



IMPORTANT NOTICE

Date: December 3, 2010

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. **New Guidelines**

The following guidelines have been developed to assist researchers in meeting submission requirements. These guidelines are now available on the BCCA REB website. Each guideline includes a brief preamble explaining the background and purpose for the guideline.

[Guideline for Applications for Combined Phase I/II Clinical Trials](#)

For future access this guideline is posted on the BCCA REB "[New Applications](#)" webpage

[Guideline for Mandatory Tissue Collection \(BCCA REB Interim Guidance\)](#)

A link to the guideline has also been added to the [Main Consent Template](#).

For future access this is posted on the BCCA REB "[Informed Consent templates](#)" webpage".

Re-Consent:

[Guideline for Providing New Information and Obtaining Consent to Continue to Participate](#)

[Addendum Consent form Template](#)

This guideline outlines the appropriate methods that can be applied in order to meet the desired level of transparency and documentation required when providing significant new findings to research participants and obtaining consent to continue to participate. The REB requires that one of these methods is chosen. Please see the full guideline and new "Addendum Consent Form Template" for details.

For future access; these are posted on the BCCA REB "[Informed Consent Templates](#)" webpage"
<http://www.bccancer.bc.ca/RES/REB/ConsentTempl.htm>

2. **Consent Document – Compensation for Injury**

Please ensure that the current consent document(s) for each study reflects coverage available to participants in the event of illness or injury as a result of participating in the study. Subjects should be informed that coverage will be provided by the subject's medical plan to the extent that coverage is available and whether any additional costs will be covered and how (for example for physiotherapy or pain medications that might not be covered by their medical plan). Please refer to the updated compensation section in the [Main Consent Template](#) (page 12) and [Optional Consent Template](#) (page 5).

3. **Protocol Required for ALL Submissions (including retrospective chart reviews)**

The UBC REB's require that a research protocol/research plan be submitted with all applications, including pilot studies and retrospective chart reviews. *These guidelines are noted in the [RISe application form \(section 5\)](#). Applications that do not include a protocol/research plan will be returned as incomplete.* The research proposal submitted to a granting agency may be used to meet this requirement; in this case, ensure that the appropriate section of the grant application is referenced. For all other studies, including those that are submitted for expedited review, investigators must submit a protocol.

Reference: [UBC CREB POLICY #1: Requirement for Research Protocol](#)

4. Amendments - Opinion of the Principal Investigator (PI)

In order for the REB to provide a timely response to an amendment; it is important to provide a clear description of the amendment(s) within the submission. This is particularly important for an amendment submission with multiple changes and revisions to the protocol and consent document that requires full board review. Please follow the guidelines in the RISE amendment application. It is also important that the REB is assured that any significant new information has been evaluated by the principal investigator with regard to possible related risk to subjects. Section 1.5.3 of the RISE Amendment PAA Coversheet which asks; "*Indicate whether or not this amendment will result in any increase in risk or discomfort for the study subjects, and if so, please explain what these are and why they are required.*" Amendments that state only the sponsor's risk evaluation or indication for required further action will be returned for confirmation of the PI's opinion.

5. Questions

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

Questions about your research project; please contact
REB Admin by email to: reb@bccancer.bc.ca or
604-877-6283 (Marcilyn) / 604-877-6223 (Melissa)
Our list of contacts is posted on our webpage: [Contacts](#)
(Please quote your project number from RISE (i.e. H0x-yyyy))

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

A copy of this notice is posted under What's New? <http://www.bccancer.bc.ca/RES/REB/default.htm#New>