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

REB Submission Requirements and Initial Review of REB Submissions

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CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	January 5, 2017
SUB-CATEGORY	Section III: REB Operations	**Original Issue Date:**	December 21, 2012
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 Women's College Hospital (WCH) Research Ethics Board (REB) submission requirements, and the preliminary administrative review procedures conducted by the Research Ethics Office (REO). This SOP applies to all submissions including but not limited to: new research projects for initial review, amendments or modifications to approved research and consent forms, updated safety information, applications for continuing approval, reports of unanticipated problems including serious adverse events, and protocol deviations.

REB members rely on the documentation provided by the principal investigator for initial and continuing review. Therefore, the materials submitted must provide sufficient information to conduct the review and make the required determinations.

The REB is supported by administrative procedures that ensure that REB members not only have adequate time for assessment of proposed research, but that the materials they receive allow them to adequately assess whether the research meets the criteria for REB approval.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Vice-Chair, Research Ethics Coordinator and REO staff

4.0 PROCEDURES:

The REO is responsible for maintaining submission requirements, and for making such information available to investigators. The instructions to the investigators regarding submission requirements, including deadlines and meeting dates, are available on the WCH REO website or by contacting the Research Ethics Coordinator.

4.1 Submission Requirements:

4.1.1 The required documents, checklists, number of copies, format, and submission procedures are outlined on the WCH REB website and on the appropriate REB application and checklists including but not limited to:

- Toronto Academic Health Sciences Network (TAHSN) Human Subject Research Application
- TAHSN Application Guidelines

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- ICF Checklist
- Application Checklist
- Amendment Form
- Renewal/Termination Form
- Adverse Event Reporting Form
- Protocol Deviation Form

4.2 Preliminary Review

4.2.1 Upon receipt of a submission, the WCH Research Ethics Coordinator date will stamp the package and screen the submission for overall completeness using the Research Ethics Coordinator Checklist for guidance.

4.2.2 If a submission is incomplete, the WCH Research Ethics Coordinator or Assistant will contact the investigator within two working days to request the missing or incomplete documentation for inclusion with the submission. The Research Ethics Coordinator or REB Assistant will also notify the Investigator that submissions will not be sent for review until complete.

4.2.3 Upon receipt of a complete submission package, the WCH Research Ethics Coordinator will assign the project a unique WCH REB number (if not previously assigned), enter it into the WCH REB access database, and create a new labeled project file folder, if not previously created.

4.2.4 The WCH REB number will not be released outside the REO until a complete REB submission is received.

4.2.5 When the submission is complete, the submission is then assigned to appropriate reviewer(s) for either full board or delegated review by the WCH Research Ethics Coordinator in consultation with the WCH REB Chair.

4.2.6 The review packages are prepared either electronically or in hard copy and distributed to REB members for the full REB meeting and/or delegated review based on the procedures outlined in the *WCH REB Document Management SOP*.

4.2.7 Original submission materials are retained in the REO office.

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

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5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.108.
6. FDA Information Sheets
7. WCH REB Standard Operating Procedure: REB Document Management (REB-SOP-III-03-002)