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

REB Document Management

SOP NO:	REB-SOP-III-03.003	**Revision Date:**	January 5, 2017
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 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 requirements for document management, including document retention and archiving. This SOP applies to documents submitted to and reviewed by the Women's College Hospital (WCH) Research Ethics Board (REB), as well as REB administrative documents.

The WCH Research Ethics Office (REO) must retain all relevant records (e.g. documents reviewed/approved/rejected by the REB, meeting minutes, correspondence with investigators, written SOPs, membership lists, etc.) to provide a complete history of all actions related to REB review, approval, and oversight of submitted research. Such records must be retained securely as per Part C Division 5 of the Food and Drug Regulations of Health Canada.

Relevant records must be made accessible to authorized regulatory authorities, representatives of the institutions, researchers and funding agencies within a reasonable time upon request.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBIILITY

This SOP applies to the REB Chair, Vice-Chair, REB members, and REO Staff.

The REO staff are responsible for maintaining complete files on all research submitted to and reviewed by the REB, and for maintaining administrative documents related to such research (e.g. agendas, minutes, correspondence).

The Research Ethics Coordinator and REB Assistant are responsible for retention and archiving of REB files.

4.0 PROCEDURES:

4.1. Study Related Documents

4.1.1. Upon receipt of an initial submission, the WCH Research Ethics Coordinator or REB Assistant creates a research project-specific paper file as well as a secure electronic file.

WOMEN'S COLLEGE RESEARCH INSTITUTE
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4.1.2. The WCH Research Ethics Coordinator or REB Assistant adds any research-related documents received throughout the course of the research project to the paper and electronic files.

4.1.3. The REO retains records of the research submitted for REB review – regardless of whether the research is approved – as per Part C Division 5 of the Food and Drug Regulations of Health Canada and Health Canada regulations.

4.1.4. Research-related documents that are retained include, but are not limited to, the following (as applicable):

- signed REB application forms;
- research protocols;
- scientific evaluations;
- investigator brochures or product monographs;
- participant recruitment materials, survey instruments, and questionnaires;
- approved consent documents;
- research budgets;
- Health Canada No Objection Letter (NOL);
- correspondence regarding activities such as:
    - reports of unanticipated problems involving risks to participation and others, including reports of local serious adverse events
    - amendment or modifications to the research protocol
    - reported significant deviations from the research protocol
    - reported significant new findings provided to participants
    - monitoring reports
    - protocol-specific queries from researchers and research team members to the REB
- progress reports and study completion reports;
- copies of correspondence between the REB and regulatory agencies;
- reports of any complaints received from research participants or regulatory agencies, and their resolution.

4.2. REB Administrative Documents

4.2.1. The REO retains all administrative records related to the REB review activities as per Part C Division 5 of the Food and Drug Regulations of Health Canada;

4.2.2. REB administrative documents that are retained include, but are not limited to, the following:

- agendas and minutes of all REB meetings;
- submitted REB member reviews/reports;
- REB member records:
- current and archived membership lists
- curricula vitae and training records of current and past REB members;
- signed Conflicts of Interest and Confidentiality Agreements
- current and archived Standard Operating Procedures (SOPs);
- current and archived documentation of the WCH REB Chair's delegation of authority, responsibilities, or specific functions;
- records of registration of the REB with the US Office of Human Research Protection (OHRP).

4.3. Document Storage and Archiving

4.3.1. Paper copies of REB documents are retained onsite in a secure file cabinet accessible to the WCH REB Chair, Vice Chair, and REO staff;

4.3.2. Closed research project files may be barcoded and archived with an off-site storage facility;

4.3.3. The REB database stores both current and historical data for all research projects entered in the database.

4.4. **Confidentiality and Document Retention and Destruction**

4.4.1. All materials received by the REB are considered confidential and are distributed only to REB members, external reviewers/consultants (as appropriate), the WCH REB Chair, REO staff and/or other representatives of WCH authorized by the Vice President, Research;

4.4.2. The WCH REB Chair, REO staff, REB members, external reviews/consultants, and guests must sign a *Conflicts of Interest and Confidentiality Agreement*;

4.4.3. All relevant documents are stored in REB files with access limited to the WCH REB Chair or delegate, REO staff, and REB members (upon request);

4.4.4. Paper files are stored in cabinets in a locked, secure area at the end of each day;

4.4.5. Electronic data for REB projects are stored in the WCH REB access database and in the secure electronic drive and is accessible only to the] REO staff and/or other representatives of WCH authorized by the Vice President, Research;

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

Research Ethics Board Standard Operating Procedures

REB Document Management

4.4.6. Guests of the REB are not allowed access to the REB files unless they are members of regulatory agencies, or representatives of the sponsor or principal investigator and are reviewing the files related to their specific research;

4.4.7. All confidential materials received in excess of the required documentation will be shredded. REB members without access to secure disposal must return their REB materials to the REO for disposal;

4.4.8. All REB documents (study-related and administrative) should be retained for a length of time specified by the WCH Destruction of Records Policy (Policy Number 1.130.002).

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Article 6.17;
2. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, Section 3.4;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Tile 21, Parts 56.115;
5. OHRP Guidance on Written IRB Procedures;
6. FDA Information Sheets
7. WCH Destruction of Records Policy (Policy Number 1.130.002)