

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

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|--|---|-----------------------------------|-----------------|
|  | <b>REB ORGANIZATION</b>   |                                   |                 |
| <b>POLICY: REB-201</b>                           | <b>COMPOSITION OF THE BOARD</b>   |                                   |                 |
| <b>This policy pertains to:</b>                  | The activities of the Research Ethics Board (REB) operating under the authority of Holland Bloorview Kids Rehabilitation Hospital |                                   |                 |
| <b>Responsibility for executing this policy:</b> | Chair, Holland Bloorview REB (or designate)   |                                   |                 |
| <b>Approval authority:</b>                       | Research, Teaching & Learning Advisory Committee (RTLAC) of the Holland Bloorview Board of Trustees                               |                                   |                 |
| <b>Effective date:</b>                           | September 30, 2014  | <b>Supersedes documents date:</b> | V3: August 2013 |
| <b>Approved:</b>                                 | Chair of the REB<br>Research, Teaching & Learning Advisory Committee  |                                   |                 |

## 1. PURPOSE

The purpose of this SOP is to state the requirements for the composition of the REB responsible for reviewing research conducted by staff and students at Holland Bloorview Kids Rehabilitation Hospital.

## 2. POLICY STATEMENT

The membership of the REB will be sufficient to ensure the appropriate expertise, multi-discipline backgrounds, and independence required for competent research ethics review. The board members will be qualified to ascertain the acceptability of the research in terms of Holland Bloorview's mission, vision, and values, all applicable laws and standards of professional conduct and practice. The membership will be diverse so selection will include consideration of race, ethnicity, gender, cultural backgrounds, disability, research, healthcare or professional experience and sensitivity to such issues as community attitudes and perspectives to assess the research submitted for review.

The REB shall consist of at least 5 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) at least one member is knowledgeable in the relevant Canadian law;
- (d) at least one member has primary experience and expertise are in a non-scientific discipline;
- (e) at least one member has no affiliation with Holland Bloorview and who is not part of the immediate family of a person who is affiliated with the institution, but is recruited from the community

## REFERENCES

Health Canada Food and Drugs Act, Div 5/ ICH Harmonized Tripartite Guidelines, Good Clinical Practices

TCPS2, Article 6.4

21 CFR 56.107  
45 CFR 56.197

CAN/CGSB-191.1-2013 – (4.3.1.1)

Holland Bloorview REB Terms of Reference

CAN/CGSB-191.1-2013 – (4.3.2.1)  
45 CFR 46.107  
21 CFR 56.107(d)

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served by Holland Bloorview; and  
(f) at least one member knowledgeable in considering privacy issues.

The majority of the members of the REB should have both the training and the expertise to make sound judgments on the ethics of research proposals involving human participants. Its membership should be broad enough to reflect the context of society within which it operates.

A member of the REB may not fulfill more than two representative capacities and disciplines.

CAN/CGSB-191.1-2013 –  
(4.3.2.2)

For research involving pharmacological interventions, the membership shall also include at least 2 alternate members who have expertise in medical pediatric practice/ pharmacology. For research involving natural health products, the membership shall include at least 1 alternate member who has expertise in natural health products.

Natural Health Products  
Regulations Part 4

CAN/CGSB-191.1-2013 –  
(4.3.2.1)

### 3. SPECIFIC POLICIES

#### 3.1 Membership selection criteria

The REB Chair in consultation with the appropriate manager or administrator appoints the members of the REB for a term of three years, renewable once. Holland Bloorview management is responsible for nominating new members when terms near completion. The membership terms are renewable and are staggered in such a manner as to safeguard the continuity of the REB. Holland Bloorview's Bioethicist is a standing member of the REB and may assume the role and responsibilities of Vice-Chair, as needed.

Holland Bloorview REB Terms of  
Reference

CAN/CGSB-191.1-2013 –  
(4.2.2.4)

Members will be selected according to the criteria outlined above. In addition, as the size of the REB increases, the number of community representatives will also increase.

CAN/CGSB-191.1-2013 –  
(4.3.2.5)

#### 3.2 Composition of the Board

**3.2.1 Regular Members:** The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the REB. The majority of regular members must be Canadian citizens or permanent residents under the Immigration Act.

Food and Drugs Act, Div 5,  
C.05.001 – definition of "research  
ethics board"

CAN/CGSB-191.1-2013 –  
(4.3.2.3)

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A. **Community member(s):** The community member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals from the communities from which Holland Bloorview researchers will draw their research participants. The community member(s) should not be vulnerable to intimidation by the professionals on the REB.

