WOMEN'S COLLEGE RESEARCH INSTITUTE
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Research Ethics Board Standard Operating Procedures

Delegated Review Procedures

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ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH Research Ethics Office (REO) webpage version of this document is considered the most current.
Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for determining whether research meets the criteria for delegated ethics review and the delegated review procedures.

All research will be subject to a full board review by the convened Research Ethics Board (REB) for research involving human participants submitted to the Women's College Hospital (WCH) REB. However, in some unique circumstances, research may be eligible for delegated REB review. In keeping with a proportionate approach to research ethics review as mandated by the Tri Council Policy Statement (TCPS) 2, the selection of the level of REB review shall be determined by the level of foreseeable risks to participants. While all research must be reviewed adequately, proportionate review is intended to reserve most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research.

In practice, proportionate review implies different streams of REB review for different research studies. The two streams of review utilized by the WCH REB are full board review at a convened WCH REB meeting, or delegated review by one or more experienced WCH REB members as determined by the WCH REB Chair or delegate.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB members and Research Ethics Office (REO) staff.

The REB Chair, or designee, is responsible for determining if research is eligible for delegated review. If the REB Chair delegates this task to an REO staff member, the responsibility for oversight remains with the REB Chair.

The REB Chair, designee or subgroup of the REB is responsible for conducting the delegate review.

4.0 PROCEDURES:

4.1. Determination of Qualification for Delegated Review

4.1.1. All research will be subject to a full board review by the convened WCH REB for research involving human participants submitted to the WCH REB. However, in certain circumstances, the

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WCH REB may consider some research protocols for delegated review based primarily on the limited potential risk for harm that could arise from the research.

4.1.2. Where it is clearly demonstrated that the research involves minimal risk of harm, the WCH REB may authorize a delegated ethics review. Below are examples of research that may be eligible for delegated REB review. Any exceptions to those categories noted below are at the discretion of the Chair (TCPS2 Article 6:14):

- Categories of research that are expected to involve minimal risk;
- Minimal –risk changes to previously approved research;
- Annual renewals of approved minimal risk research;
- Annual renewals of more than minimal risk research where the research will no longer involve participants, and the remaining research activities are limited to data analysis;
- Evidence that conditions or other requirements laid down by the REB in an initial review have been met;

4.1.3. The REB may authorize a delegated ethics review of research that has undergone a full board review at another Toronto Academic Health Sciences Network (TAHSN) institution, provided the REB review letter and approval letters are included in the submission to the WCH REB;

4.1.4. The REB Chair, or delegate, is responsible for determining if research is eligible for delegated review. If the WCH REB Chair delegates this task to a Research Ethics Office (REO) staff member, the responsibility for oversight remains with the WCH REB Chair.

4.1.5. In the event that the WCH REB Chair and REO staff do not agree on the appropriate level of review (full board or delegated), the research study should be put forward to full board review.

4.2. Authority of Delegated Reviewer(s)

4.2.1. For research that meets the criteria, delegated REB review shall be conducted by the WCH REB Chair, Vice Chair or delegate. In cases where additional expertise is required, the WCH REB Chair may request additional input from a qualified WCH REB member. This WCH REB member would serve as a secondary reviewer, while the WCH REB Chair, Vice Chair or delegate remains the primary reviewer for all delegated reviews.

4.2.2. The WCH REB Chair or delegate may exercise all authorities of the REB, except that they may not reject the research. A research study may be rejected only after full review by the convened WCH REB.

4.2.3. The WCH REB Chair or delegate(s) reviewing research under delegated review must not have a conflict of interest.

4.2.4. The WCH REB Chair or delegate will sign the REB review and approval letters associated with delegated REB review.

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4.3. Continuing Review: Proposed Revisions to the Protocol and/or Informed Consent Form, Amendments, and Renewals

4.3.1. Research that was previously reviewed by delegated review procedures may be reviewed at the time of continuing review using delegated review procedures.

4.3.2. Research that was previously reviewed by full review by the convened WCH REB may be reviewed at the time of continuing review using delegated review procedures when there are minimal-risk changes, or no changes to previously approved research. However, if the WCH REB Chair or delegate determines that the risks are now more than minimal, he or she shall refer the study for full board review at a convened WCH REB meeting.

4.3.3. The WCH REB Chair or delegate may use delegated review procedures for changes proposed to consent documents that do not affect the rights, safety and welfare of study subjects and do not involve increased risk or significant changes in study procedures.

4.4. Serious Adverse Events and Safety Updates

4.4.1. The WCH REB Chair or delegate may use delegated review procedures for reports of unanticipated problems (including serious adverse events) and safety updates such as reports from Data Safety Monitoring Committees.

4.4.2. If the WCH REB Chair or delegate subsequently considers that action is needed to protect the safety of research participants, he/she may take such action and/or request that the full WCH REB or designated subcommittee review reports of unanticipated problems or safety updates to determine what further action, if any, is required.

4.5. Additional Items

4.5.1. The WCH REB Chair, or delegate, may use delegated review procedures for other types of minor changes to previously approved research and miscellaneous items, including but not limited to the following:

- Participant materials such as recruitment posters or scripts, diaries, or validated questionnaires
- Clinical trial identification/wallet cards
- Protocol deviations
- Translations of English documents previously-approved by the WCH REB
- Correspondence from the investigator
- WCH REB minutes contingent upon approval by the convened WCH REB

4.6. Notification to the WCH REB

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The WCH REB is informed at the next convened WCH REB meeting of new research submissions that were approved using delegated review procedures, through the provision of a list, including project title, investigator name, REB assigned number and status.

4.7. Documentation

4.7.1. The type of REB review conducted (i.e. full Board or delegated) will be noted in the review and approval letters sent to the investigator.

4.7.2. The WCH REB minutes and or attachments will include documentation (list) of research that was approved using delegated review procedures.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Chapter 1 section C; Chapter 2 section B; Article 6.12;
2. The International Conference on Harmonization Good Clinical Practices (GCP Guidelines as adopted by Health Canada, Section 3.0;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR), Title 45 CFR 46.102, 46.110;
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 CFR 56.102, 56.110;
5. Department of Health and Human Services (DHHS) Federal Register: *Categories of Research That May Be Reviewed by the Institutional Review Board through a Delegated Review*
6. DHHS/OHRP Guidance on the use of Delegated Review Procedures
7. FDA Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators
8. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Delegated Review Procedure* (REB-SOP-IV-02.003)