Holland Bloorview
Kids Rehabilitation Hospital

	REB FUNCTIONS AND OPERATIONS		
POLICY: REB-304	**DOCUMENTATION AND DOCUMENT MANAGEMENT**		
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:**	V3: August 2013
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

The purpose of this SOP is to describe the requirements for document management, including:

1. Document Retention
2. Administrative Documents and Archiving.

2. POLICY

The REB files must be maintained in a manner that contains a complete history of all REB actions related to review and approval of a protocol, including scientific reviews, approved informed consent and assent forms, progress reports submitted by investigators, and reports of serious adverse events. The REB Office must also retain all relevant records respecting REB activities, including minutes as described in Policy REB- 302, records of continuing review activities, copies of all correspondence between the REB and investigators, REB membership lists as described in Policy REB-202, and written procedures relating to review, and reporting and statements of significant new findings.

REFERENCES

ICH GCP, Article 3.4 - Records

Health Canada Food and Drugs Act, Div 5
21 CFR 56.115

45 CFR 46.115

CAN/CGSB-191.1-2013 – (4.5.1.1), (4.5.2.1), (4.5.3.1)

Records must be accessible for inspection as described in Policy REB-901 - Audits and Inspections and a copy will be provided upon request by authorized representatives of the REB to sponsors, funding departments, agencies and institutional auditors.

SOP REB-901

Required documents will be submitted to the appropriate funding entity as required.

All records and documentation pertaining to applications that are reviewed by the REB shall be kept confidential within the limits allowed by applicable statutes.

3. SPECIFIC POLICIES

3.1. Document Retention

All records regarding a project must be retained in an appropriate manner as follows:

Regulated Trials: Health Canada Division 5 regulations (Drugs for Clinical Trials Involving Human Subjects) stipulate that the Sponsor or Investigator shall maintain all records referred to in the regulations for a period of 25 years.

Health Canada Food and Drugs Act, Div 5

Non-intervention Trials: The investigator shall maintain all records referred to in the regulations for a period of 7 years.

REB Retention Period: Health Canada Guidance for Records related to Clinical Trials (Article 6.2) further specifies that "Records relevant to clinical trials and to the roles and responsibilities of the Research Ethics Boards are subject to the provisions of the record requirements. Records, including membership, qualifications of members, procedures for the conduct of reviews for approval of biomedical research, communications with principal investigators should be retained for 25 years. Other essential documents that are not unique to the REB, such as records of drug reactions and reviewed documents, should be retained for a period of at least 3 years after the completion of the trial as per GCP guideline."

Health Canada Guidance for Records related to Clinical Trials (Article 6.2)

ICH GCP, Article 3.4 - Records

CAN/CGSB-191.1-2013 – (4.5.4.1)

3.2 <u>Study related documents</u>:

Adequate documentation of REB activities will be prepared, maintained and retained, including:

CAN/CGSB-191.1-2013 – (4.5.3.2)

A. The Initial Submission for REB Review:
- Application for REB Review;
- research protocol or project description;
- Participant information/consent/assent documents;
- Recruitment materials
- Study Instruments
- Investigator Brochures;
- Local Serious Adverse Event Reports;
- Data Safety Monitoring Board Reports;
- Sponsor-generated Safety Reports;
- Health Canada/FDA No Objection Letters;
- Protocol Deviation Reports;
- Amendment Request Forms and supporting materials;
- Annual (Interval) Renewals;
- Study Closure Forms

B. Copies of all correspondence between the REB and the investigators.

C. Copies of all correspondence between the REB and regulatory agencies.

D. Copies of all submitted monitoring reports, site visit reports and other continuing review activities.

E. Statement of significant new findings provided to participants as submitted by the investigator.

F. Reports of any complaints received from participants, regulatory agencies and their resolution.

3.3. REB Administration Documents

The REB Office must maintain and retain all Agendas and Minutes of all REB meetings.

21 CFR 56.103
45 CFR 46.115

CAN/CGSB-191.1-2013 – (4.5.2.1), (4.5.3.2)

3.3.1. Rosters of regular and alternate REB members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the REB's deliberations; and any employment or other relationship between each member and the REB and/or the Holland Bloorview.

Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular member for whom the alternate may substitute.

Current and obsolete membership rosters will remain in the REB Office and then archived after 25 years.

3.3.2. Current and obsolete copies of the Standard Operating Policies.

3.4 Archiving

All documents and materials relevant to REB determinations of regulated trials are kept on site and archived for 25 years after the study completion report is received and the study is closed. All documents and materials relevant to REB determinations of non-regulated studies are kept on site and

Health Canada Food and Drugs Act, Div 5

ICH GCP 3.4

CAN/CGSB-191.1-2013 – (4.5.4.1)

archived for 7 years after the study completion report is received and the study is closed.

Revision History

V3/August 2013: Under Section 2, Policy: Added reference to SOP REB-901 for audits and inspections.

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 2: added that records and documents related to applications reviewed by the REB will be kept confidential within the limits allowed by applicable statutes. Revised section 3.4: clarified that archiving begins when the study file is closed.