SOP Title	**100: REB Administration**
Number. Version	**REB SOP 102 Documentation and Document Management**
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Approved By	**REB**
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1.0 PURPOSE

The policies in this section describe the requirements for document management, including:

1. Document Retention
2. Administrative Documents

2.0 GENERAL PROCEDURE STATEMENT

A research project's file will contain study-related documents and a complete history of REB actions related to the review and approval of a protocol (e.g., annual renewals, unanticipated event reports, non-compliance reports). REB administration must also retain all relevant records with respect to REB activities, including minutes, records of continuing review activities, and REB membership lists, etc.

Records must be accessible for inspection and compliance confirmation by authorized representatives of sponsors, funding departments or agencies and institutional auditors.

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

3.0 RESPONSIBILITY AND AUTHORITY

The Chair, Vice-Chair and the REB Administration are responsible for executing this SOP.

4.0 SPECIFIC PROCEDURES

4.1 Document Retention

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

4.1.1 REB Retention Period: The REBs must retain all records regarding a project or protocol application (regardless of whether it is approved) for at least **five years**. If the project is subject to Health Canada regulations, it must be retained **for 25 years** (i.e., a drug, device or natural health product clinical trial).

4.1.2 Study related documents: Adequate documentation of REB activities will be prepared, maintained, and retained, including (as appropriate):

A. The Research Project File:

- Request for release of funds;
- Application for REB review;
- Participant information/consent/assent documents;
- Recruitment materials;
- Study measures or instruments;
- REB clarification letter and responses;
- REB approval letters;
- Change request forms and supporting materials;
- Annual renewals;
- Unanticipated event reports;
- Study completion reports.

Additional Documentation for Biomedical Trials:

- Investigator brochures;
- Applications to granting agencies, as appropriate;
- Data Safety Monitoring Board reports;
- Sponsor-generated safety reports;
- Health Canada No Objection letters;
- Protocol deviation reports;
- Statement of significant new findings.

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

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

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

E. Reports of any complaints received from participants or regulatory agencies and their resolution.

4.2 REB Administration Documents

The REB Administration must maintain and retain all agendas and minutes of all REB meetings. In addition, the Administration will retain rosters of regular and alternate REB members identified by name and qualifications. Former membership rosters will be retained by the REB Administration.

The Office for Human Research Protections (USA) will be consulted when the research pertains to American funded studies.