



## IMPORTANT NOTICE

**Date:** October 29, 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

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### 1. **New** Criteria and Method for Reporting of Non-local (external) SAEs

A new policy and guidelines will be implemented October 30, 2009 for all UBC REBs regarding the criteria and method for reporting non-local (external) SAEs (serious adverse events) to the REB. The new policy and guidelines are available at <http://www.bccancer.bc.ca/RES/REB/SAEs.htm>

There is no change to the criteria or method for reporting local SAEs.

#### **How will this affect SAE reports submitted to the BCCA REB?**

Effective October 30<sup>th</sup>, 2009 individual non-local (external) serious adverse events should be reported to the REB **in the form of periodic summary reports** rather than submitting individual SAE reports. The periodic summary report must at minimum include a sponsor analysis of the significance of the adverse events or such an analysis from an independent Data Safety Monitoring Board (DSMB), with (where appropriate) a discussion of previous similar events.

Periodic summary reports should be submitted using the Request for Acknowledgement Form in RISe.

Periodic summary reporting may be either quarterly or six monthly as preferred by the sponsor. If periodic summary reporting is not provided, then individual SAEs must continue to be reported by your current method of entering them individually into the BCCA REB SAE database and will continue to be subject to the REB SAE Review Fee per individual report. We therefore, urge investigators to encourage their sponsors to provide periodic summary reports as soon as possible.

#### **Exceptions:**

Non-local (external) SAEs that meet the criteria as noted in the FDA guidelines <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079753.pdf> require prompt reporting, and should not wait for the periodic summary report. These criteria include the following:

- a) the individual non-local SAE is unexpected (not known to be associated with the underlying condition for which the experimental agent or device is being used and not previously associated with the experimental agent or device as described in the consent document(s));
- b) the non-local SAE is strongly associated with drug or device exposure; or
- c) the non-local SAE may be associated with drug or device exposure and is otherwise uncommon in the study population (e.g. tendon rupture, progressive multifocal leukoencephalopathy) and thus should be considered a reportable event.

**Individual reports meeting these criteria must contain a sponsor analysis of the significance of the event or such an analysis from an independent DSMB and if applicable a corrective action plan.**

**These reports must be entered into the SAE Database and are subject to the REB SAE Review Fee.**

### Method of Reporting Individual SAE reports:

If quarterly or six-monthly summary reports are unavailable or you are reporting an SAE which is local or meets the criteria for prompt reporting noted above and, therefore, you are submitting individual SAE reports to the BCCA REB, these must be entered into the BCCA REB SAE database (refer to <http://www.bccancer.bc.ca/RES/REB/SAEs.htm> )

**Exception:** The RISE system may be used for individual SAE reports if AND ONLY IF either of the following applies;

1. If the Study is not yet "activated", then the RISE system may be used to submit these as a Request for Acknowledgment, (**once the study is activated, you must use the BCCA REB SAE database**).
2. If the BCCA REB has specifically granted permission to use RISE because you cannot access the BCCA SAE database. (To request access to the BCCA REB SAE database, contact the BCCA REB Administration: [reb@bccancer.bc.ca](mailto:reb@bccancer.bc.ca)

### 2. SAE Review Fee (applies to periodic summary reports).

The BCCA REB will continue to charge a \$20 fee to review individual SAE documents for studies sponsored by for-profit entities. The cost to sponsors can, however, be minimized by recourse to periodic summary reporting as this will be counted as a single document.

Specifically, each of the following will constitute an SAE document and incur a \$20 fee:

1. A quarterly or 6-monthly summary report submitted via RISE.
2. An SAE report, local or external, submitted via the SAE database
3. An SAE follow-up report, local or external, submitted via the SAE database
4. An SAE report or follow-up report, local or external, submitted via RISE for those who have specifically been granted permission to use the RISE system because they cannot be granted access to the BCCA REB SAE database.

### 3. **New** Investigator Brochures & Product Monographs – Submit as an Amendment

Once a study is approved, updated Investigator Brochures or addendums to the IB and/or Product Monographs must be submitted as an amendment (attached to Section 9 of the RISE application). This change is necessary for harmonization amongst all UBC REBs so that the current version is readily accessible in all applications in section 9, for applicable studies. Please ensure that the next updated version is submitted as an Amendment.

### 4. Updated Documents Posted to BCCA REB Website Related to this Update

Documents are in .pdf format

REB Webpage	Information Recently Updated or Posted
<a href="#">Adverse Events</a>	<ul style="list-style-type: none"><li>▪ A copy of this update is posted on the REB homepage under <a href="#">What's New?</a></li><li>▪ <a href="#">Policy for Reporting SAEs</a> (Oct 30, 2009)</li><li>▪ <a href="#">Guidance for Reporting SAEs</a> (Oct 30, 2009)</li></ul>
<a href="#">RISe Tips and Help</a>	<a href="#">Quick Reference Guide - SAES, Safety Letters, and IBs</a> (Oct 30, 2009)
<a href="#">Amendments</a>	<a href="#">Guidance for Amendments</a> (Oct 30, 2009)
<a href="#">Acknowledgements</a>	<a href="#">Guidance for Requests for Acknowledgement</a> (Oct 30, 2009)

### 5. QUESTIONS

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

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