Holland Bloorview
Kids Rehabilitation Hospital

	Review of Research		
POLICY: REB-402	**DELEGATED REVIEW**		
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:**	V2: January 2012
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

REFERENCES

The purpose of this SOP is to describe the research that can be reviewed by the REB Chair or designate and outlines the process to determine if the research meets criteria for delegated review.

2. POLICY STATEMENT

Full REB review is the default requirement for all research involving human participants at Holland Bloorview. However, the proportionate approach to REB review is intended to direct the most intensive scrutiny, time and resources, and the greatest protection to the most ethically challenging research. Consequently, regulations allow for delegated review based on minimal risk to participants and researchers that expected to arise from the research.

Health Canada Food and Drugs Act, Div 5
ICH GCP E6
CAN/CGSB-191.1-2013 – (4.4.4.3.1)

Proportionate Approach – see TCPS2, Article 2.9 and Article 6.12

A delegated review consists of a review of research involving humans by the REB Chair or designate, the REB Coordinator (or other REB Office staff appointed to the REB), and by other REB members designated by the Chair.

CAN/CGSB-191.1-2013 – (4.4.4.1.1), (4.4.6.4)

Research that may be reviewed through a delegated review procedure includes research that presents no more than minimal risk to participants and requires no more than minor changes to approved research. Delegated review procedures may also be used for research that has received approval from another primary REB that adheres to the mandatory requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)* or equivalent. As described below, special considerations for delegated reviews involving vulnerable populations are necessary even if the risk to participants is minimal.

CAN/CGSB-191.1-2013 – (4.4.4.5.1)
CAN/CGSB-191.1-2013 – (4.3.4.6)

3. SPECIFIC POLICIES

3.1 CRITERIA AND PROCESS FOR DELEGATED REVIEW

3.1.1 Definition of Minimal Risk

Minimal Risk – see TCPS2 page 23

Minimal risk research is defined as research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of everyday life that relate to the research.

3.1.2 Definition of Minor Change

Minor changes to REB approved research are amendments that do not increase the risk, materially change the risk-benefit ratio of the research study, increase the vulnerability of participants, or substantially change the specific aims or design of the study.

3.1.3 Special Considerations Regarding Participant Vulnerability and Minimal Risk

Individuals or groups in vulnerable circumstances typically include children, those with substantive cognitive or communication impairments, and others with diminished capacity for self-determination. Participant vulnerability in the context of a research project often results from limited capacity, or limited access to social goods, such as rights, opportunities, and power.

CAN/CGSB-191.1-2013 – (4.4.4.2.14)

The REB has special ethical obligations to protect individuals or groups whose situation or circumstances make them vulnerable and those who live with relatively high levels of risk on a daily basis. The level of vulnerability is judged by the REB Chair or designate in consultation with the investigative team who proposes the research. As such, the type of REB review based on risk level and participant vulnerability shall be guided by the decision matrix below.

Scenario 1: Holland Bloorview clients, family members, or other human participants are recruited by researchers. The primary REB may or may not be the Holland Bloorview REB.

		Participant Vulnerability	
		low	high
Health Risk	minimal	Delegated 'A': Chair or designate + REB coordinator	Delegated 'B': Chair or designate + REB coordinator + one other REB member
	greater than minimal	Full REB	Full REB

Scenario 2: Participants are not recruited through Holland Bloorview and the primary REB is not the Holland Bloorview REB.

		Participant Vulnerability	
		low	high
Health Risk	minimal	Delegated 'A': Chair or designate + REB coordinator	Delegated 'A': Chair or designate + REB coordinator
	greater than minimal	Delegated 'A' Chair or designate + REB coordinator	Delegated 'A' Chair or designate + REB coordinator

3.2 Authority of the Reviewer

The REB Chair or designate may exercise all of the authorities of the REB, except that he/she may not disapprove the research. A research proposal may be disapproved only after follow-up review by the full REB. If the delegated reviewers cannot reach a unanimous decision concerning the application, the application as submitted shall be referred for review at a convened REB meeting.

CAN/CGSB-191.1-2013 – (4.4.4.3.1), (4.4.4.5.2), (4.4.4.5.3)

3.3 Other Processes Eligible for Delegated Review

3.3.1 Approvals with Modifications

REB required revisions to consent forms and application documents, and responses submitted by the investigator

CAN/CGSB-191.1-2013 – (4.4.4.4.11)

following full REB review may undergo delegated review by the REB Chair or designate and/or other REB members as necessary.

3.3.2 Amendments

Amendments to REB approved research may be assigned a delegated review procedure only if the investigator requests no more than minor changes during the period for which approval has been authorized.

3.3.3 Annual Renewals

The REB Chair or designate may use the delegated review procedure to review and approve annual renewal requests provided there are no more than minor changes noted.

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3.3.4 Adverse Event Reports, Unanticipated Problems and Safety Updates

Adverse event reports, protocol deviations, unanticipated problems and safety updates such as reports from Data Safety Monitoring Committees may be reviewed by the Chair or his/her designate. If the REB Chair or designate considers that action is needed to protect the safety of research subjects, he/she may take such action immediately and/or request a full review of the report at the next REB meeting.

3.4 Notification of the Board

When the delegated review process is used, all REB members shall be informed of actions taken by the REB Chair or designate. Delegated review actions and the rationale for this type of review must be documented in the agenda and minutes of the next REB meeting.

CAN/CGSB-191.1-2013 – (4.4.4.5.4)

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 2.: clarified that other REB office staff may perform delegated reviews. Revised section 3.2: clarified that if delegated reviewers do not reach a unanimous decision regarding approval, the study will be referred to a convened REB meeting.