Holland Bloorview
Kids Rehabilitation Hospital

	REB REVIEW OF RESEARCH		
POLICY: REB-409	**AMENDMENT REQUEST**		
This policy pertains to:	The activities of researchers operating under the authority of the Bloorview Research Institute and 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:**	V2:January 2012
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

The purpose of this SOP is to describe the policy for amendment request review by the Holland Bloorview REB.

2. POLICY

Researchers must not deviate from or make changes to an REB-approved protocol without prior written approval of an amendment or as requested by the Holland Bloorview REB except where subject safety is at risk.

3. SPECIFIC POLICIES

An amendment is a permanent intentional action or process that revises/amends/modifies a previously approved research protocol.

Changes in approved research may not be initiated without prior REB review and approval **except** where necessary to eliminate apparent immediate hazards to human participants or researchers, or to implement minor logistical or administrative amendments such as changes to contact information for research staff. Refer to Policy REB- 406 when researchers are required to implement protocol deviations that eliminate immediate hazards to humans or make inadvertent changes prior to REB approval.

3.1 Amendment Submission Requirements

Local PIs must submit amendments for REB approval using the REB Amendment Request Form. The amendment request must include, but not be limited to, the following explanations:

- What changes are being requested
- Rationale for the changes
- What aspects of and how the protocol, consent form,

REFERENCES

TCPS 2, Article 6.14

Health Canada Food and Drugs Act, Div 5
ICH-GCP 3.2

45CFR46.103(b)(4)(iii)
21CFR56.108(a)(3)(4)

information sheet and/or recruitment materials are affected.
- The revisions must be highlighted on an attached, revised document.
- Any increase in risk or discomfort for study participants and why it is required
- Any need for a change in the consent process
- Whether previously or currently enrolled study participants need to be re-consented.
- Whether or not the amendment meets minimal risk criteria

3.2. Amendment Review Procedure

TCPS2, Article 6.16

FDR C.05.012(g)

CAN/CGSB-191.1-2013 – (4.4.6.2), (4.4.6.3)

Amendments may be reviewed under the delegated review procedure at the discretion of the REB Chair, provided that the proposed changes are minor or administrative in nature, and/or the amendment does not involve increased risks to the study participants such that the study would no longer meet the criteria for minimal risk as outlined in Policy REB-402. If the proposed change represents more than minimal risk, or affects the rights, safety, or well-bring of the research participant or the integrity of the study, it must be reviewed by the full REB at a convened meeting and must meet all REB criteria for approval.

3.2.1. The following types of amendments for previously approved studies must be referred to the Full Board for review.

- Addition of genetic testing, new types of genetic tests, or biobanking where genetic testing may, or will be performed;
- Addition of an open label extension phase following a randomized trial;
- Emergency amendments that arise because of participant safety concerns that are submitted after implementation, and:
- Significant changes to a protocol that may affect participant safety and may include (but are not limited to) a:
    - Change in drug dosing/duration of exposure
    - Change that affects the selection, monitoring or withdrawal of research participants
    - Change in recruitment technique that may affect confidentiality or the perception of coercion
    - Change that extends the duration of participation in the study
    - Change in protocol (e.g. change that affects the evaluation of the clinical efficacy or safety

evaluation of the investigational product or intervention)
    - Change in study population or sample size
- Any amendment for a regulated clinical trial that requires approval from Health Canada including
    - Amendments to the protocol that affect the selection, monitoring, or dismissal of a clinical trial participant
    - Amendments to the protocol that affect the evaluation of the clinical efficacy of the drug
    - Amendments to the protocol that alter the risk to the health of a clinical trial participant
    - Amendments to the protocol that affect the safety evaluation of the drug
    - Amendments to the protocol that extend the duration of the clinical trial
    - Amendments to the chemistry and manufacturing information that may affect the safety or quality of the drug.

3.2.2. For studies that are funded or supported by other authorities such as the US Federal government and are subject to the regulations of the US Food and Drug administration, only minor changes in previously approved research may be reviewed by the REB under delegated review procedures.

45CFR46110(b)(2)
21CFR56.110(b)(2)

Revision History

V3/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 amendment requests that affect the rights, safety or well-being of a participant or that affect the integrity of a study must be reviewed at the full board. Revised section 3.2.1: added examples of significant changes to the protocol that, may affect participant safety that must be reviewed at a full board meeting.