participants who have withdrawn
2. question 1.3.2 (a) – attach the most recent monitoring or summary report
3. question 1.3.2 (b) – provide a brief summary of any recent monitoring
4. question 1.5.1 – regarding new information and what actions are proposed if applicable.
5. question 1.5.2 – new info or literature that could potentially impact subject safety and proposed action
6. question 1.5.3 – if an amendment has been submitted about the new info – provide the PAA number
7. question 1.6 – changes in relation to conflict of interest
8. question 1.7 - asks whether the study should continue
9. question 1.8 – (previously questions 1.5.1 through 1.5.4) regarding expired study
10. question 1.9 – no change, just re-numbered – used to be 1.6

Request for Acknowledgment PAA Coversheet

The Request for Acknowledgment PAA Coversheet was amended regarding new information and unanticipated problems, which are not SAE's.

1. changes to question 1.A
2. inserted new question 1.B
3. added new accompanying guidance notes

Completion of Study Notification to REB

1. question 1.7 – new question regarding number of serious unexpected adverse events.