Ontario Cancer Research Ethics Board
MaRS Centre, Suite 510 | 661 University Avenue
Toronto, Ontario | Canada M5G 0A3
416-673-6649 or 1-866-678-6427 ext. 6649 | https://ocreb.ca

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

SOP Section	OCREB Addendum
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); **5.1.4** • The REB Chair or designee may be authorized by the full Board to use delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;	**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;** **5.1.4** • **Since OCREB meeting minutes do not require approval, changes to the minutes do not require delegated review.**
5.2.4	**5.2.4**

SOP Section	OCREB Addendum
In reviewing the research under delegated 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;	In reviewing the research under delegated 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 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
October 24, 2022/002	Addition of 5.1.4 to remove reference to delegated review of changes to FB meeting minutes
March 21, 2025/004	No revisions needed