



Research Ethics Board Standard Operating Procedures

Administrative Review Procedures

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

The WCH 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 administrative ethics review and the administrative review procedures.

All research will be subject to a full board or delegated review by the 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 an administrative 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.

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 administrative 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 administrative review.

4.0 PROCEDURES:

4.1. Determination of Qualification for Administrative Review

4.1.1. All research will be subject to a full board or delegated review by the convened WCH REB for research involving human participants submitted to the WCH REB. However, in some unique circumstances, the WCH REB may consider some research protocols for administrative review based primarily on there being little to no potential risk for harm that could arise from the research.

4.1.2. Where it is clearly demonstrated that the research involves little to no potential risk of harm, the WCH REB may authorize an administrative ethics review. Below are examples of research that may be eligible for administrative review:



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- Categories of research that are expected to involve little to no potential risk of harm include;
- Projects only involving retrieval and analysis of data from the Institute for Clinical Evaluative Sciences (ICES); Research that relies exclusively on publicly available information (TCPS 2 article 2.2);
- Research involving the observation of people in public places (TCPS 2 article 2.3);
- Research that relies exclusively on secondary use of anonymous information or biological materials so long as the process of data linkage or recording or dissemination of results does not require identifiable information (TCPS 2 article 2.4);
- Creative practice through which an artist makes or interprets a work or works of art (TCPS 2 article 2.6);
- A request to post a flyer/poster at Women's College Hospital for an external study where there is no active recruitment and no other study activities occurring at WCH. In this case, investigators are required to provide the WCH REB with proof of REB approval from their home institution, a letter of support from the department where the flyer will be posted, and a copy of the advertisement.
- Quality Assurance/Quality Improvement (QA/QI) project (eg. Program evaluation activities, performance reviews, testing within normal educational requirements when used exclusively for assessment, management or improvement purposes) (TCPS 2 article 2.5); For projects deemed to be QA/QI, program evaluation and relevant similar projects, investigators will be directed to the WCH APQIP (Assessment Process for Quality Improvement Projects) process for appropriate review of their projects.

4.1.3. The REB Chair or delegate, is responsible for determining if research is eligible for administrative 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.

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

4.2. Authority of Administrative Reviewer(s)

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

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

4.3 Continuing Review

4.3.1 REB exemption does not require continuing review on an annual basis.

4.4 Notification to the WCH REB



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- 4.4.1 The WCH REB is informed at the next convened WCH REB meeting of new research submissions that were approved using REB exemption, through the provision of a list.

4.5 Documentation

- 4.5.1 The type of REB review conducted will be noted in the approval letters sent to the investigator.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Chapter 1 section C; Chapter 2 Article 2.2
2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR), Title 45 CFR 46.102, 46.110;
3. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 CFR 56.102, 56.110;