WOMEN'S COLLEGE RESEARCH INSTITUTE
Health care for women | REVOLUTIONIZED

Research Ethics Board Standard Operating Procedures

The Use of OCREB as a Board of Record

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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. POLICY STATEMENT:

The purpose of this Standard Operating Procedure (SOP) is to describe the types of research being conducted at Women's College Hospital (WCH) that may use the Ontario Cancer Research Ethics Board (OCREB) as a delegated Research Ethics Board (REB) of Record.

All research involving human participants, human remains, cadavers, tissues, biological fluids, embryos or fetuses requires review and approval by a REB prior to commencing the intervention or interaction with human participants in research, including study recruitment. Through a formal relationship and board of record agreement, OCREB may be delegated as a research ethics board of record for Women's College Hospital for multi-centre clinical trials in oncology.

2. DEFINITION(S):

Also See Glossary of Terms

Formal Relationship: The Institution (WCH) has signed a letter of intent and has registered OCREB under its Federal Wide Assurance (FWA). Once a formal relationship is established, the Institution may delegate OCREB as the BOR on a study-by-study basis by executing a BOR Study Agreement.

Federal Wide Assurance (FWA): The Federal Office for Human Research Protections (OHRP) requires that (U.S.) federally funded research involving human participants only be conducted at facilities covered by a Federal Wide Assurance (FWA). Through the FWA, an institution commits to the Department of Human Health and Human Services (HHS) that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

REB Board of Record: The REB that has been granted ultimate authority for the ethics review and ethical oversight of a research study.

Multi-Centre: In the context of OCREB, multi-centre means that the research is reasonably expected to be conducted at more than one centre in Ontario.

3. RESPONSIBILITY:

This SOP applies to the WCH REB Chair/Vice-Chair, Manager, REO Staff, Investigators and associated research staff for the purpose of understanding the type of human subject/materials that may be submitted to OCREB for review and approval.

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Research Ethics Board Standard Operating Procedures

The Use of OCREB as a Board of Record

4. PROCEDURES:

4.1. Research within the Scope of OCREB Review

4.1.1. OCREB will accept all phases (including pilot studies) of multi-centre oncology research in adult populations for review from WCH under the formal relationship agreement with OCREB. Oncology research includes, but is not limited to, medical radiation and surgical oncology research.

4.1.2. OCREB may also accept submission of other types of oncology research that involve multiple Ontario centres including but not limited to: epidemiology research, quality of life, symptom management, or other companion studies; retrospective or prospective chart review studies; development or use of human cell or tissue repositories; and development or use of clinical research databases.

4.1.3. The opinion of OCREB should be sought whenever there is any doubt about the applicability of submitting a particular research project to OCREB prior to completing an application form.

4.2. Research Outside the Scope of OCREB Review

4.2.1. Any research that is not multi-centre oncology research or is not expected to be conducted at more than one Ontario centre does not fall within OCREB's mandate.

4.2.2. Other research that falls outside of the scope of OCREB review includes but is not limited to: research in children, healthy volunteers (not including at risk prevention populations), prisoners or other vulnerable populations; emergency uses of an investigational drug; planned emergency research; single-centre research; student-conducted research; case studies; and quality assurance studies.

4.2.3. Research outside of OCREB's mandate must be directed to the WCH REB.

4.3. Determination of Whether Research Falls within the Scope of OCREB Review

4.3.1. An REB coordinator at OCREB will correspond with the Investigator as needed to assist in the determination of whether their research falls within the scope of OCREB review.

4.3.2. When the determination of scope is unclear, the decision will be made by the Executive Director and/or Chair at OCREB.

4.3.3. The WCH PI may initiate the review submission process with OCREB directly or choose to have this process facilitated through the WCH REO. On occasion, the WCH REO may suggest that a study be reviewed by OCREB.

4.4. Notification to the WCH REB of the BOR Agreement and OCREB Approval

4.4.1. Upon receipt of OCREB approval, the Investigator or delegate will send an electronic copy of the Board of Record Agreement and Approval Letter to the WCH REO on a study-by-study basis.

WOMEN'S COLLEGE RESEARCH INSTITUTE
Health care for women | REVOLUTIONIZED

Research Ethics Board Standard Operating Procedures

The Use of OCREB as a Board of Record

4.4.2. The Manager or delegate will enter the study and relevant approval information into the database for tracking and reporting purposes only. OCREB maintains the responsibility for ethical oversight of the conduct of the study.

4.4.3. The Manager functions as Institutional Representative for OCREB and is notified by OCREB of each approval.

4.4.4. The Manager is the primary contact person for any changes related to the formal relationship with OCREB.

5. REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2)
2. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Tile 21, Parts 50.3; 50.24;5 6.108
5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.102; 46.103
6. US FDA Information Sheets for IRB and Investigators
7. Women's College Hospital Research Ethics Board Terms of Reference
8. The Federal Wide Assurance Terms of Reference v. 06/17/2011.
9. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Using OCREB as the Board of Record Approval* (REB-SOP-I-02.003)