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

Research Ethics Board Standard Operating Policies and Procedures

Notification of Study Completion

SOP NO:	REB-SOP-IV-07.003	**Revision Date:**	February 13, 2017
CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	February 13, 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 procedures for the closure of research studies with the Women's College Hospital (WCH) Research Ethics Board (REB).

The completion of a research study is a change in activity that must be reported to the WCH REB. Although research participants will no longer be at risk under the study, a final report allows the WCH REB to close its files.

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.

The REO staff is responsible for verifying that all study competition documents are received, reviewed and signed by the REB Chair or designee. Reports are filed appropriately by the REO staff.

4.0 PROCEDURES:

4.1. Criteria for Closing a Study

When all data collection, clarification, and transfers are complete (including access to the research participant's medical record) and there is no further participant involvement, a Study Termination Form should be submitted. This can be obtained from the WCH REB website. Submission of this report indicates that these activities have ceased, the study does not require continuing ethics approval, and the WCH REB study file can be closed.

4.1.1. For research studies that are only being conducted at WCH (single-centred research), when the study is complete the principal investigator (PI) or delegate shall direct Research Ethics Office (REO) staff to close and archive the file by completing the Study Termination Form.

4.1.2. For multi-centre research, an individual centre may be closed when contact with research participants and data collection has ceased at the centre and the sponsor has conducted their study closeout procedures (if applicable).

4.2. Study Completion Reports

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

Research Ethics Board Standard Operating Policies and Procedures

Notification of Study Completion

4.2.1. When the study is ready to be closed, the investigator shall submit a completed Study Termination Form to the REB;

4.2.2. If the research is prematurely terminated for any reason, the PI shall promptly direct REO staff to close and archive the file by completing the Study Termination Form. When the Study Termination Form (and supporting documents) indicating a premature termination of the study is received by the REO, the WCH Research Ethics Coordinator will notify the REB Chair or designee who will act according to the SOP on suspensions and terminations (REB-SOP-IV-06.002).

4.2.3. The WCH Research Ethics Coordinator will review the Study Termination documents and associated study files and request any outstanding information, clarification, or documentation from the investigator if needed.

4.2.4. Once all outstanding issues have been addressed, the WCH REB Chair will sign the Study Termination Form. The Research Ethics Coordinator will send an email to the PI, acknowledging the study closure. The Research Ethics Coordinator will also appropriately enter the study termination date into the WCH REB database.

4.2.5. The WCH Research Ethics Coordinator will store the closed WCH REB files in a separate location from active WCH REB files. If appropriate, the Manager or delegate will coordinate off-site storage of closed studies for archiving as per Health Canada and WCH institutional regulations.

5.0 REFERENCES:

1. The international Conference on Harmonization Good Clinical Practices, Section 4.13
2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Article 6.14
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109
4. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109
5. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Study Completion* (REB-SOP-IV-07.003)