

**Holland Bloorview Research Ethics Board (REB)
Standard Operating Procedures**

	REB REVIEW OF RESEARCH		
POLICY: REB-404	REB REVIEW PROCESS		
This policy pertains to:	The activities of the Research Ethics Board (REB) operating under the authority of Holland Bloorview Kids Rehabilitation Hospital		
Responsibility for executing this policy:	Chair, Holland Bloorview REB (or designate)		
Approval Authority:	Research, Teaching & Learning Advisory Committee (RTLAC) of the Holland Bloorview Board of Trustees		
Effective date:	September 30, 2014	Supersedes documents dated:	V3: August 2013
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

The purpose of this SOP is to describe the REB review process.

REFERENCES

2. POLICY

All research involving human participants must be submitted for REB review according to the specified application format and process, otherwise the REB Office will notify the Local Principal Investigator (LPI) that the REB will not review the research activity until all required elements are submitted. No intervention or interaction with human subjects in research, including recruitment, may begin until the REB has reviewed and approved the research protocol, consent documentation and recruitment materials.

Holland Bloorview REB Terms of Reference

As a result of its review, the REB may determine to approve or disapprove the proposed research activity, or to require modifications to the project/protocol/documents in order to secure REB approval of the research activity. Except when the delegated review procedure is used, these actions will be taken by a vote of a quorum of the regular and alternate members present, except for those members present but unable to vote in accordance with the REB's conflict of interest policies. When reviewed via delegated review, the REB Chair or his/her designate can take any of the following actions except to disapprove a study.

Policy REB-402.

Policy REB-106.

3. SPECIFIC POLICIES

3.1 The Application Process.

REB Office staff will review each application for completeness. If there are elements missing, the Investigator will be notified.

3.2 Review Procedures

Initial applications are pre-screened for completeness and assessment of the level of risk and vulnerability of participants. If the application does not meet the criteria for delegated review as per Policy REB-402, it will be reviewed by the full Research Ethics Board in accordance with the following procedures:

- The REB Office will send all materials and relevant documents to all members of the REB approximately 2 weeks prior to the REB meeting at which the study is scheduled to be reviewed. If the study is a regulated trial, at least one of the reviewers must be a medical doctor. The protocol may also be assigned to an additional expert (external reviewer) who is not a member of the REB if the nature of the protocol warrants the need for additional expertise.
- For projects reviewed by the full REB, the LPI or designate may be requested to attend the meeting of the Research Ethics Board and if so, he/she will be given an appointment time. If the LPI cannot attend on the specified date and cannot delegate this responsibility to a co-investigator or a designated team member approved by the REB Chair, review of the project may be deferred to the next scheduled REB meeting. For student projects, the LPI (or a qualified researcher designate) is expected to attend the REB meeting with the student researcher. Otherwise, the project's review may be deferred to the next scheduled REB meeting. LPI's shall be excluded when the REB discusses its decisions, reaches consensus or votes.
- Discussion of the protocol at the REB meeting is led by the Chair. By unanimous consensus or by majority vote, the REB may make any of the determinations outlined in article 3.3 below.

CAN/CGSB-191.1-2013 –
(4.4.4.4.8)

3.3 REB Determinations

Communications about REB determinations made at convened meetings are sent to the LPI in writing. For full REB reviews, a copy of the REB membership roster in effect on the date of the meeting and a statement confirming that quorum was present during the meeting regarding the LPI's study will be provided upon request.

