Ontario Cancer Research Ethics Board
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Ontario Cancer Research Ethics Board N2/CAREB REB SOP Addendum

OCREB has adopted the N2/CAREB REB SOPs. However, in order to reflect specific OCREB requirements, this addendum must be used in tandem with the SOP noted below*.

N2/CAREB SOP 401 – Delegated Review

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5.1.2 Submissions that meet the following criteria may be eligible for delegated review: • Research projects that involve no more than minimal risk, • Minor or minimal risk changes to approved research, • Continuing review of approved minimal risk research, • Continuing review of research that is more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified, • Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full REB; if permissible under all applicable governing Regulations; • The submission by the Researcher in response to the REB review as a condition of approval, as authorized by the Board, • Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures, • Reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB);	**5.1.2** Submissions that meet the following criteria may be eligible for delegated review: • Research projects that involve no more than minimal risk, • Minor or minimal risk changes to approved research, • Continuing review of approved minimal risk research, • Continuing review of research that is more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified, • Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full REB; if permissible under all applicable governing Regulations; • The submission by the Researcher in response to the REB review as a condition of approval, as authorized by the Board, • Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures, • Reportable events, including **privacy breaches, protocol deviations,** adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB), , • **Centre initial and continuing review applications,** • **Institutional requests for centre-specific pre-approved changes;**
5.2.4 In reviewing the research under expedited procedures, the Chair or designee may exercise all of the authorities of the full Board, except that he/she may not disapprove the research; the research may be disapproved only after it has been reviewed by the full Board at a convened meeting;	**5.2.4** In reviewing the research under expedited procedures, the Chair or designee may exercise all of the authorities of the full Board, except that he/she may not disapprove the research; the research may be disapproved only after it has been reviewed by the full Board at a convened meeting. **Additionally,** • If the Chair or designee considers that action is

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	needed to protect the safety of research subjects, he/she may take such action immediately and/or request a review of the reports of unanticipated problems or safety updates at a convened meeting or by a subcommittee, to determine what further action, if any, is required;

Revision History	
Date/Version	**Summary of Changes**
August 28, 2018/001	Original version.