Holland Bloorview
Kids Rehabilitation Hospital

	GENERAL ADMINISTRATION		
POLICY: REB-101	**AUTHORITY AND PURPOSE**		
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		

1.0 PURPOSE

REFERENCES

The purpose of this SOP is to:

1. State the institutional authority under which the REB is established and empowered.
2. Define the purpose of the REB.
3. State the principles governing the REB to assure that the rights and welfare of subjects are respected and protected.
4. State the authority of the REB.
5. Define the independent relationship of the REB to other committees and to officials within the Hospital and University system.

2.0 POLICY STATEMENT

2.1. Statement of Institutional Authority

CAN/CGSB-191.1-2013 – (4.2.1.1), (4.2.2.1)

The Holland Bloorview Research Ethics Board (REB) is established and empowered under the authority of the Board of Trustees through the Research, Teaching & Learning Advisory Committee (RTLAC). Holland Bloorview requires that all research projects involving humans as participants, including their data and biological samples, be reviewed and approved by the REB prior to initiation of any research related activities, including recruitment, screening activities and enrolment.

2.2. Purpose of the REB

Food an d Drugs Act – Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials), Division 5 Drugs for Clinical Trials Involving Human Subjects

Health Canada Food and Drugs Act, Div 5, C.05.001/ ICH Harmonized Tripartite Guidelines, Good Clinical

The REB's purpose is to protect the rights and welfare of human participants in research studies conducted at Holland Bloorview and by researchers based at Holland Bloorview. The REB reviews and oversees such research to assure that it meets ethical principles and that it complies with all applicable regulations and standards pertaining to human

subject protection. These include but are not limited to Health Canada's Food and Drugs Act, the International Conference on Harmonization Good Clinical Practice: Consolidated Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, National Standard of Canada, Research Ethics Oversight of Biomedical Clinical Trials (CAN/CGSB-191.1-2013, and to the extent applicable, US Federal Regulations.

Practices

Tri-Council Policy Statement on Research Involving Humans 2 (TCPS2)

45 CFR 46
21 CFR 56

2.3. Governing Ethical Principles

The REB is guided by the ethical principles regarding all research involving humans as participants as set forth in the Tri-Council Policy Statement 2: Ethical Conduct of Research Involving Humans, as follows:

TCPS2

Holland Bloorview REB Terms of Reference

Respect for Persons which recognizes the intrinsic value of human beings and the respect and consideration that they are due; considers how people of all ages are treated as research participants; incorporates the moral obligations to respect autonomy; and protects those with developing, impaired or diminished autonomy.

Concern for Welfare which considers the impact on individuals of factors including physical, mental and spiritual health, as well as their physical, economic and social circumstances; encompasses factors including privacy and control of information about the person and the assessment of foreseeable risks and benefits; and the treatment of data and human biological materials according to the free, informed and ongoing consent of the person who was the source of the information and materials.

Justice which recognizes the obligation to treat people fairly and equitably.

2.4. REB Authority

2.4.1. The Holland Bloorview REB is established to review research involving human participants that is conducted by Holland Bloorview faculty, staff and students, or anyone conducting research at or under the auspices of Holland Bloorview. This policy applies to funded and non-funded research involving human participants.

Holland Bloorview REB Terms of Reference

2.4.2. The Holland Bloorview REB has the authority to

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ensure that research is designed and conducted in such a manner that it protects the rights and welfare and privacy of research participants. Specifically: (4.2.3.1), (4.2.3.2)

- The REB has the authority to approve, require modification to, or disapprove, any research activity that falls within its jurisdiction.
- The REB has the authority to conduct continuing ethical review as it deems necessary to protect the rights and welfare and privacy of research subjects. Continuing review activities include, but are not limited to, CAN/CGSB-191.1-2013 – (4.4.6.9)
    - review of progress reports,
    - review of changes in the design or conduct of the study prior to implementation,
    - review of serious adverse events,
    - monitoring to determine that the study is conducted as approved,
    - observation of the informed consent and assent processes, and
    - any other review procedures deemed to be necessary to protect the rights and welfare of human participants.
- The REB may suspend or terminate approval of a study. If this occurs, the communications to the LPI shall include a clear statement of the reasons for that decision. CAN/CGSB-191.1-2013 – (4.4.5.7)
- The REB may place restrictions on a study.

3.0 SPECIFIC POLICIES

3.1 Federally funded research

All federally-funded protocols involving human participants must be reviewed by the Holland Bloorview REB before the expenditure of any grant funds. Memorandum of Understanding between Holland Bloorview Kids Rehabilitation Hospital and the Canadian Federal Granting Authorities

3.1.1 US Federally Funded Research

If a study is funded or supported by the US Federal government and/or is a clinical investigation regulated by the US Food and Drug Administration, the provisions of those regulations, to the extent applicable to the REB and to the study will apply. The provisions of those regulations are specifically not extended to any other research reviewed by the Holland Bloorview REB. 45 CFR 47
21 CFR 56

3.2 Relationship of the REB to Hospital officials and other committees

3.2.1 The Board of Trustees, the Research, Teaching & Learning Advisory Committee (RTLAC), or any other administrative body within Holland Bloorview cannot override decisions made by the REB. However, these bodies retain the authority to deny the implementation of REB-approved research protocols for reasons other than research ethics (such reasons may be administrative, programmatic, or resource-based in nature). Further, those entities may not approve research if it has been disapproved by the REB.

Holland Bloorview REB Terms of Reference

CAN/CGSB-191.1-2013 – (4.2.2.5)

3.2.2 The REB functions independently of the hospital.

The Holland Bloorview REB uses common research ethics application forms created for the Toronto Academic Health Sciences Network (TAHSN) but maintains an independent review and approval mechanism.

3.3. Use of Policies and Procedures

The REB will maintain and follow all written policies and procedures consistent with federal and provincial regulations, good clinical practice, and ethics guidelines when reviewing, approving, and monitoring research activities conducted at Holland Bloorview or by its researchers.

3.4 Authorization

The Vice-President of Research, reporting through to the CEO and The Board of Trustees, has authorized the Holland Bloorview REB to review, approve/disapprove, and monitor research involving human participants that is conducted by Holland Bloorview researchers, clinical staff and students.

CAN/CGSB-191.1-2013 – (4.2.2.1)

Revision History

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 2.4.2: added that communications for suspension or termination of REB approval must indicate the reasons for such a decision.