Title	Document Management
SOP Code	303.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager		12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023
Jacob Brower, Chair GREB		May 8 2024
Dean Tripp, Chair HSREB		May 7 2024

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 continuing review and 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, and 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 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):

- 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 REB registration 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 **ethics applications ~~projects~~** and related documents is role-based to ensure that users only have access to documents and activities required by their role.

5.3.2 The REB records are housed securely with backup, disaster, and recovery systems.

5.3.3 **All documents submitted to the REB must contain a title and a version date within the document itself. The electronic file name of the document is recommended to correspond to the document's title. NOTE: the title of the document and version date in the document will be listed on REB correspondence, approval, and acknowledgement letters. The title and version date in the electronic file name will not.**

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), and the REB Office Personnel.

5.4.2 Relevant research **ethics application ~~projects~~** and associated documents may be made accessible to organizational officials and sponsor or CRO

representatives if the Researcher or their research team submits a request for access to the research.

5.4.3 Relevant research **ethics applications** ~~**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/**study** or for the maximum amount of time stipulated in any applicable governing regulation(s);

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.
SOP303.003	08-Mar-2019	5.1.2: deletion of 'signed' from first bullet; 5.3.1: deletion of 'and to centre and Researcher profiles'; 5.4.1: deletion of 'as well as to organizational official(s)'; 5.4.2: deletion of 'other' and 'guest'
SOP303.004	15-May-2023	5.4.4: remove specific reference to HC retention requirement
SOP303.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text