Holland Bloorview
Kids Rehabilitation Hospital

	REB REVIEW OF RESEARCH		
POLICY: REB-408	**STUDY COMPLETION OR TERMINATION**		
This policy pertains to:	The researchers under the authority of the Bloorview Research Institute and 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:	Chair, Holland Bloorview REB (or designate)		
Effective date:	September 30, 2014	**Supersedes documents dated:**	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 process to report the closure of a research project and the required notification of the REB.

2. POLICY

The completion or termination of the study must be reported to the REB. Although participants will no longer be "at risk" under the study, a final report/notice to the REB allows it to close its files as well as providing information that may be used by the REB in the evaluation and approval of related studies.

ICH-GCP Article 4.13

CAN/CGSB-191.1-2013 – (4.4.6.6)

3. SPECIFIC POLICIES

REFERENCES

3.1 Determining When a Study can be Closed

Once a study is considered completed a Study Closure Form should normally be submitted to the REB within 90 days. The following guidance may be used to determine when a study can be closed:

- Studies that involve direct human participation are complete when no further participant contact is required and all data collection procedures and analyses have been completed as per the approved protocol.
- Studies that do not involve direct human participation (i.e., secondary use of data) will be complete when the acquisition of data is complete (i.e., no new cases are being added to the study dataset) and the data analyses have been completed as per the approved protocol.
- Studies that analyze human tissue will be considered completed when no additional tissue samples are being harvested or being deposited to the tissue bank, and the

analysis is completed as per the approved protocol. The REB will be provided with details for end of study handling and destruction.

- For others such as samples being acquired from another research group the terms of the contract and protocol will be adhered as reported to the REB.
- Industry sponsored clinical trials shall be reported as completed or terminated promptly following the sponsor's and the LPI's close-out activities at that clinical trial site. A copy of the official "close-out letter" will be sent to the REB together with applicable details that address the above.

CAN/CGSB-191.1-2013 – (4.4.9.1)

3.2 US Federally Funded Research

Studies that are funded or supported by the US Federal Government are considered open and subject to annual review requirements even where (i) the research is permanently closed to the enrollment of new participants; and (ii) all participants have completed all research-related interventions. Such studies may not be considered completed until all follow up of participants is final. If the remaining activities are limited to data analysis, then the study may close if there is no further analysis of individually identifiable information.

OHRP Guidance on IRB Continuing Review of Research 10 Nov 2010

3.3 Completion Reports

Final reports (or in its place relevant published or unpublished manuscripts and conference papers) must be submitted with the Study Closure Form. The REB Chair (or designate) will review all reports of study completion and, if needed, request further information from the Local Principal Investigator (LPI) to clarify any questions that may arise.

The final report will contain, but not be limited to, the following:

- The LPI's affirmation that participant enrollment is closed and data analysis as per the approved protocol is completed;
- Reason for study termination/closure;
- Number of participants enrolled at Holland Bloorview;
- Number of participants who completed the study;
- Number of participants who dropped out or were withdrawn;
- The number of serious and unexpected adverse events;
- A summary of the results and/or any publication that arose from the study.

3.4 Termination

Once the final report and the Study Closure Form have been reviewed by the REB, the REB will issue an Acknowledgement and the study will automatically be listed as "Completed". The study cannot be amended or reactivated.

CAN/CGSB-191.1-2013 – (4.4.9.1)

3.5 Administrative Study Closure by the REB

3.5.1 When REB approval has lapsed, the REB Office will send a written notification to the LPI to promptly submit an Annual (Interval) Renewal form or a Study Closure Form within 14 calendar days of the date of notification.

3.5.2 If the LPI has not submitted an Annual (Interval) Renewal form or a Study Closure Form to the REB Office within 90 days after the expiration date, the REB Office staff will close the study.

3.5.3 A Study Closure Notification Letter signed by the REB Chair or his/her designate will be sent to the LPI to notify him/her of the study closure and closure of the REB file.

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. Revised section 3.1: clarified that industry sponsored trials should be reported as complete promptly following the sponsors close-out activities. Revised section 3.2: clarified that US federally funded research may be closed when there is no further analysis of individually identifiable information. Added section 3.5: added a description of the process for the closure of studies with lapsed approval by the REB office.