Ontario Cancer Research Ethics Board
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Guidance

To: All Ontario Oncology Trial Centres Using OCREB

From: Ontario Cancer Research Ethics Board

Date: May 5, 2017

RE: Approval for 'administrative changes' to provincially approved participant materials/documents including the ICF - e.g., the addition of contact information, the removal of instructional text, and the approval for centre-specific changes to the ICF Compensation language

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All provincially approved OCREB study documents (including participant materials such as wallet cards and consent forms), are pre-approved for use by all participating centres with the application of 'administrative changes' to the documents. The provincially approved document version date must be maintained once the administrative changes have been applied.

This process for applying centre-specific information to the provincially approved documents, without modifying the version dates, is based on a controlled honour system: i.e., centres are mandated to comply with the specified implementation of the specified changes, which are pre-identified and approved by OCREB, (as indicated in the guidance and in other centre-specific documentation (as applicable); periodic reviews of implemented study documents, including de-identified, signed ICFs are conducted to demonstrate compliance with the process.

For all participating centres the following administrative changes to the provincially approved document(s), are pre-approved for implementation:

- modification of the Compensation (reimbursement) section of the provincially approved ICF as follows: The statement, "You will be reimbursed for study-related expenses such as [specify, e.g., parking, etc.]", may be removed, or modified, as applicable, and in accordance with local policy and/or study contract terms;

- the inclusion of centre-specific information in the provincially approved ICF, [as identified in the yellow highlighted areas of the template], such as the designation of procedures/tests taking place at another centre. e.g., MRI;

- the exclusion or inclusion by a centre of a clearly identified study component/activity in the provincially approved ICF. e.g., tissue collection: a component of the study that may not be conducted at every centre but which does not preclude centre participation. The provincial ICF will include instructional text to indicate that the centre should either include or remove the 'following information' as per centre requirements;

- the addition to the document(s) of centre contact information, centre letterhead, correction of spelling errors, the calibration of # of pages (including reference to the # of pages on the signature page for COG studies), and the removal of instructional text.

All other changes to the content of the document(s), including formatting and corrections to grammar, require a re-submission of the document and approval by OCREB.

Note: Requests for any other centre-specific, pre-approved ICF changes must be submitted to OCREB with supporting documentation for approval prior to implementation; contact Alison.vannie@oicr.on.ca

Centres with pre-approved centre-specific ICF changes should request a copy of the approved change document from OCREB: contact Alison.vannie@oicr.on.ca