



University of British Columbia - British Columbia Cancer Agency Research Ethics Board  
(UBC BCCA REB)



**BC Cancer Agency**  
CARE & RESEARCH

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## Important Announcement: SAE Reporting and SAE Fees

**Date:** December 7, 2011  
**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

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### **NEW** 1. BCCA REB SAE Database Closing (SAE Reporting Migrating to RISe)

**Effective January 1, 2012**, the BCCA REB SAE database will no longer be available for data entry and all safety reporting must be submitted using the RISe system.

It has been over two years since the UBC REBs implemented a new safety reporting policy (October 2009) due to the over-reporting of individual SAE reports. At that time, the new policy emphasized the criteria for reporting of 'individual' SAEs and the requirement for quarterly or six monthly periodic safety update reports (as provided by the sponsor) in lieu of those which did not meet the requisite criteria. The REB anticipated a significant decrease in the number of individual SAEs reports as sponsors migrated to this new reporting method. However, the SAE database continues to be over-populated with reports that do not meet the criteria. The REB has provided sufficient time to allow for transition to the new reporting method and now in order to effectively apply the policy, has decided to discontinue the use of the database. All local and non-local SAE reports that meet the criteria for individual reporting (see item 3 below), must be submitted using the RISe system (to be submitted as a Request for Acknowledgment).

The same criteria applies when submitting a new study (only the most recent periodic safety update report or individual SAE reports that meet the criteria may be submitted with the new submission).

The BCCA REB SAE database will be retained as a matter of record on the PHSA network (h:\Research Ethics Board SAE) as a read/print only database for the purpose of monitoring or audits.

### **NEW** 2. BCCA REB SAE Fee Will be Discontinued

**Effective January 1, 2012**, the BCCA REB SAE Fee will be discontinued as a result of the migration of safety reporting to the RISe system which will align the BCCA REB with the UBC affiliated REBs' policy and processes for safety reporting. A final statement will be issued shortly after the database is closed, and all SAE fees will be expected to be paid in full within 30 days of receipt of the final statement.

### 3. Criteria and Timelines for SAE and Periodic Safety Summary Reporting

A revised policy and guidance for all UBC affiliated REB's is forthcoming. In the interim, due to the migration to RISe for the BCCA REB, the following is provided to clarify the reporting criteria, which is applicable to local and non-local (external) events. **Only reports that meet the criteria should be submitted.**

**The principal investigator for a study is responsible for ensuring that the study sponsor is aware of these requirements so that the sponsor can provide the appropriate documents for submission to the REB.**

## Criteria

### Individual SAE Reports

An individual SAE report; **local or non-local (external)**, must meet the criteria (definition of an unanticipated event) of being **serious AND related or possibly related to the study drug or treatment, AND unexpected/unanticipated** (meaning that it would have to *suggest 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.* **In other words, the SAE necessitates a change in the conduct of the study, the protocol and/or consent document.** If the report meets these criteria, then the event has implications for the conduct of the study and requires a significant and usually safety-related change in the protocol (such as revising inclusion/exclusion criteria or including a new monitoring requirement, or revised informed consent, or revised investigator's brochure.)

**Individual SAE reports that do not meet the above criteria** for individual reporting must instead be reported to the REB either quarterly or six monthly in the form of a periodic safety update report (as provided by the sponsor to the Principal Investigator (PI) for submission to the REB (see below).

**Periodic Safety Update Reports** must include a meaningful interpretation of the pattern of events (i.e. a sponsor analysis of the significance of the adverse events or such analysis from an independent Data Safety Monitoring Board (DSMB), with where appropriate, a discussion of previous similar events, and a position statement as to whether these warrant a change. The report should be provided by the sponsor to the PI for submission to the REB and may be either quarterly or six monthly as preferred by the sponsor.

**Line listings** should not be submitted to the REB *unless* the listing is accompanied by a summary provided by the sponsor of their interpretation of the pattern of SAEs, and a position statement as to whether these warrant a change. If the line listing is quarterly or six monthly and accompanied by such a summary it qualifies a periodic safety update report.

**Safety Reports such as CIOMS, Med Watch, etc.** should not be submitted unless the report *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.* 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.

If the report does meet the criteria, then it may be submitted in one of the following two ways (and include the planned course of action);

- a) A Request for Acknowledgement (in RISE); 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.
- b) An Amendment (in RISE) 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.

These types of reports do not qualify as a substitute for a quarterly or six-monthly periodic safety summary report.

**Investigator Brochure (IB) or IB Update** should be submitted to the REB as an amendment in RISE. However, it does not qualify as a substitute for a quarterly or six monthly periodic safety update report. Although the IB Update may list events that have occurred since the previous edition, it doesn't include specific details about those events that better characterize relatedness such as the participant's baseline risk factors, concurrent co-suspects (medications or conditions), or the timeframe of occurrence of the SAE relative to treatment date. It also doesn't include events in which subjects may still be blinded, or events that are evolving in the interim.

## Timelines for Reporting to REB:

**Local and non-local (external) serious adverse events** that meet the definition of an **unanticipated problem** should be reported to the REB as soon as reasonably possible (i.e., 48 hours but in any case **no later than seven (7)** days subsequent to the occurrence of the local event or the sponsor's determination that the event constitutes an unanticipated problem.

**Other unanticipated problems** (i.e., protocol deviations, breach of confidentiality), should be reported to the REB as soon as reasonably possible but in any event **no later than seven (7)** days of occurrence of the event or the receipt of the report of the unanticipated problem by the Investigator from the Sponsor.

**Periodic Safety Update Reports**, should be reported to the REB as soon as reasonably possible, but in any case **no later than fifteen (15) calendar days**, after the Principal Investigator has become aware of or received the report from the Sponsor.

## References

- Even if the study is not US affiliated, the criteria for reporting adverse and serious adverse events is well articulated in the document from the US Department of Health and Human Services (DHHS) and the U.S. Food and Drug Administration (FDA), January 2009; Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting (Page 3 Section III A: ***How to Determine If an AE is an Unanticipated Problem that Needs to Be Reported***)  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079753.pdf>
- The Canadian Association of Research Ethics Boards (CAREB) guidance document is also available at; <http://www.careb-accer.org/?q=en/node/240>.

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## Questions

Questions or concerns regarding this notice; please contact  
Bonnie Shields, Manager, UBC BCCA REB by email: [reb@bccancer.bc.ca](mailto:reb@bccancer.bc.ca) or call: 604-877-6284.

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

*A copy of this notice will be posted on the BCCA REB web page under What's New?*  
<http://www.bccancer.bc.ca/RES/REB/default.htm#New>