Holland Bloorview
Kids Rehabilitation Hospital

	Functions and Operations		
POLICY: REB-301	**RESEARCH ETHICS BOARD SUBMISSION REQUIREMENTS**		
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:**	V3: August 2013
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

The purpose of this SOP is to outline the documents and supporting information required from investigators for Research Ethics Board (REB) submission at Holland Bloorview Kids Rehabilitation Hospital.

2. POLICY STATEMENT

The REB relies on complete submissions for its initial and continuing reviews. In particular, the application documentation must provide the REB with enough information to assess whether the proposed study meets the ethical principles and mandatory requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)* and other applicable regulatory requirements before providing REB approval. Consequently, the REB will review submissions that are complete and provide an adequate description of the proposed research.

3. SPECIFIC POLICIES

3.1 Submission Processes

REFERENCES

CAN/CGSB-191.1-2013 – (4.4.3.1)

Investigators must submit applications for initial and continuing REB review of studies involving humans using forms available on the Research Ethics Board home page of the Holland Bloorview web site. All REB submissions are to be delivered as hard copies to the Research Ethics Office using the REB mailbox within the Bloorview Research Institute.

3.1.1 Initial Submission

Investigators applying for initial approval of proposed research must follow the Science & Ethics Review Process posted on the REB web page of the Holland Bloorview

web site. All applications must include hard copies of the following components:

- Holland Bloorview REB Application Checklist (including written informed consent and assent form(s), participant recruitment procedures, written information to be provided to participants, information about payments and compensation available to participants)
  ICH GCP 3.1.3
  TCPS article 6.11
  CAN/CGSB-191.1-2013 – (4.4.3.2)
- Additional information required for regulated clinical trials including: Local Principal Investigator's (LPI's) curriculum vitae (unless a version updated no more than one year earlier is on file in the REB office), Investigator's Brochure or Product Monograph and any available safety information related to the investigational product
  ICH GCP 3.1.2
  CAN/CGSB-191.1-2013 – (4.4.4.2.4)
- Letter(s) of support from the senior director(s) of the applicable program(s) at Holland Bloorview indicating suitability and feasibility of the available facilities as well as available care in case of emergency (if applicable)
- Toronto Academic Health Sciences Network (TAHSN) Human Subjects Research Application. The TAHSN application must include the disclosure of any financial interest or other potential conflict of interest related to the LPI that may affect the research and attestation that the LPI agrees to abide all applicable regulatory requirements)
  CAN/CGSB-191.1-2013 – (4.4.3.2)
  TCPS article 7.2, 7.4
  42 CFR 50 subpart F
  Policy REB-106
- Full research proposal with the following sections as applicable:
  - Study rationale and objectives
  - Design and description of methodology
  - Eligibility criteria
  - Recruitment and consent process
  - Study interventions
  - Treatment allocation
  - Primary and secondary outcome measures
  - Assessment of safety
  - sample size justification
  - Data analysis
  - Data monitoring
  - Ethical considerations/issues
  - Knowledge translation plan,
  - Study budget (must be in sufficient detail to ensure that conflicts of interest are identified, minimized and managed)

  CAN/CGSB-191.1-2013 – (4.4.4.2.3)
  TCPS article 11.10, 11.11
- Completed science review form (or other evidence of a

scholarly review of the proposal), documentation of all previous decisions, if known, by other REBs or Regulatory Authorities for the proposed study and indication for modification(s) to the protocol and any reasons for negative decisions

- All other documentation checked as relevant on the REB Application Checklist. CAN/CGSB-191.1-2013 – (4.4.3.4)
- Any other documents requested by the REB to fulfill its responsibilities.

All relevant sections of the application forms including all required accompanying documentation must be complete. Further, dated original, electronic, and/or faxed signatures of all investigators and the Holland Bloorview VP Research, CEO, or designate) must be provided on at least one of the two copies of the TAHSN forms included in the submission.

