Holland Bloorview
Kids Rehabilitation Hospital

	FUNCTIONS AND OPERATIONS		
POLICY: REB-302	**REB MEETING ADMINISTRATION**		
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 provide the framework to ensure that REB meetings are conducted and documented in a consistent manner in order to meet regulatory and institutional requirements

2. POLICY STATEMENT

Except when a delegated review procedure is used, the REB will review proposed research at convened meetings at which a quorum is present. The REB will meet monthly or at some other frequency as determined by the Chair and outlined in the REB meeting dates.

Holland Bloorview REB Terms of Reference

3. SPECIFIC POLICIES

3.1. Quorum

3.1.1. REB Quorum: a quorum is established when attendance meets the minimum requirements of membership outlined in Section 3.3 of Policy REB-201. 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 6.9

Health Canada Food and Drugs Act, Div 5

45 CFR 46.107
21 CFR 56.107

CAN/CGSB-191.1-2013 – (4.4.4.4.4)

3.1.2. For drug trials, at least 1 member must be from a medical discipline, or if regarding a dental drug, from a medical or dental discipline. A member who is knowledgeable in complementary or alternative health care must be in attendance to review clinical trials

The Natural Health Products Regulations, part 4

involving natural health products for therapeutic purposes.

3.1.3. In all cases the Chair will ensure that there is adequate expertise to provide appropriate ethical and scientific review of the study(ies) in question.

3.1.4. An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.

3.1.5. Ad hoc advisors attend to participate in REB deliberations, but will not be used to establish a quorum nor be allowed to vote on REB decisions. CAN/CGSB-191.1-2013 – (4.3.2.6)

3.1.6. No votes will be taken without a quorum.

3.1.7. Observers: The REB may allow observers to attend meetings. Observers shall not participate when the REB discusses its decisions, reaches consensus or votes on the application. Observers shall sign a confidentiality agreement prior to the REB meeting and maintain the confidentiality of the REB proceedings. If the REB finds that the observer has the necessary qualifications or expertise in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to discussion CAN/CGSB-191.1-2013 – (4.4.4.4.12)

3.2. Full Review

All REB members are expected to review all submission documentation prior to the meeting. The same expectation applies to amendments and annual renewals that are required to be reviewed by the full board in accordance with regulatory or sponsor requirements.

Written comments from absent members shall be allowed to inform the consideration of an application but only members participating in the meeting shall participate in any vote or decision. CAN/CGSB-191.1-2013 – (4.4.4.4.7)

3.2.1. Meeting Materials Sent Prior to REB Meetings

All REB members will be sent study documentation required for review in sufficient time prior to the meeting to allow for adequate review. These include:

Agenda: A meeting agenda will be prepared by the REB administrator and distributed to REB members

prior to each meeting. A copy of the agenda and attached materials will be maintained on file with the meeting minutes.

Reviewer materials: All REB reviewers receive all documentation relevant to each application, including:

- Holland Bloorview Research Ethics Board Application Checklist
- TAHSN Human Subjects Research Application Form
- Proposed informed consent form(s)
- Proposed assent form(s)
- All participant data collection forms including participant diaries
- Complete research protocol (if new)
- Detailed budget sheet
- Non-standardized questionnaires & assessment instruments
- Investigator's Brochure (if required)
- Any other supporting material, such as examples of recruitment advertising or any additional information given to the participant
- Science Review Form including an itemized response from the investigator (or equivalent)

3.3. Minutes

3.3.1. Recording: Designated REB Office staff will take minutes of each meeting. Minutes will be written in sufficient detail to show the following:

- Meeting attendance; presence of any ad hoc reviewers, guests or observers;
- Declarations of conflicts of interest and recusals, if any;
- Actions taken by the REB on each agenda item requiring full REB action, including, the basis for disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- Documentation regarding the expertise and contributions to REB discussions by observers in attendance;
- Voting results, including for, against (if applicable) and members who abstain from voting (for clinical trials).

