



Research Ethics Board Standard Operating Procedures

Communication – Research Participants

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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 the Women's College Hospital (WCH) Research Ethics Board (REB) communications with study participants involved in research overseen by the WCH REB.

In the interest of enhancing human research participant protection and harmonization of policies and procedures, it is important for the WCH REB to foster collaboration and open communication.

Research participants should be able to confidently voice their concerns or questions, or request information regarding their participation or potential participation in a research project, to an informed individual on the WCH REB or in the Research Ethics Office (REO).

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. Communication with Research Participants

- 4.1.1. Research participants are encouraged to contact (via telephone or in writing) the WCH REB with questions and concerns using the contact information provided in the informed consent documents. If requested, the identity of the participant will not be recorded or shared.
- 4.1.2. REO staff will relay communications immediately to the WCH REB Chair or delegate when the participant shares concerns or problems encountered while participating in a research project.
- 4.1.3. In the absence of the WCH REB Chair or delegate, REO staff will immediately forward all communication from participants to the Manager or delegate.
- 4.1.4. The WCH REB Chair or delegate works to resolve participant concerns, including follow-up with the investigator or the investigator's supervisor or Institutional Official, and appropriate federal agencies, as indicated;



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4.1.5. The WCH REB Chair or delegate documents all communication with the research participant and keeps a record on file at the REO.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Chapter 1 Section B;
2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115
3. US Food and Drug Administration (FDA) CFR Title 21 Part 56.115;
4. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure–*Communication: Research Participants* (REB-SOP-IVI-02.003)