Research Ethics Board

Standard Operating Procedure

SOP File #	**REB.SOP.303**
Title	Documentation and Document Management
Effective Date	October 24, 2022
Next Review	2026
Next Administrative Review	2023

1. 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. Definitions

See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. Scope

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

4. Responsibilities

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

5. Procedures and/or Specific Policies

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 human participant research that has 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;
- Research study related correspondence between the REB and the Researcher regarding 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 shall be housed in an electronically secure location with back-up, disaster and recovery systems in place per MSVU Information Technology & Services (IT&S) protocols.

5.4. Confidentiality and Document Destruction

5.4.1. All submissions received by the REB are considered confidential and are accessible only to REB Office Personnel and REB members (including the REB Chair and Vice-Chair), as well as to Organizational Official(s) as required or necessary;

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 normally retain required records (e.g., research-related or REB administrative documents, as applicable) per MSVU Records Management policy (Research Management – 9200 – Research Ethics) for 10 years after completion/termination of the research study, Research study documentation for trials and some other types of human participant-related research may be retained 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.

5.4.6. The REB will securely destroy electronic documents when the retention period expires.

5.4.7. Researchers should, at minimum, retain their copy of ethics clearance certificate and/or renewal and modification certificate(s) until the corresponding data are securely destroyed.

6. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved July 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved July 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.303	Minor revisions for clarity; revisions to document retention to ensure compliance with MSVU Records Management (9200 – Research Ethics)	October 2022
REB.SOP.303	Formerly SOP 106 (now retired); Extensively revised - Replaced with N2/CAREB harmonized SOP 303	September 2021
REB.SOP.106	Minor Revisions, pulled into unique SOP	March 2012
Section 8 – Record Keeping	Policies & Procedures: Ethics Review of Research Involving Humans (original UREB Policy Handbook)	2000

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