

SOP Title:	Document Management		
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Issued by:	Research Ethics Office (REO)	Revision Date:	October 1, 2019
Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

This standard operating procedure (SOP) describes the requirements for document management, including document retention and document archiving. This SOP applies to documents submitted to the Research Ethics Board (REB) for initial or for continuing review, as well as to all REB administrative documents.

2.0 POLICY STATEMENT

The REB office must retain all relevant records (e.g., documents reviewed and approved or disapproved, REB meeting minutes, correspondence with Researchers, written SOPs, REB membership rosters) to provide a complete history of all actions related to the REB review and approval of submitted research. Such records must be retained for the length of time required by applicable regulations and guidelines.

Relevant records must be made accessible to authorized regulatory authorities, representatives of the organizations, Researchers and funding agencies within a reasonable time upon request.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

All REB members and REO Personnel are responsible for ensuring that the requirements of this SOP are met.

5.0 PROCEDURES

5.1 Research-Related Documents

- 5.1.1 The current system of record is electronic and paper based;
- 5.1.2 Records of applications submitted from March 2016 onwards are strictly electronic;
- 5.1.3 Upon creation of an initial application in the electronic system, a research study file is created;
- 5.1.4 All research-related documents are uploaded to the electronic application by the study team;

- 5.1.5 The REO retains the application materials for all research that have been submitted for REB review and have been either approved, acknowledged or disapproved;
- 5.1.6 Research-related documents include, but are not limited to, the following (as applicable):
- REB initial application form and all associated attachments;
 - Correspondence between the REB and the Researcher, including REB approval letters, requests for modifications, etc.;
 - Records of ongoing review activities such as,
 - Reportable event submissions, including reports of significant new findings, Data and Safety Monitoring Board (DSMB) reports, interim analysis reports, local adverse events and non-local (external) adverse events, research deviations, privacy breaches, any investigations into allegations of serious or continuing non-compliance, and reports of inspections and audits by regulatory agencies or others,
 - Modifications to the application including amendments to the research and/or any changes to the consent(s), participant materials or Investigator Brochures;
 - Continuing review and closure applications;
 - Copies of correspondence between the REB and regulatory agencies;
 - Reports of any complaints received by the REB and their resolution.

5.2 REB Administrative Documents

- 5.2.1 The REO retains all administrative records related to the REB review activities;
- 5.2.2 REB administrative records include, but are not limited to, the following:
- Agendas and minutes of all REB meetings;
 - Submitted REB member reviews;
 - Current and obsolete SOPs;
 - Current and obsolete documentation of the REB Chair or designee's delegation of authority, responsibilities, or specific functions;
 - Records of registration of the REB with the US Office of Human Research Protection, if applicable, and REB membership updates.
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- 5.2.3 REB member records:
- Current and obsolete REB membership rosters, including alternate REB members;
 - CVs and training/qualification documentation of current and past REB members;
 - Signed conflict of interest and confidentiality agreements;

5.3 Document Retention Period

- 5.3.1 Health Canada Regulated Drug/Medical Device/Natural Health Product Trials: Study related documents and REB Administrative documents that are subject to Health Canada regulations will be retained for 25 years;

5.3.2 The REO must retain all records regarding a project or protocol submission (regardless of whether it is approved) for at least seven (7) years after completion of the research or termination of REB approval.

5.4 Document Storage and Archiving

5.4.1 REB documents are retained securely onsite accessible to the REB Chair, Vice-Chairs, and REO personnel;

5.4.2 Records from March 2016 onwards are retained on the eREB system. Records prior to this date may be retained in paper copies or electronically;

5.4.3 Closed research study files may be archived with an off-site storage facility;

5.4.4 The electronic REB records are housed in a physically secure onsite location with back-up, disaster and recovery systems in place.

5.5 Confidentiality and Document Destruction

5.5.1 All applications received by the REB are considered confidential and are accessible only to REB members (including the REB Chair and Vice-Chair), as well as to the Organizational Official(s) and the REO Personnel;

5.5.2 Relevant research projects and associated documents may be made accessible to other organizational officials, as well as to sponsor or CRO representatives, if the Researcher or his/her research team submits a request for guest access to the research;

5.5.3 Investigators or their designated staff shall be provided reasonable access to files related to their research on a case-by-case basis. This access must be approved by the Manager of the REO;

5.5.4 Relevant research projects and associated documents may be made accessible to members of regulatory agencies, or representatives of the sponsor or Researcher for review. Access is limited to the applicable research and research-related submissions;

5.5.5 Electronic data for REB study files are stored in the SickKids electronic REB system (eREB) and in the secure electronic drive and is accessible only to the Manager, REO Personnel, REB members and representatives of SickKids authorized by the Associate Chief of Research;

5.5.6 Requests for access to REB study files must be in writing and contain the following information:

- The name of the person requesting the information;
- The information requested;
- The reason for the request;
- Assurance of confidentiality;

5.5.7 Any confidential materials in paper format in excess of the required documentation will be shredded.

6.0 REFERENCES

See References