Normally, a BRI scientist must be identified as the LPI. If the investigative team does not include a BRI scientist, then a Local PI must be identified to assume responsibility of the ethical conduct of the study at Holland Bloorview. A LPI who is not a BRI scientist, must be approved by the Holland Bloorview VP Research (or designate) prior to submission of documentation to the REB Office. (NB: The VP Research provides prior approval of a non-BRI scientist as a LPI on an exceptional and project-by-project basis.) CAN/CGSB-191.1-2013 – (4.4.3.2)

The Panel on Research Ethics offers the Course on Research Ethics (CORE) as an on-line tutorial to provide basic education in the ethical principles and requirements of the TCPS2. **As of January 1, 2012, all designated LPIs must submit to the REB Office a certificate of completion of the CORE.**

The REB Office will not initiate a review process for applications and LPIs that do not meet these submission requirements. If there are mandatory elements missing, the REB office will notify the contact person identified on the application within two weeks of submission. Policy REB-409

Health Canada Food and Drugs Act, Div 5/ICH GCP E6

3.2 Amendments to Approved Studies

Policy REB-407

During the term of the approval and the conduct of the research study, investigators must submit documentation to inform the REB about changes in the status of the study. Any changes to study

Health Canada Food and Drugs Act, Div 5 /ICH GCP E6

documents requiring REB approval (e.g. study protocol, informed consent form, other written materials for subjects, study advertisements, case report forms) must be submitted to the REB Office by the LPI for review and approval. Submission requirements are outlined in the *Amendment Request* form.

CAN/CGSB-191.1-2013 – (4.4.3.1)

3.3 Unexpected Serious Adverse Events and Unanticipated Problems

Health Canada Food and Drugs Act, Div 5/ICH GCP E6

During the conduct of a study which is a clinical trial, all unexpected, serious adverse events and unanticipated problems must be reported to the REB by the LPI in accordance with applicable regulations and guidelines. Submission requirements are outlined in the *Adverse Event/Unanticipated Problem Report* form.

Policy REB-405
Policy REB-408

3.4 Annual Renewal Form

Investigators requesting renewal of an approved research project must submit a completed *Annual Renewal Form* four to six weeks before the relevant REB approval expiration date. All of the submission requirements are outlined in the form. Research that is completed prior to the REB approval expiration date must use a Study Closure Form to close the research file. Normally, research is not completed until investigators have shared a lay summary of the findings with research participants.

Policy REB-402

3.5 Deadlines and Timelines

The default review is a full REB review at a regularly scheduled meeting for all applications. Submissions may be directed toward a delegated review as per Policy REB-402. (Application deadlines are posted on the Holland Bloorview web site on the REB Office home page.) Investigators of minimal risk/low vulnerability study should allow a lead time of at least 4 weeks for an initial response by the REB. Studies with higher risks or higher participant vulnerability and multijurisdictional REB submissions may require longer lead times. Most other submissions for delegated REB approval (amendments, requests for renewal) are usually processed within 2 weeks.

CAN/CGSB-191.1-2013 – (4.4.4.4.1)

CAN/CGSB-191.1-2013 – (4.4.3.1)

Revision History

V3/August 2013: Added that the LPI for regulated studies must submit a current CV with the application unless a current version is on record in the REB office to document evidence of qualification. Additional documentation required for regulated trials was included.

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 3.1: added that REB submissions are to be submitted as hard copies to the REB mailbox. Revised section 3.1.1: added that the following be included with new submissions: letters of support, disclosure of any conflict of interest, documentation of any previous REB decisions. Added itemized list of required sections within a

study protocol. Clarified that the REB must receive a least one dated and authenticated copy of the application. Replaced 'Director, Bloorview Research Institute' with 'Holland Bloorview VP Research'. Revised section 3.2: added clarification regarding submission of amendment request. Revised section 3.5: added clarification regarding the default review requirement and response time.