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

Amendments, Notifications, Change in Study Personnel, and Ongoing Communication Submissions and Review Procedures

SOP NO:	REB-SOP-IV-04.003	**Revision Date:**	February 12, 2017
CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	February 12, 2017
SUB-CATEGORY	Section IV: Review of Research	**Original Issue Date:**	December 21, 2012
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 process for submission and review of amendments, change in study personnel notifications, and ongoing communications associated with the Women's College Hospital (WCH) Research Ethics Board (REB) approved research.

In addition to the formally scheduled continuing review, the WCH REB must receive and review all new information and changes (amendments, notifications, and ongoing communications) generated throughout the course of the research.

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.

4.0 PROCEDURES:

4.1. Submission and Review

Investigators must submit to the REB any new information and changes to the approved protocol and associated documents.

4.1.1. Prior to implementation of any changes to WCH REB approved research, investigators must notify the WCH REB of any new information and changes to the approved protocol and associated study documents using the *Amendment Application Form*.

4.1.2. Any changes in research staff (e.g. addition of co-investigators, change in research assistants, new investigator covering the principal investigator (PI) temporarily for a leave, etc.) must be documented to the WCH REB using the *Change in Study Personnel Form.*

4.1.3. The WCH REB Chair or delegate reviews the documents to determine the appropriate level of WCH REB review required.

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4.1.4. Delegated review may be done when the proposed changes are minor or involve no more than minimal risk (as per definition).

4.1.5. The WCH REB Chair or delegate has the authority to direct any delegated review request to the full board for review.

4.1.6. Full board review may be required when the proposed change(s) represents more than minimal risk (as defined above) AND is determined by the WCH REB Chair or delegate to require more intense scrutiny by the full WCH REB, or is required by the regulatory body. Examples that may require full board review may include:

- Proposed changes to the scientific intent of the research
- Reports of any changes significantly affecting the conduct of the research or increasing the risk to the research participants
- New information that may adversely affect the safety of the research participants or the conduct of research

4.1.7. The WCH REB must find that the criteria for approval are still met in order to approve the amendment, notification, and ongoing communication.

4.1.8. Modifications to approved research may not be initiated without prior WCH REB review and approval except where necessary to eliminate apparent immediate hazards to human subjects. If changes are made to eliminate immediate hazards, the PI must notify the WCH REB immediately and provide justification.

4.2. Documentation and Communication

4.2.1. WCH REB review activities will be documented, filed, and retained per Research Ethics Office (REO) operational procedures (*WCH REB Document Management SOP*).

4.2.2. Investigators will be notified in a timely manner whether they have received approval of the amendment or whether further information will be required.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Chapter 1 Section C; Chapter 2 Section B;
2. The International Conference on Harmonization Good Clinical Practices, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;
4. OHRP Guidance on Continuing Review;

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5. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Tile 21, Parts 56. 108, 56.109, 56.110, 56.111, 56. 115;
6. FDA Information Sheets: FAQ Section IV;
7. ISO 14155 Clinical investigation of medical devices for human subjects – Good Clinical Practice;
8. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Amendments, Notifications, Ongoing Communications, Submission and Review Procedures* (REB-SOP-IV-04.003)