CAN/CGSB-191.1-2013 –
(4.4.5.1), (4.4.5.6), (4.4.4.4.10)

Holland Bloorview REB Terms
of Reference

The REB may make one of the following determinations as a

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result of its review of research submitted for initial or continuing review:

- a) **Approval:** The protocol and accompanying documents are approved as submitted. Research may begin as soon as the LPI receives a letter of approval to proceed from the REB Chair or designate. A letter indicating the REB decision will be sent to the LPI by the REB Chair within 30 days. The period of approval will commence on the day the study is approved by an action of the convened REB or the REB Chair or his/her designate and expire within one (1) year of the meeting date in which the study was approved or at the end of a period assigned by the REB. CAN/CGSB-191.1-2013 – (4.4.7.1)
- b) **Approval pending minor revisions:** The Board may decide that a protocol may be conditionally approved provided that certain conditions are met or required changes are made. A written explanation of the conditions and/or modifications is sent to the LPI by the REB Office staff within 30 days. When the LPI provides the Research Ethics Board with proof that the conditions have been met and the documents have been amended, (as confirmed by the REB Office staff and the Chair), an approval letter will be sent to the LPI. The period of final approval will commence on the day that the authorization letter is sent. CAN/CGSB-191.1-2013 – (4.4.4.4.11)
- c) **No decision, revisions required for full REB review:** The REB may defer a decision on any submitted research if it does not have sufficient information to arrive at a determination, or if the REB requires extensive revisions to any part of the research application. The REB will provide the LPI with a detailed list of deficiencies, the required modifications and the rationale for the required changes within 30 days of the determination so that the investigators can amend the proposal and re-submit for consideration by the full REB. CAN/CGSB-191.1-2013 – (4.4.5.4)
- d) **Rejected.** The full REB may reject any submission which does not meet its standards for ethical or scientific review and where revision is unlikely to enable the REB to reach a positive determination. A letter indicating the REB decision and the rationale for that decision will be sent to the LPI by the REB Chair within 30 days. The LPI has the right to appeal (see section 3.4 below).

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No other Institutional Board or individual may approve a study which has been rejected by the REB. However, the Institution has the right to reject a study for reasons outside the research ethics jurisdiction of the REB (e.g., resource issues or contrary to the vision and mission of the Institution.).

CAN/CGSB-191.1-2013 –
(4.4.5.5)

3.4 Appeal Process

The Toronto Academic Health Science Network (TAHSN) Hospital REB Appeals Policy provides a mechanism for the LPI to appeal a negative decision by the REB. An appeal can be launched for procedural or substantive reasons. This process will only be initiated when all reconsideration processes have been exhausted. The onus shall be on the LPI to justify the grounds for requesting an appeal and to indicate any breaches to the research ethics review process or any element of the REB decision that is not supported by applicable regulations and standards. A Board of Record agreement must be made with the University of Toronto to empower the U of T Health Sciences REB to act as Holland Bloorview's REB of record for the purpose of the appeals process.

CAN/CGSB-191.1-2013 –
(4.4.8.1), (4.4.8.2), (4.4.8.3)

TAHSN Hospital REB Appeals
Policy (Spring 2013)
TCPS2 Article. 6.18 to 6.20

The Appeals Board will have the power to approve, reject, or request modifications to the research proposal. The decision of the Appeals Board as the REB board of record on behalf of Holland Bloorview will be final.

Revision History

V3/August 2013: Changed 'REB Manager' to 'REB office staff' to accommodate growth and job title changes within the REB administrative office. Revised Section 3.4: The TAHSN Hospital REB Appeals Policy (Spring 2013) provides a mechanism for the Local Principal Investigator to appeal a negative decision by the Holland Bloorview REB.

V4/July 2014: CAN/CGSB-191.1-2013 references incorporated to reflect compliance. Changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee. Revised section 2: clarified the notification process for incomplete applications. Revised section 3.2: replaced 'medical intervention' with 'regulated trial', and clarified that the LPI may attend the meeting to present the study but cannot be present during REB decisions, deliberations or voting. Revised section 3.3: clarified that REB determinations will be sent to the LPI in writing and that LPI may request a copy of the REB roster and a statement regarding quorum. Revised section 3.3 C and D: added that rationale and required modifications will be sent in writing. Revised section 3.4: clarified that the LPI must justify the grounds for appeal.