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

Standard Operating Procedure Development and Maintenance

SOP NO:	REB-SOP-I-01.003	**Revision Date:**	January 05, 2017
CATEGORY:	Research Ethics Board	**Reviewed/Effective Date:**	January 05, 2017
SUB-CATEGORY:	Section I: General	**Original Issue Date:**	June 13, 2012
ISSUED BY:	Research Ethics Office		
APPROVED BY	CEO		

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 processes necessary to establish and maintain written SOPs to facilitate compliance with the principles, guidelines, and regulations regarding application to ethical review and oversight of research involving human participants or human materials.

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants or human materials. SOPs describe the processes that must be followed and documented to assure that the rights and welfare of the human participants of such research are overseen and protected in a uniform manner.

The Women's College Hospital (WCH) Research Ethics Board (REB) reports to the Board of Directors through the Medical Advisory Committee (MAC) and as such, the MAC may be asked for input on SOPs as necessary. A delegated sub-committee of the MAC may also be asked for input or guidance on the SOPs.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to REB members and REO Staff. The REB Coordinator is responsible for coordinating the development, review and revision of the SOPs. The REB will be responsible for initial approval of any new or revised SOPs. The REB Chair and Vice President, Research are responsible for granting final SOP approval.

4.0 PROCEDURES:

4.1 Development, Review, Revision, and Approval of SOPs

4.1.1 The REB Coordinator is responsible for coordinating the development, review, and revision of SOPs. The REB Chair and REB Coordinator are responsible for reviewing SOPs and making a recommendation for approval to the REB and subsequently, the Vice President, Research.

4.1.2 For existing SOPs, the REB Chair, REB coordinator, and REB Assistant will review SOPs every two years. Applicable SOPs will be reviewed earlier if changes to regulations, guidelines, or standard practice warrant revisions or creation of new SOPs.

4.1.3 SOP(s) may be revised due to: changes to applicable regulations or guidance documents; new policies determined by the WCH REB Chair; or changes to WCH REB or REO administrative practices.

4.1.4 The REB Chair and a qualified member of the REO staff will make necessary modifications to existing SOPs, or draft new SOPs. SOPs are controlled documents and new drafts will be indicated by the addition of a DRAFT version date, and removal of the previous version date.

4.1.5 Each SOP will be identified by a number. The number will be formatted according to the following sequence: the letters REB, followed by the letters SOP, followed by the section number, followed by the SOP number, followed by the version number (e.g. REB-SOP-I-01.001).

4.1.6 Once the SOP has been drafted, it will be brought to the REB for review and initial approval. This review will take place during the monthly REB meetings. Any changes suggested by Board members will be considered for the draft SOP. The final draft will be approved by the REB Chair and will then be provided to the VP Research.

4.1.7 Once the final draft is approved by the VP, Research, the DRAFT version date will be removed and the date of the approved revision will be entered. For an original SOP, the original issue date will be recorded in the header. For subsequent SOPs, the version date will be recorded in the header.

4.1.8 A revision summary will be completed for each SOP. The revision will also serve as the approval form for any SOP. REB Policies, as designated in the title, may require approval from the VP Research and the WCH Medical Advisory Committee (MAC), as appropriate.

4.1.9 SOP(s) will be archived as per Health Canada requirements in the REO or designated storage facility.

4.2 Distribution and Communication

4.2.1 The REB Chair, REB Coordinator, and REB Assistant are responsible for ensuring new or revised SOPs and associated guidance documents will be communicated and disseminated to all relevant individuals.

4.2.2 Training will be provided to all members of the WCH REB and REO staff for any new or revised SOPs as applicable

4.2.3 REB members will be provided with access to all applicable SOPs and policies

4.2.4 REO staff must review all new and revised SOPs and policies.

4.3 Forms

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4.3.1 Forms, including checklists and worksheets, are used to facilitate compliance with SOPs. Forms are either controlled or non-controlled.

4.3.2 Controlled forms are documents that require formal change control through use of version dates and are part of the permanent record of REB operations and processes;

4.3.3 Non-controlled forms are management tools that are not part of the permanent record of REB operations and processes. Non-controlled forms should also contain version dates.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (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 56.108, 56.115
5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.108
6. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *SOP Development and Maintenance* (REB-SOP-I-01.003)