

<b>SOP Title:</b>	<b>Appeals of REB Decisions</b>		
<b>SOP #:</b>	IV.12.001	<b>Original Issue Date:</b>	February 23, 2015
<b>Category:</b>	REB Review of Research	<b>Reviewed/Effective Date:</b>	October 1, 2019
<b>Issued by:</b>	Research Ethics Office (REO)	<b>Revision Date:</b>	October 1, 2019
<b>Approved By:</b>	Dr. Elizabeth Stephenson		

### 1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe how appeals of decisions made by the SickKids Research Ethics Board (REB) will be managed.

### 2.0 POLICY STATEMENT

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.

### 3.0 DEFINITIONS

See Glossary of Terms

### 4.0 RESPONSIBILITY

All REB members and REO Personnel are responsible for ensuring that the requirements of this SOP are met.

### 5.0 PROCEDURES

#### 5.1 Appeals

5.1.1 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 Network (TAHSN) Research Committee's Working Group on Human Subjects in Research.

- 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;
- In addition, neither the Chair of the SickKids REB nor the SickKids Chief/Associate Chief of 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 SickKids 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 SickKids 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 SickKids 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 Associate Chief of Research & Associate Provost of the general nature of the appeal and the action taken.

## 6.0 REFERENCES

See References