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# Memo

To: Sponsors and Participating Centres

From: OCREB

Date: (2019) 24 April 2023

**RE: Submission of DIL And Protocol Clarification Letters**

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## Dear Investigator Letters (DIL)

Please note that OCREB has determined that the submission of a DIL as a provincial reportable event (PRE) is not required and will not be accepted. A DIL may be submitted as supporting documentation for an amendment.

1. DILs do not provide sufficient information to enable the REB to make an informed decision regarding the relevance and 'approvability' of the new information for implementation with participants via a consent update;
2. The integrity of the consent update form is based on the ability to provide new information that is relevant to the ongoing consent of the participant. The lack of robust information in the DIL does not meet this requirement;
3. OCREB reviews new information through an amendment submission with revised documents, that include the new information, and evidence and rationale for its inclusion;
4. The DIL is addressed to the PI who has a responsibility to determine the relevance, to study participants, of the information in the DIL. If the information is associated with actions necessary for the prevention of an immediate hazard the PI will act prior to the submission of the information to OCREB (as per regulatory and ethics guidance).

## Protocol /IB clarification letters

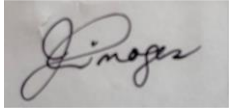
Please note that OCREB has determined that the submission of protocol clarification documents is not required. Please do not submit these letters.

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*The Ontario Cancer Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: TCPS 2 - 2nd edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable*



*Regulations. OCREB is registered with the U.S. Department of Health & Human Service under the IRB registration number IRB00003960.*



Jacqueline Limoges PhD RN  
Chair, Ontario Cancer Research Ethics Board



OCREB is qualified under the Clinical Trials Ontario REB Qualification Program