

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

	REB ORGANIZATION		
POLICY: REB-203	DUTIES OF REB MEMBERS		
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 document date:	V3: August 2013
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

The purpose of this SOP is to define the duties required of Holland Bloorview REB members.

2. POLICY

Each REB member’s primary duty is to ensure that all research that falls under its review meets the highest ethical standards for research involving humans. All members must consider a number of factors in its review of research protocols including: social and scientific merit; the risks and benefits to participants; participant vulnerability; participant selection and recruitment; privacy and confidentiality; the consent and assent processes; and inclusiveness and justice. Above all, members must ensure that the research respects the rights, dignity, welfare, and autonomy of research participants.

Holland Bloorview REB Terms of Reference

The REB member must understand that s/he is not serving on the Board to expedite the approval of research, but to serve as a link between the investigator and the research participants. In order to fulfill his or her duties, REB members are expected to be knowledgeable of the guidelines and regulations governing human participant research ethics, and the policies of Holland Bloorview, relevant to human participant protection. The REB must be perceived to be fair and impartial, immune from pressure either by the Holland Bloorview administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

REB members and ad hoc advisors shall maintain the confidentiality of the documents submitted for ethics review and of the REB discussions as described within the confidentiality agreements signed prior to commencement of their duties.

CAN/CGSB-191.1-2013 – (4.3.2.9)

3. SPECIFIC POLICIES

3.1. Duty to the Institution

REB members serve Holland Bloorview as a whole, rather than a particular department or program. Therefore, members must not allow their own interests or those of their departments or programs to supersede their duty to protect the rights and welfare of research participants.

3.2. Term of Duty

REB members are expected to commit to a 3-year term and during that time, fulfill certain duties. These duties will be described prior to appointment and each REB member will be aware of his/her responsibilities as an REB member prior to accepting appointment to the REB.

3.3. Specific Duties

3.3.1 Regular and Alternate Members

- A. **Community member(s):** Community members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective. The primary role of the community member is to reflect the perspective of the participant.
- B. **Non-scientific members:** Non-scientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or provincial requirements regarding consent. Non-scientific members should advise the Board if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of participants and to comment on the comprehension of communications with those who are invited and participate in research.
- C. **Scientific members:** Scientific members are expected to contribute to the evaluation of a study on its ethical, scientific and statistical merits. These members should also be able to advise the Board if additional expertise in a scientific or non-scientific area is required to assess if the protocol adequately protects the rights and welfare of

Health Canada Food and Drugs
Act, Div 5

TCPS2, Article 6.4

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

participants.

- D. **Chair:** In addition to the above responsibilities (relevant to the member's capacity), this person chairs meetings of the REB. The REB Chair is responsible for ensuring that the REB review process conforms to all regulatory requirements including TCPS2, CGSB, and ICH GCP, where relevant.

TCPS2, Article 6.8

CAN/CGSB-191.1-2013 –
(4.3.3.3)

The Chair performs or delegates to an appropriate voting board member authority to perform delegated review when appropriate.

The Chair is empowered to suspend the conduct of a research project or clinical trial deemed to place individuals at unacceptable risk pending discussion by the full REB. The Chair is also empowered, to suspend the conduct of a study if s/he determines that an investigator is not following the REB's policies or procedures.

The REB Chair may appoint a Vice-Chair to assist or act on behalf of the chairperson in particular REB matters and at REB meetings, either as a general procedure, or on a case-by-case basis. The REB Chair also may delegate any of his/her responsibilities, as appropriate, to the Bioethicist REB member, or to other qualified REB members.

The REB Chair, in consultation with REB Office staff, the Vice-Chair or other voting members of the REB, determines the level of risk, participant vulnerability, and the appropriateness of a submission for delegated or full REB review. The REB Chair may delegate this responsibility to another REB member.

The REB Chair, in conjunction with the Research Ethics Board and other institutional representatives as appropriate, is responsible for ensuring that REB members are informed of all new legislation, regulations and guidelines which bear on REB review.

The REB Chair, in conjunction with appropriate individuals will review REB policies and procedures to ensure that they meet current standards every 2 years unless otherwise needed due to regulatory changes.

The REB Chair, in collaboration with administrative staff, shall advise the organization on policies and procedures related to the ethical conduct of research involving human subjects. The Chair shall advise the organization on the

CAN/CGSB-191.1-2013 –
(4.3.3.2)

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

evaluation of performance of REB members and administrative staff.

- E. **Vice-Chair**: The REB Vice-Chair or designate shall discharge the responsibilities of the Chair when the Chair is unable to do so; discharge the responsibilities assigned by the Chair and assist in the overall operations of the REB as required. CAN/CGSB-191.1-2013 – (4.3.3.4)
- F. **REB Office Staff Member**: The REB Office staff member shall be knowledgeable in research ethics, national and international guidelines and regulations as well as institutional policies. CAN/CGSB-191.1-2013 – (4.3.4.4)

Revision History

V3/August 2013: Changed 'REB Manager' to 'REB office staff' to accommodate growth and job title changes within the REB administrative office.

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: added that REB members and ad hoc advisors must maintain the confidentiality of documents submitted for ethics review as per signed confidentiality agreements. Revised section 3.3.1 B: clarified that non-scientific members should advise the board if further expertise is required to comment on the comprehension of communications with those who are invited and participate in research. Revised section 3.3.1 D: added that REB Chair and staff will advise the organization on policies and procedures related to ethical conduct of research. Added that the REB Chair will advise the organization on the evaluation of REB members. Revised section 3.3.1 E: added that the REB Vice-Chair or designate will discharge the responsibilities of the Chair when the Chair is unable to do so and when required, discharge assigned responsibilities to assist in the operations of the REB. Revised section 3.3.1 F: added that the REB office staff must be knowledgeable in research ethics, institutional policy, national and international guidelines and regulations.