Holland Bloorview
Kids Rehabilitation Hospital

	REB REVIEW OF RESEARCH		
POLICY: REB-403	**INITIAL REVIEW – CRITERIA FOR REB APPROVAL**		
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 document date:**	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 minimal requirements that all research proposals that involve human participation must meet in order to be approved for conduct at or under the auspices of Holland Bloorview.

2. POLICY

All research proposals that intend to enroll human participants must meet specific criteria before study related procedures can be initiated. The criteria are based on the guiding ethical principles of the Tri-Council Policy Statement 2, ICH Good Clinical Practice Consolidated Guideline E6 (Health Canada), CGSB standard, and FDA Regulations and are specified below.

Health Canada Food and Drugs Act, Div 5/ICH GCP

TCPS2

CAN/CGSB-191.1-2013

3. SPECIFIC POLICIES

REFERENCES

3.1 Minimal criteria for approval of research

In order for a research project to be approved, the REB must find that:

a) The Local Principal Investigator (LPI) (and his/her research team) has the credentials to conduct the research.
b) There are no conflicts of interest which will compromise the safety or well-being of participants.
c) The research will generate knowledge that could lead to improvements in health or well-being.
d) The methodology is scientifically sound and capable of answering the research question.

45 CFR 46.111
21 CFR 56.111

CAN/CGSB-191.1-2013 – (4.4.4.2.5) , (4.4.4.2.6)

Health Canada Food and Drugs Act, Div 5/ ICH GCP, Article 4.1.1

CAN/CGSB-191.1-2013 – (4.4.4.2.2), (4.4.4.2.3),(4.4.4.2.4 (c))

TCPS2, Chapter 7, Article 1.1, 2.7

e) Risks to participants are minimized:
   (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and
   (ii) Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

TCPS2 Article 1.1
45 CRF46.11 1ai
45 CRF46.11 1aii

f) Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the REB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies those participants would receive even if not participating in the research).

TCPS2 chapter 2B
45 CFR46.111(a)(2)

g) Selection of participants is equitable. In making this assessment, the REB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable or often marginalized populations, including children who do not have the capacity to consent and/or those who use alternate forms of communication.

TCPS2 Article 1.1
TCPS2, Chapter 4
45 CFR46.111(a)(3)
CAN/CGSB-191.1-2013 – (4.4.4.2.7)

h) Recruitment methods which respect the privacy of individual participants must be followed. Except under unusual circumstances, only members of the person's healthcare team may approach the person regarding interest in participation in the study.

TCPS2 Chapter 5A
45 CFR46.111(a)(7)

i) Informed consent will be sought from each prospective participant or the participant's substitute decision maker, in accordance with local, provincial and national guidelines or regulations.

TCPS2 Article 1.1, 3.1, 3.2
45 CFR46.111(a)(4)
ICH GCP, Article 4.8.10
CAN/CGSB-191.1-2013 – (4.4.4.2.8), (4.4.4.2.12)

j) Informed consent will be appropriately documented as required by local, provincial and federal regulations.

TCPS2 Article 3.12
45 CFR46.111(a)(5)

k) Assent will be appropriately documented as required by REB directives.

l) Any waiver or alteration of the informed consent process will be properly justified and documented.

TCPS2 Article 3.7

m) Where appropriate, the research plan makes adequate provision for on-going monitoring of the data collected to ensure the safety of participants.

TCPS2 Article 2.8
45 CFR46.111(a)(6)
CAN/CGSB-191.1-2013 – (4.4.6.8)

n) Where appropriate, there is adequate provision to protect the privacy of participants and to maintain the confidentiality of data.

TCPS2 Chapter 5
45 CFR46.111(a)(7)
CAN/CGSB-191.1-2013 – (4.4.4.2.4 (f))

o) When some or all of the participants, such as children, are likely to be vulnerable to coercion or undue influence or international sites are used, additional safeguards have been included in the study, and in the

TCPS2 Article 1.1, 8.3, 8.4, 3.9, 4.6
45 CFR 46.111(b)
CAN/CGSB-191.1-2013 – (4.4.4.2.14)

REB review process to protect the rights and welfare of these participants.

p) The resources required for successful completion of the study are committed (e.g., funding, space, personnel, etc.).

3.2. Other Criteria

The REB may require verification of information submitted by an investigator. The need to verify any information will be determined by the REB at a convened meeting. The purpose of the verification will be to provide necessary protection to participants when deemed appropriate by the REB.

3.3. Discrepancies

In some instances, the REB may find that there are discrepancies among good clinical practices, statutory or regulatory requirements or ethical considerations that the REB must evaluate during its review. The REB shall attempt to strike a balance between the compliance with applicable regulatory and ethical requirements for ensuring the protection of the rights, safety and well-being of research participants. When discrepancies are encountered, the REB shall document the rationale for its decisions in writing either in the REB meeting minutes or in the specific REB study file.

CAN/CGSB-191.1-2013 – (4.4.1.2)

3.4. US Federally Funded Research

For research that is subject to the provisions of 45 CFR 46 or 21 CFR 56, the REB shall consider the listed criteria in the applicable regulations, to the extent that they differ from or vary the criteria noted in 3.1.

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. Added section 3.3: described the process for documenting the rationale for REB decisions should discrepancies between applicable regulatory and ethical principles occur.