Documentation and Document Management - See Policy REB-304

Criteria for approval – See Policy REB-403 (Initial Approval) and Policy REB- 405 (Continuing Review)

Health Canada Food and Drugs Act, Div 5/ICH GCP CAN/CGSB-191.1-2013 – (4.4.4.4.12)

45 CFR 46.115

CAN/CGSB-191.1-2013 – (4.5.3.3)

In the case of US federally funded or regulated studies, the minutes will reflect that the following criteria required to approve the research are satisfied:

- Risks to participants are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) when appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes. 45 CFR 46.111
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
- Selection of participants is equitable.
- Informed consent will be sought from all prospective participants or their legally authorized representative.
- Informed consent will be appropriately documented.
- When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the participants.
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these participants.

3.3.2. Approval: Minutes will be distributed to members prior to the next REB meeting for review and approval.

Corrections requested by the REB at the next meeting will be noted in the minutes of that meeting and the minutes with corrections (if any) will be approved. REB Office staff will amend the prior meeting minutes in accordance with the approval. The REB Chair shall sign and date the final approved minutes.

The REB Office will maintain copies of the approved

minutes, as well as the agenda and pertinent materials on file (e.g. observer confidentiality agreements).

3.3.3. Record Retention: The REB office will retain all relevant records (written procedures, membership lists, lists of occupations/affiliation of members, submitted documents, minutes of meetings and correspondence for a period of at least 7 years after the completion of a study/trial and make them available upon request from the regulatory authorities for non regulated trials. For regulated trials the REB Office will retain all relevant records for 25 years.

Health Canada Food and Drugs Act, Div 5

ICH GCP 3.4

CAN/CGSB-191.1-2013 – (4.5.4.1)

3.4. Meetings and Attendance:

3.4.1. Convened meeting :

REB meetings are to be face-to face in order for there to be appropriate discussion of research projects.

TCPS2 Article 6.10

Attendance by REB members at meetings is of the utmost importance and frequent absences will be construed as notice of resignation.

3.4.2. Convened meeting using speaker phone or remote contact

In unusual circumstances, should a member not be able to be physically present during a convened meeting, but be available by telephone, or video-conference link, the meeting can be convened using a speaker phone or videoconference link. The member who is not physically present will be connected to the rest of the members via speakerphone or video-conference link. In this manner, all members will be able to discuss the protocol. Members participating by such speakerphone call may vote provided they have had an opportunity to review all the material the other members have reviewed. Remote participation by members will be documented in the minutes of the REB meeting.

TCPS2 Article 6.21

CAN/CGSB-191.1-2013 – (4.4.4.4.3)

3.4.3 Meeting Conducted Via Telephone Conference Calls

Under very unusual circumstances (e.g. public health alerts and quarantines) the Chair may, at his/her discretion, convene an REB meeting via telephone

conference call. A quorum (as defined in 3.1 above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place – "telephone polling" (where members are contacted individually) will not be accepted as a conference call. This will be recorded in the minutes of the REB meeting.

3.5. Approval by Consensus

Members of the REB generally approve studies by consensus, which is noted as a unanimous vote in the REB minutes. Where consensus is not achieved the decision will be made by majority vote, with the minutes reflecting who was opposed to the majority decision. The REB may make determinants as described in Policy REB-404. Members also will determine the level of risk, the frequency of review for each protocol, appropriate monitoring, and whether third party assessment and follow up will be needed.

CAN/CGSB-191.1-2013 – (4.4.4.4.5)

45 CFR 46 115 (a)(2)

Exception for US Federally Funded and FDA Regulated Research

If the REB is reviewing a study that is funded by the US Federal Government or that is subject to the US Food and Drug Administration Regulations, study approvals shall be made by a formal counted vote specifying the number of REB members present at the time of approval, the number of members voting for, against and abstaining. The votes will be recorded in the minutes in the following format as an example:

Total = 8; Vote: For – 7, Opposed – 0, Abstained-1.

Revision History

V3/August 2013: Changed 'REB Manager' to 'REB office staff' to accommodate growth and job title changes within the REB administrative office. Subparagraph 3.1.1: Correction made to reference REB-201 (was REB-202) for meeting quorum requirements.

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 3.2: clarified that members absent from a convened meeting can provide their written comments. Revised section 3.1.5: clarified that ad hoc advisors are not permitted to vote. Added section 3.1.7: added information about observers attending REB meetings and the scope of their participation. Revised section 3.3.1: added that if observers with subject matter expertise provide their opinion during meetings, that it will be documented within the minutes.