Holland Bloorview
Kids Rehabilitation Hospital

	REB REVIEW OF RESEARCH		
POLICY: REB-405	**ANNUAL RENEWAL**		
This policy pertains to:	The activities of researchers operating under the authority of the Bloorview Research Institute and 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 (RTALC) of the Holland Bloorview Board of Trustees		
Effective date:	February 2016	**Superseded document date:**	V3: July 2014
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

The purpose of this SOP is to describe the policy for annual (interval) renewals and related continuing review prior to the expiration of the Holland Bloorview REB approval period.

2. POLICY

The Holland Bloorview REB conducts continuing review of approved research taking place within its jurisdiction at intervals appropriate to the degree of risk to which participants are exposed, but not less than once per year. The Holland Bloorview REB makes the determination concerning the duration of the approval period and the interval by which continuing review must occur at the time of initial review and approval.

3. SPECIFIC POLICIES

3.1 Annual (Interval) Review of Research Involving Human Participants

Annual/interval renewals are required of all investigators at a frequency determined by the REB at initial approval or subsequently by the Chair as deemed necessary. At minimum, the REB will require a report once per year. The research must be reviewed on or before the one-year anniversary date of the previous REB review, even though the research activity may not have begun until some time after the REB granted approval. Annual (Interval) Renewal must be submitted until all contact with study participants has concluded, all data have been collected and analyzed, and the objectives of the approved study are met to the extent

REFERENCES

ICH-GCP 3.1.4

TCPS2 Article 2.8, 6.14, 6.15

Health Canada Food and Drugs Act, Div 5
ICH-GCP 3.1.4

45 CFR 46.109(e)
21 CFR 56.109 (f)

CAN/CGSB-191.1-2013 – (4.4.7.1)

possible. With few exceptions, renewals of research must continue until the letters of appreciation and lay summaries of findings are shared with participants.

Local Principal Investigators are required to submit a request for annual renewal and other materials as outlined on the Annual (Interval) Renewal Form. The Annual (Interval) Renewal Form should normally be submitted by the Local Principal Investigator 4 to 6 weeks before the study approval period ends.

3.2 Level of Review

3.2.1 Full REB review is the default requirement for renewals of research involving human participants at Holland Bloorview. If the Annual (Interval) Renewal is brought to full REB, then the approval must take place at a convened meeting at which an REB quorum is present.

TCPS2 Article 2.9, 6.12
REB Terms of Reference

CAN/CGSB-191.1-2013 – (4.4.7.4), (4.4.7.5))

The authority to approve Annual (Interval) Renewal may be delegated to the REB Chair or his/her designate when there has been little or no change in the ongoing investigation. If this criteria is met, the Chair or designate will review the Annual (Interval) Renewal under the category of delegated review. The Chair or designate can at any time put a request for annual renewal forward for review by the convened Board.

Annual (Interval) Renewal will be reviewed by the Full Board if required by the study Sponsor, Funding Agency, or Regulatory Agency.

3.2.2. Annual (interval) review of studies funded by the US Federal Government or regulated by the US Food and Drug Administration must be reviewed by the fully convened Board unless they clearly meet the following criteria:

45 CFR 46 110
21 CFR 56. 110

- The research is (i) permanently closed to the enrollment of new participants; (ii) all participants have completed all research related interventions; and (iii) the research remains active only or long-term follow up of participants; **OR**
- Where no participants have been enrolled and no additional risks have been identified; **OR**
- Where the remaining research activities are limited to data analysis.

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3.3 Criteria for determining which projects require review more than annually

The Board will require Annual (Interval) Renewal on an annual basis unless it designates otherwise. The Board considers the following when determining which projects require review more often than annually and in determining the appropriate interval for progress reporting:

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- The nature of any risks posed by the research project;
- The degree of uncertainty regarding the risks involved;
- The vulnerability of the participant population;
- The experience of the investigators in conducting research
- The REB's previous history with the investigators
- The projected rate of enrollment; and
- Whether the research project involves novel interventions.

3.4 Annual (Interval) Review of Research Content

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Annual (Interval) Renewal will include:

a) Any changes to the investigators' situation or qualifications
b) Current protocol version identifier
c) Current status of the study (what stage it is in at this site, at other sites, and what is left to accomplish)
d) Number of participants enrolled in the total study
e) Number of participants enrolled at this site
f) Number of participants withdrawn and reasons
g) Enrollment status compared to plans at the time of initial approval
h) Projected end of the study
i) Summary of all amendments since last renewal or initial approval, protocol number and date, and the date of REB approval
j) A discussion of any difficulties in conducting the study including findings, study design, recruitment and data management
k) The current version of all consent and/or assent form(s)
l) Summary of all unanticipated problems since last renewal or initial approval submitted to the REB and current status of remedial actions
m) A copy of the annual secondary protocol deviation log (if applicable). Refer to SOP-406 (Protocol Deviations) for more information.
n) Any new information that would alter the REB's prior determination, particularly with respect to the REB's prior evaluation of the potential benefits or risks of the participants.

