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

Research Ethics Board Standard Operating Procedures

Submitting External Safety Reports to the REB

SOP NO:	REB-SOP-IV-09.003	**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 how and when to submit external safety reports to the Women's College Hospital (WCH) Research Ethics Board (REB) and the criteria for review of these reports.

REB's must establish procedures for conducting continuing review of approved research involving research participants. In addition to formally scheduled continuing review, in keeping with current regulations, the WCH REB requires that Principal Investigators (PIs) participating in multi-centre trials submit external safety reports in some limited circumstances for severe adverse effects (SAEs) that occur at any other centre involved in a study using the same investigational agent.

The PI shall only submit to the WCH REB, External Safety Reports that are:

- Serious, AND
- Unexpected, AND
- Related (unlikely, possibly, probably, definitely), AND
- Requires a change to the protocol and/or informed consent form and/or requires immediate notification to participants for safety reasons.

It is the responsibility of the PI at WCH to review all External Safety Reports and retain copies. Only those that are deemed by the PI to meet ALL of the above submission criteria are to be submitted to the WCH REB. All other Reports not meeting the submission criteria are to be kept on file in the Investigator Study File and available for review by the WCH REB upon request. Failure by the investigator to ensure timely submission of External Safety Reports to the WCH REB for review is a serious matter that may lead to suspension or termination of the research at WCH.

It is the expectation of the WCH REB that the sponsor and/or PI will notify the WCH REB when the reported information is considered to affect the rights and welfare of research participants, and the recommended actions to follow. In turn, through review of the new information, the WCH REB may require that the research be further modified, suspended, or terminated.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the Investigator, the REB Chair, Vice-Chair, REB members and Research Ethics Office (REO) staff.

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

Research Ethics Board Standard Operating Procedures

Submitting External Safety Reports to the REB

4.0 PROCEDURES:

4.1. Submitting External Safety Reports to the REB

4.1.1. Upon receipt of an External Safety Report from the sponsor, it is the PI's responsibility to review each report.

4.1.2. The PI must determine whether the Report is:

- Serious, AND
- Unexpected, AND
- Related (unlikely, possibly, probably, definitely), AND
- Requires a change to the protocol and/or informed consent form and/or requires immediate notification to participants for safety reasons.

4.1.3 Reports determined by the PI to meet ALL of the above criteria must be reported to the WCH REB using the Unanticipated /Adverse Event form located on the Research Ethics web page under forms.

4.1.4 The PI is required to include the manufacturer Report number, indicate the type of Report (i.e. initial or follow-up), the type of event, and recommended action.

4.2 Review of External Safety Reports by the REB

4.2.3 Upon receipt of the Unanticipated/Adverse Event Report Form and accompanying Reports that meet ALL of the above criteria, the Research Ethics Coordinator will review the submission and request any clarifications, or missing documentation or information.

4.2.4 The Reports will be reviewed by the WCH REB Chair or delegate and the submission form will be signed indicating review has occurred.

4.2.5 If the reported information is considered to affect the rights and welfare of research participants, the WCH REB may require that the research be modified, suspended, or terminated. The WCH REB will also consider if this new information should be communicated to research participants.

4.2.6 The signed submission form will be returned to the PI for filing.

4.2.7 If the WCH REB receives External Safety Reports that do not meet the submission criteria, the WCH REB reserves the right to return such Reports, without review, to the PI.

4.3 Documentation and Communication

1.3.1 WCH REB notice of receipt and review of the Reports that meet the submission criteria will be distributed to PIs in a timely manner.

1.3.2 External Safety Report WCH REB review activities will be documented, filed, and retained per REO operational procedures (see *Document Management SOP)*.

1.3.3 It is the PI's responsibility to review all External Safety Reports and retain copies in the Investigator Study file.

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

Research Ethics Board Standard Operating Procedures

Submitting External Safety Reports to the REB

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Articles 6.15; 11.9
2. The International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, Section 3, 4.4, 4.5, 4.10, 4.11, 4.12
3. Health Canada Food and Drug Regulations, Division 5, C.05.014
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Tile 21, Parts 56.108, 56.109, 56.110, 56.111, 56,115
5. US Department of Health and Human Services (HHS) CFR Title 45, Parts 46.109, 46.110, 46.111, 46.115
6. US Office for Human Research Protections (OHRP) Guidance “Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events”
7. OHRP Guidance on Continuing Review;
8. FDA Draft Guidance on Adverse Event Reporting, April 2007;
9. FDA Information Sheets;
10. Canadian Association of Research Ethics Boards “Guidance on Reporting of Unanticipated Problems Including Adverse Events to Research Ethics Boards in Canada” July 2010
11. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Submitting External Safety Reports to the REB* (REB-SOP-IV-08.003)