TITLE	**402: Delegated Review**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

The HREB Chairperson or designee or qualified HREB member(s) is responsible for conducting the delegated review.

4.0 PROCEDURE

HREB will adopt a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed or ongoing research, the greater will be the care in assessing the research. Full Board review by the HREB is the default requirement for all research involving human participants unless the HREB decides to authorize delegated review based primarily on the harms that are expected to arise from the research.

Requirements for proportionate review allow the HREB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research, while still requiring that the foreseeable risks and potential benefits, as well as the ethical implications of the research, will be considered in delegated reviews.

In practice, proportionate review implies different levels of HREB review for different research projects. The levels used by HREB are Full Board review and delegated review as outlined in Appendix A.

4.1 Definition of Minimal Risk

4.1.1 Minimal risk research is defined as research in which the probability and magnitude of possible harms in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

4.1.2 For studies that are funded or supported by the U.S. federal government or regulated by the U.S. Food and Drug Administration (FDA), minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

4.2 Determination of Qualification for Delegated Review

4.2.1 Full Board review is the default for most new research projects submitted to the HREB; however, some research may be eligible for delegated review.

4.2.2 Studies that are funded or supported by the U.S. federal government or regulated by the U.S. Food and Drug Administration, are eligible for delegated review if listed in the OHRP and FDA guidance and are no more than minimal risk, or include only minor changes in previously approved research as defined by the applicable regulations.

4.2.3 Submissions that meet the following criteria will 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 HREB; if permissible under all applicable governing regulations;
- researcher response to HREB review, including changes to applications and events, as authorized by the HREB;
- changes to consent documents that do not affect the rights and welfare of research participants, involve increased risk, affect data integrity, or require significant changes in research procedures; and
- reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB).

4.2.4 Delegated review procedures will be used for the review of other types of minor changes to the research including, but not limited to, the following: participant materials (such as,

recruitment posters or scripts, diaries, validated questionnaires and clinical trial identification/wallet cards) and authorized translations of English versions of documents previously approved by the HREB.

4.2.5 The HREB Chairperson 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.

4.2.6 When determining if initial review of research, or modifications to previously approved research, are eligible for delegated review, the HREB Chairperson or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable.

4.3 Delegated Review Process

4.3.1 Qualified REO Personnel will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review as determined by the HREB will be forwarded for delegated review. For all other submissions, the HREB Chairperson or designee will make the determination of whether the submission meets the criteria for delegated review.

4.3.2 For research that meets the criteria, delegated review will be conducted by the HREB Chairperson, or by one or more qualified HREB members as designated by the HREB Chairperson or designee, or by applicable REO personnel.

4.3.3 The HREB Chairperson or designee/personnel reviewing research under delegated review must not have a conflict of interest in the research.

4.3.4 In reviewing research in Level 3 and Level 4 (Appendix A) under delegated procedures, the HREB Chairperson or designee will exercise all of the authorities of the HREB, except that he/she may not refuse to approve the research; the research may be refused to be approved only after it has been reviewed by the HREB at a Full Board meeting.

4.3.5 HREB member(s) conducting a delegated review will contact the HREB Chairperson or designee to request the expertise of an ad hoc advisor, if applicable. Ad hoc advisors will not participate in the final decision regarding approval of the research.

4.3.6 If a delegated reviewer determines that the level of risk for the submission is greater than minimal, the submission will be referred to a Full Board meeting for review.

4.3.7 The HREB Chairperson or designee will record the decision regarding the designation of the research (i.e., either requiring Full Board or delegated review) and the outcome of the review. The responsible REO Personnel will issue the review or decision letter.

4.3.8 If in reviewing the research under delegated procedures the HREB Chairperson or designee considers that action is needed to protect the safety of research participants, they will take

such action immediately and/or request a review of the report at a Full Board HREB meeting or by a designated sub-committee to determine what further action, if any, is required.

4.4 Notification to the HREB

4.4.1 At its next applicable Full Board meeting, the HREB will be informed of research that was reviewed and approved using delegated review procedures.

4.5 Documentation

4.5.1 The type of REB review conducted (i.e., Full Board or delegated) is documented in the HREB records and noted in the decision letter issued to the Researcher, where appropriate.

4.5.2 The HREB will be provided with a list of submissions that were reviewed and approved using delegated review procedures from the time that the agenda for the previous HREB meeting was issued.

5.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 2: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 6, Article 6.12: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46)): 45 CFR 46 | HHS.gov

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56)): 21 CFR §56 Institutional Review Boards - Code of Federal Regulations (ecfr.io)

U.S. Food and Drug Administration, Regulations Relating to Good Clinical Practice and Clinical Trials: https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm#FDARegulationsU.S

Office for Human Research Protections, Expedited Review Procedures Guidance: Protocol Review | HHS.gov

Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997, *(ICH-GCP* 3.3.9): ICH Official web site : ICH