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3.5 Criteria for Renewal

Annual (Interval) Renewal must be substantive and meaningful, the rigor of which shall be in accordance with a proportionate approach to ethics assessment.

TCPS2 Article 2.9 and 6.12

In order for continuation of approval to be granted, the REB will determine that:

a) All of the requirements set forth in Policy REB-403 for approval of research continue to be satisfied.
b) There have been no changes to the investigators, study protocol, consent form, or consent process since the last Annual (Interval) Renewal unless these have been submitted as Amendments and approved.
c) There is no conflict of interest that has emerged since approval that might adversely affect the safety or well-being of study participants.
d) The risk to participants continues to be minimal and reasonable in relation to the anticipated benefits.
e) There is no new literature which might affect the willingness of study participants to participate.
f) There have been no complaints from study participants which require further investigation.

Policy REB -403

For regulated clinical trials, the reports of Data Safety Monitoring Boards and Sponsor-generated Safety Reports must also be favourable for continuation of the study.

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3.6 Extensions of Approval Period

There is no grace period extending the conduct of the research beyond the expiration date of REB approval for regulated clinical trials. Extensions beyond the expiration date will not be granted. If progress reports are not submitted as scheduled, the study will be suspended. No research related activities may occur after the approval expiration date unless the Local Principal Investigator contacts the Research Ethics Board and a determination is made that it is in the best interest of individual participants to continue during the lapse in REB approval.

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The REB Office, in collaboration with the REB Chair, is fully authorized to do one or more of the following as deemed appropriate:

- Hold the review or approval of current or future submissions by the Local Principal Investigator until the status of the expired study has been addressed.
- Notify the funding agency, industry sponsor or the

appropriate regulatory authority of the expiry of the ethics approval for the study.
- Notify financial accounts personnel to advise them that the study is no longer approved and that no further funds from the account should be released.

It is ultimately the responsibility of the investigators to provide in a timely manner the information needed by the REB to perform an annual (Interval) review and any reminder notices regarding the need to do so, from the REB to investigators, are a courtesy.

Approximately 60 days before the Annual (Interval) Renewal is due, the REB office will send the Investigator a reminder letter. The completed form should be submitted at least 30 days before the interval review date to ensure that appropriate REB review takes place prior to expiry to avoid interruption to the study. If the Annual (Interval) Renewal is not received by the deadline date, a final notice of expiry of REB approval will be sent to the Investigator.

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3.7 The Point at which an Annual Renewal is no Longer Necessary

Annual (Interval) Renewal of a research project at least annually is required so long as the project continues to involve human participants and their research data. A research project continues to involve human participants as long as the investigators conducting the research continue to obtain;

- Data about the participants of the research through intervention or interaction with them
- Identifiable private information about the participants of the research (this includes obtaining biological specimens origination from living individuals)

Obtaining identifiable information includes:

- Collecting or receiving identifiable private information (including identifiable biological specimens) from any source (i.e., not already in the possession of the investigator);
- Collecting identifiable private information by observing or recording private behavior without interacting or intervening with the human participants; and
- Using, studying, or analyzing identifiable private information (including identifiable biological specimens), even if the information was already in the possession of the investigator before the research begins. This includes using, studying, or analyzing any of the following:
    - Identifiable private information obtained by

interacting or intervening with the human participants;

- Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings provided to the investigators from any source;
- Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings already in the possession of the investigator before the research begins;
- Identifiable private information obtained about an individual by interviewing other people (e.g., an individual's healthcare provider or teacher);
- Identifiable biological specimens provided to the investigators from any source;
- Identifiable biological specimens already in the possession of the investigator before the research begins.

A research project no longer involves human participants once the investigators have finished obtaining data through interaction or intervention with participants or obtaining identifiable private information about the participants, which includes using, studying, or analyzing identifiable private information. Once all such activities described in the REB-approved protocol are finished and in most cases after a lay summary has been provided to research participants, the research project no longer needs to undergo Annual (Interval) Renewal. At that point the REB can formally close the REB file for that project and advise the investigator of that action as per Policy REB-408.

Revision History

V3/July2014: CAN/CGSB-191.1-2013 references incorporated to reflect compliance. Changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee.
V4/February 2016: Added that a copy of the secondary protocol deviation log must be included with the annual renewal report if applicable. Minor changes in the language of what is to be included in a renewal to align with new Annual (Interval) Renewal Form.