

SOP 303.001

Title	Document Management
SOP Code	303.001
Effective Date	

Site Approvals

Name and Title	Signature	Date dd/mm/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 policies and guidelines.

3.0 RESPONSIBILITIES

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 policies, regulations and guidelines.

Relevant records must be made accessible to authorized organization personnel, 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):

- Initial REB 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:
 - Modifications to the application including amendments to the research application and respective documents (recruitment and consent materials, research tools),
 - Protocol deviations, adverse and unanticipated event reports,
 - Audit, quality assurance reports
- Continuing review applications;
- 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;
- Copies of appointment letters;
- 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;

5.3 Document Access, Storage and Archiving

- 5.3.1 Access to individual research projects and related documents, and to 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 in a physically and electronically secure location 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 Organizational Official(s) and REB Office Personnel;
- 5.4.2 Relevant research projects and associated documents may be made accessible to other parties, by the Researcher submitting a request for guest access to the research;
- 5.4.3 Relevant research projects and associated documents may be made accessible for quality assurance and compliance purposes;
- 5.4.4 The REB will retain required records (e.g., research-related or REB administrative documents, as applicable) as per organizational policy or for a minimum of 3 years after completion/termination of the trial, or for the maximum amount of time stipulated in any applicable requirement;
- 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		Original version