

Research Ethics Board Standard Operating Procedures

Appeals

SOP NO:	REB-SOP-IV-10.003	Revision Date:	February 13, 2017
CATEGORY	Research Ethics Board	Reviewed/Effective Date:	February 13, 2017
SUB-CATEGORY	Section IV: Appeals	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 PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to describe how appeals of decisions made by the Women's College Hospital (WCH) Research Ethics Board (REB) will be managed.

As per *Tri-Council Policy Statement (TCPS2) on Reconsideration and Appeals*, "in cases where researchers do not receive ethics approval, or receive approval conditional on revisions that they find compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the REB. If that is not successful, they may appeal using the established appeal mechanism in accordance with the institution's procedures".

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.

4.0 PROCEDURES:

4.1 Appeals

As per TCPS 2 Article 6.18, "Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project".

Appeals will be dealt with according to the following Guidelines established by the Committee on Human Subjects in Research at the University of Toronto:

- Decisions of any Research Ethics Board established by the University of Toronto may be appealed. Appeals may be made only by the affected investigator(s), and not by third parties. Grounds for appeal include procedural irregularities, bias and interpretation of the TCPS2.
- Decisions of any Research Ethics Board established by an affiliated teaching hospital shall be subject to procedures approved by the Toronto Academic Health Sciences Council (TAHSC) Research Committee's Working Group on Human Subjects in Research.



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- Appeals should be in writing, include all relevant documentation and present both the grounds for the appeal and the desired remedy. They should initially be directed to the Chair of the Committee on Human Subjects in Research, who will determine whether there is sufficient basis in fact or circumstance for the case to be heard by the Committee. The Chair's decision shall be final and not subject to appeal.
- Appeals will be heard by a Sub-Committee of no more than seven members of the Committee, selected by the Chair. The Sub-Committee's composition must meet the requirements of the TCPS2 for quorum which includes:

At least five members, including both men and women, of whom:

- a) At least two members have broad expertise in the methods or in the areas of research that are covered by the REB;
 - b) At least one member is knowledgeable in ethics;
 - c) For biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and
 - d) At least one member has no affiliation with the institution, but is recruited from the community served by the institution.
- In addition, neither the Chair of the WCH REB nor the WCH Vice President, Research shall participate. As provided in the Committee's Terms of Reference, additional members may be added to ensure that the Committee has the necessary expertise.
 - The appellant shall be required to present a written statement outlining the complaint, along with copies of relevant documents. This statement will be sent to the Chair of the WCH REB, who will present a written response. Both statements and the documentation will be given to all members of the Sub-Committee. The Sub-Committee may ask both the appellant and the WCH REB Chair to appear before the Sub-Committee to present verbal arguments and answer questions. If the appellant is a student, his/her supervisor will also be asked to appear.
 - After hearing from both sides, the Sub-Committee shall decide whether to reject or accept the appeal. If the appeal is accepted, the Sub-Committee shall determine what action should be taken. The Sub-Committee's decision is not subject to further appeal.
 - Appeals should normally be filed within a month of the WCH REB's decision. They should normally be heard by the Sub-Committee within 60 days of receipt of the complaint. The Sub-Committee's decision and the reasons for it should normally be delivered to the parties within two weeks of the decision.
 - Normally, documents and statements relating to the appeal will be treated as confidential. The Sub-Committee shall, however, inform the full Committee and the Vice-President (Research) & Associate Provost of the general nature of the appeal and the action taken.



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5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2)
2. University of Toronto: Guideline and Practices Manual for Research Involving Human Subjects v.1.0 (Approved March 2007).