Holland Bloorview
Kids Rehabilitation Hospital

	GENERAL ADMINISTRATION		
POLICY: REB-102	**ACTIVITIES REQUIRING REB 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

The purpose of this SOP is to describe specific research activities that require REB review and, conversely, those activities that do not require REB review.

2. POLICY STATEMENT

All research involving human participants (as defined below), and all other activities which even in part, involve such research, regardless of sponsorship, must be reviewed and approved by the Holland Bloorview REB. No intervention or interaction with human participants in research, including recruitment, may begin until the REB has reviewed and approved the research protocol, recruitment materials, and consent/assent documents. Specific determinations as to the definition of "research" or "human participants", and their implications for the jurisdiction of the REB under Holland Bloorview policy are determined by the REB Chair or designate. Determination of exemption from REB review must be based on regulatory and institutional criteria.

REFERENCES

Holland Bloorview REB Terms of Reference

Tri-Council Policy Statement on Research Involving Humans 2 (TCPS2) Article 6.11

3. SPECIFIC POLICIES

3.1. Activities that require REB Review

Research is defined as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation." The following requires ethics review and approval by an REB before the research commences:

a. research involving living human participants
b. research involving human biological material as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

TCPS2, Article 2.1, Article 6.11

Health Canada Food and Drugs Act, Div 5, C.05.010d

Examples of types of research involving human participants include:

- administering a drug, taking a blood sample, doing a test or performing a procedure, clinical, therapeutic or otherwise, upon the person of himself/herself or someone else, for research rather than treatment;
- asking people information whether by telephone, letter, e-mail, internet, survey, questionnaire or interview;
- using material derived from biological samples, cadavers, tissues, biological fluids, embryos or fetuses,
- using non-public records that contain identifying information previously gathered about anyone, either directly or indirectly;
- use information previously gathered about anyone (e.g., secondary data analysis);
- observing anyone's responses or behaviour, either directly or indirectly.

All research involving people (clients and their family members, staff, students or members of the community), all research involving tissues, fluids or cadaveric remains, all research in which access to human participants involves any records maintained by Holland Bloorview, and all research involving data collected from human participants which is to be carried out by researchers or staff with appointments at Holland Bloorview, or their students, shall be reviewed and approved in advance by the REB. All research that involves living human subjects, human remains, cadavers, tissues, biological fluids, embryos or fetuses shall be reviewed by the REB.

3.2 Research Exempt from REB Review

TCPS2, Article 2.2.

Research activities that rely exclusively on publicly available information do not require REB when:

a. the information is legally accessible to the public and appropriately protected by law; or
b. the information is publically accessible and there is no reasonable expectation of privacy

TCPS2, Article 2.3

Research activities involving the observation of people in public places do not require REB when:

a. it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
b. individuals or groups targeted for observation have no

reasonable expectation of privacy; and

c. any dissemination of research results does not allow identification of specific individuals

Research activities that rely exclusively on secondary use of anonymous information or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information, do not require REB.

TCPS2, Article 2.4

3.3. Activities Not Requiring REB Review

Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB.

TCPS2

- Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

TCPS2, Article 2.5

- Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

TCPS2, Article 2.6

3.4. Failure to Submit Project for REB Review

The implications of engaging in activities that qualify as research without obtaining REB review are serious. Results from such studies may not be published unless REB approval was obtained prior to collecting the data. In addition, conducting research without REB approval can constitute research misconduct in accordance with the provisions of the Tri-Agency Framework: Responsible Conduct of Research. It is also against policy to use data derived from unapproved research protocols to satisfy thesis or dissertation requirements unless deemed exempt from REB review.

Tri-Agency Framework: Responsible Conduct of Research, Articles 2.4 and 6.1.4.

If an investigator begins a project and later finds that the data gathered could contribute to generalizable knowledge, and has changed in some fashion that requires further REB review, or that the researcher may wish to publish the results, the

investigator must submit a proposal to the REB for review as soon as possible. If the REB does not approve the research, data collected cannot be used as part of a study, thesis or dissertation nor may the results of the research be published.

Revision History

V3/July2014: changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee.