

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

	GENERAL ADMINISTRATION		
POLICY: REB-103	POLICIES AND PROCEDURES MAINTENANCE		
This policy pertains to:	Holland Bloorview REB staff and members		
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

The purpose of this SOP is to state the REB’s commitment to maintain, and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles regarding the conduct of research with human subjects.

REFERENCES

2. POLICY STATEMENT

Following regulations and guidance of Canada’s Food and Drugs Act & Regulations, ICH- GCP, and Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, National Standard of Canada, Research Ethics Oversight of Biomedical Clinical Trials (CAN/CGSB-191.1-2013, supported by institutional policies, assures that the rights and welfare of the human participants will be overseen and protected in a uniform manner, regardless of changes in personnel. Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects, from initial application to study completion and for the adequate documentation of such oversight.

Health Canada Food and Drugs Act, Div 5
ICH-GCP 3.3

45 CFR 46. 103(4)

21 CFR 56. 108(a)

CAN/CGSB-191.1-2013 – (4.5.2.1)

CAN/CGSB-191.1-2013 – (4.4.1.1)

Standard operating policies (SOPs) or policies and procedures provide the framework for the ethical and scientifically sound conduct of human trials research.

3. SPECIFIC POLICIES

3.1. Review, Revision, Approval of Policies and Procedures

3.1.1. Changes to regulations, federal or international ethical guidelines, or research practice as well as the policies and procedures of Holland Bloorview may require a new policy or a revision to a previously issued policy.

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3.1.2. Policies will be reviewed by the appropriate institutional official(s) at intervals established by the Chair of the REB and REB Office staff, and reported to the Board of Directors through the RTLAC.

3.1.3. Approval of new or revised Policies is required by the Chair of the REB on behalf of the REB, and the RTLAC

3.2. Policy Dissemination and Training

REB SOPs are accessible internally and externally through the Holland Bloorview REB website.

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3.2.1. When new or revised policies are approved, they will be disseminated (via email or at BRI business meetings) to the appropriate individuals and departments. Dissemination activities will be documented in REB meeting minutes.

3.2.2. Training will be provided to all members of the REB and REB staff on any new or revised policy and or relevant procedure and documented in the REB meeting minutes for inspection purposes.

CAN/CGSB-191.1-2013 –
(4.3.2.7)

3.2.3. Each new REB member or staff employee must review all applicable policies prior to undertaking any responsibilities at the REB. Confirmation of training will be documented in the REB SOP training log.

3.3. Forms

Forms are used to 1) ensure that policies are integrated into the daily operations of research and review throughout Holland Bloorview; and 2) enable REB staff to manage review, tracking, and notification functions consistently.

Revision History

V3/July2014: 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 review and oversight occurs from initial application to study completion. Revised section 3.2: added that REB SOPs are available through the REB website. Revised section 3.2.1: clarified how new policies will be disseminated. Revised section 3.2.2 and 3.2.3: clarified how REB training for new policies will be documented.