B. **Scientific members:** The REB will include physicians and experts in physical, behavioural, social or biological science. When an REB encounters studies involving science beyond the expertise of the members, the REB may use ad hoc reviewers to assist in the review.

C. **Chair:** The Chair of the REB should be an experienced REB member with at least two years of experience on an REB and shall serve, normally, for a term of three years, renewable. The REB Chair shall have a broad knowledge of research ethics literature and national and international guidelines and regulations as applicable to biomedical research within the jurisdiction of the REB.

CAN/CGSB-191.1-2013 –  
(4.3.3.1)

**3.2.2 Alternate Members:** Alternate members are qualified voting members who serve as designated alternates for regular members, but they are not expected to attend each meeting. The REB Chair or his/her designate, or a designated member of the REB staff, may ask an alternate member to attend a meeting in order to draw on his/her expertise in an area that may be relevant to that meeting's deliberations. An alternate member's presence at a REB meeting in the place of an absent regular member may be used in establishing a quorum.

CAN/CGSB-191.1-2013 –  
(4.3.2.4)

**3.2.3 REB Office Staff Members:** The REB may include REB Office staff who have the necessary expertise and experience to act as non-voting members. REB Office staff will be knowledgeable in research ethics, national and international guidelines and regulations as well as

CAN/CGSB-191.1-2013 –  
(4.3.4.4), (4.3.4.5)

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institutional policies.

- 3.2.4 Ad Hoc Advisors:** The REB is able to consult ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently.

CAN/CGSB-191.1-2013 –  
(4.4.4.4.6)

In the event that the REB is reviewing a project that requires particular community or participant representation or specific disciplinary or methodological expertise not available from its members, the Chair may invite individuals with competence in special areas or knowledge to assist in the initial or continuing review of issues that require expertise beyond or in addition to that available on the REB. Consultation with an ad hoc advisor shall not alter the composition and representation of the REB.

Ad Hoc Advisors – see TCPS2  
Article 6.5 and ICH GCP, Article  
3.2.6

Ad hoc advisors may complement the REB through their experience, knowledge or expertise. Their input is a form of consultation that may or may not be considered in the final decision of an REB. They are not REB members and, as such, do not necessarily have the knowledge and experience gained from reviewing research proposals as members. Ad hoc advisors shall not be counted in the quorum for an REB, they shall not participate in the decisions of the REB nor be allowed to vote on REB decisions.

CAN/CGSB-191.1-2013 –  
(4.3.2.6)

- 3.3 REB Quorum:** a quorum is established when attendance meets the minimum requirements of membership representations outlined in Section 2 of this SOP. Decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.

TCPS2 Article 6.54

Health Canada Food and Drugs  
Act, Div 5

CAN/CGSB-191.1-2013 –  
(4.4.4.4.4)

REB Office staff members shall not be counted in determining quorum.

CAN/CGSB-191.1-2013 –  
(4.3.4.5)

- 3.3.1** When reviewing research that does not involve drugs or natural health products, a minimum of 5 members must be present. These five members must fulfill the requirement outlined in Section 2. Each member must meet the requirements in one capacity only for each of the membership categories.

CAN/CGSB-191.1-2013 –  
(4.3.2.1 (h))

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- 3.3.2** For drug trials the same as above (3.3.1) is true with the addition of at least 1 REB member who has expertise in medical practice/ pharmacology.
- 3.3.3** For research involving natural health products, the same as above (3.3.1) is true with the addition of at least 1 REB member who has expertise in natural health products.

**3.4 REB Membership Roster:** The REB membership roster shall document each member's academic qualifications, affiliations, representative capacity, gender, and specify their status as either a regular or alternate member.

CAN/CGSB-191.1-2013 –  
(4.4.5.6 (b))

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Revision History

V3/ August 2013: added clarification to section 2 (c) to specify that a member must be knowledgeable in Canadian law and 2 (d) regarding affiliations of the community member and reference to 45 CFR 46.107 and 21 CFR 56.107(d)

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 that REB composition must include at least one member whose primary expertise is non-scientific. Clarified that REB members cannot fulfill more than two representative capacities. Revised section 3.1: removed the privacy officer as a standing REB member. Clarified that the bioethicist may assume the role of Vice-chair as needed. Revised section 3.2.1C: added that the REB chair should be an experienced REB member with at least two years of experience. Added section 3.2.3: added that REB office staff may be appointed as non-voting REB members. Revised section 3.3: clarified that REB staff members shall not be counted in determining quorum. Added section 3.4: added that the REB roster will document members' academic qualifications, affiliations, gender, status as regular or alternate member.