

Title	Document Management
SOP Code	303.002
Effective Date	08-Mar-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

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 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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.

5.1 Research-Related Documents

5.1.1 The REB office retains the submission materials for all research that have been submitted for REB review and have been either approved, acknowledged or disapproved;

5.1.2 Research-related documents include, but are not limited to, the following (as applicable):

- Signed 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 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 REB office retains all administrative records related to the REB review activities;

5.2.2 REB administrative documents include, but are not limited to, the following:

- Agendas and minutes of all REB meetings;
- Submitted REB member reviews;

- 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;
- 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.

5.3 Document Access, Storage and Archiving

- 5.3.1 Access to individual research projects and related documents, and to center and Researcher profiles is role-based to ensure that users only have access to documents and activities that are required by their role;
- 5.3.2 The REB records are housed securely with back-up, disaster and recovery systems in place.

5.4 Confidentiality and Document Destruction

- 5.4.1 All submissions 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 REB Office Personnel;
- 5.4.2 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;
- 5.4.3 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;
- 5.4.4 The REB will retain required records (e.g., research-related or REB administrative documents, as applicable) for a minimum of 3 years after completion/termination of the trial, or for the maximum amount of time stipulated in any applicable governing regulation(s) e.g., 25 years for Health Canada regulated research;

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

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP303.001	15-Sept-2014	Original version
SOP303.002	08-Mar-2016	5.3.2: revised to state securely housed with removal of the reference to an onsite location.