Holland Bloorview
Kids Rehabilitation Hospital

	REB REVIEW OF RESEARCH		
POLICY: REB-411	**REB Review Involving Multiple Study Sites**		
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 designee)		
Approval authority:	Research, Teaching & Learning Advisory Committee (RTLAC) of the Holland Bloorview Board of Trustees		
Effective date:	V1: May 2015	**Superseded document date:**	
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the Research Ethics Board (REB) review procedures for research conducted by researchers at or under the auspices of Holland Bloorview that may involve multiple study sites and/or multiple REBs.

2. POLICY STATEMENT

Research involving human participants, data from participants or human biological materials may require the involvement of multiple institutions, sites and/or REBs in multiple jurisdictions. This includes, but is not limited to, the following situations:

a) a research project conducted by a team of researchers affiliated with different institutions;
b) several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;
c) a research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting participants at different institutions;
d) a research project conducted by a researcher who has multiple institutional affiliations (e.g. a university and a hospital);
e) a research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g. statisticians);
f) a research project that researchers conduct in another province, territory or country.

Holland Bloorview (HB) may use alternative ethics review models for research involving multiple REBs and/or institutions. However, HB remains responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction or under its

REFERENCES

Tri-Council Policy Statement on Research Involving Humans (TCPS2)
Chapter 8, Section A

TCPS2 Article 8.1

Holland Bloorview REB Terms of Reference

auspices irrespective of where the research is conducted.

CAN/CGSB-191.1-2013
(4.2.2.3) (4.2.2.5)

The Holland Bloorview REB (HBREB) may use joint REB review, rely upon the review of another qualified REB, or make similar arrangements to avoid duplication of effort.

U.S. Code of Federal Regulations
Title 21 Part 56.114

3. DEFINITIONS

Formal relationship: Means that HB has executed agency and study specific REB of Record agreements and, in the case of US Food and Drug Administration regulated and US government funded research studies, has registered the qualified external REB under its Federalwide Assurance. Once the relationship is established, the institution may delegate a qualified external REB as the REB of Record on a study by study basis.

Multi-jurisdictional research: Research involving multiple institutions and/or multiple REBs. It is not intended to apply to ethics review mechanisms for research involving multiple REBs within the jurisdiction or under the auspices of a single institution.

Research: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Research Ethics Board (REB): A body of researchers, community members and others with specific expertise established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.

Qualified Research Ethics Board: An externally-audited REB that adheres to a minimum standard for REB governance, membership, operations and procedures as detailed in accepted qualification manuals or accreditation standards.

Board of Record: The REB that has been delegated authority by an institution for the ethics review and ethical oversight of research conducted at that institution.

4. SPECIFIC PROCEDURES

4.1. Independent Ethics Review by Several REBs

4.1.1 The REBs involved at each participating institution conduct an independent ethics review and provide their separate decisions, either concurrently or sequentially. The level of ethics review is proportionate to the risk involved in the research: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher level of risk, the higher the level of scrutiny (full board review).

TCPS2 Article 8.1

Article 6.12

4.1.2 Researchers shall provide the name and contact information of the other REBs that will also review the project to facilitate direct communication between the REBs, and help resolve disagreements that may arise.

Article 8.1

4.1.3 The HBREB may request a written copy of the ethics review conducted by the other REB(s).

4.2 Research Ethics Review Conducted by Qualified External REBs

4.2.1 HB may establish formal relationships to assign responsibility to an external, qualified REB as the Board of Record on a study by study basis.

TCPS2 Article 8.1

CAN/CGSB-191.1-2013 (4.2.2.3)

4.2.2 Formal agreements shall clearly define the roles and responsibilities between the institution delegating the review and the institution of the REB that will review the ethical acceptability of the research.

4.2.3 Where relevant, agreements should specify how the external REB will assure familiarity with vulnerable populations.

4.2.4 Once formal agreements are established, an external Board of Record may review and approve research that falls within the scope of its review.

4.2.5 The HB Local Principal Investigator (LPI) must submit an electronic copy of the Board of Record Study Agreement and REB approval letter to the Bloorview Research Institute Operations Office before the research may be initiated by the HB LPI.

4.2.6 The Board of Record will maintain responsibility for

continuing review and ethical oversight of the study at all sites.

4.3 Research Ethics Review by HBREB as the Board of Record

4.3.1 HB may establish formal relationships to allow the HBREB to act as the qualified Board of Record for external institutions on a study by study basis.

4.3.2 The HBREB may decline to act as the Board of Record for reasons including, but not limited to, a lack of expertise in REB membership and an inability to review the submission within the timeframe requested.

4.3.3 The HBREB will conduct multi-site reviews and approvals in accordance with its written standard operating procedures. The HBREB may make discretionary accommodations for site specific requests provided these do not compromise the safety and welfare of research participants and are consistent with relevant government policies and regulatory requirements.

4.3.4 The HBREB will maintain responsibility for the continuing review and ethical oversight of the study at all sites.

Revision History