TITLE	**303: Document Management**
SCOPE	The activities of the Health Research Ethics Board (HREB) operating under direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 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 HREB for initial or for continuing review, as well as to all HREB administrative documents.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 PROCEDURE

The REO will retain all relevant records (e.g. documents reviewed and approved, approved subject to changes or refused to approve, HREB meeting minutes, correspondence with researchers, written SOPs, HREB membership rosters) to provide a complete history of all actions related to the HREB review of submitted research. Such records will be retained for the length of time required by applicable regulations and guidelines.

Relevant records will be accessible to authorized regulatory authorities, representatives of the organizations, Researchers and funding agencies within a reasonable time upon request.

4.1 Research-Related Documents

4.1.1 The REO will retain the submission materials for all research projects that have been submitted for HREB review and have been approved, approved subject to changes or refused to be approved.

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

- HREB initial application form and all associated attachments;
- Correspondence between the HREB and the Researcher, including, but not limited to, HREB approval letters and requests for modifications;
- 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; and
  - 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 HREB and regulatory agencies; and
- Reports of complaints received by the HREB and their resolution.

4.2 HREB Administrative Documents

4.2.1 The REO will retain all administrative records related to the HREB review activities.

4.2.2 HREB administrative documents will include, but are not limited to, the following:

- Agendas and minutes of all HREB meetings;
- Submitted HREB member reviews;
- HREB member records:
  - Current and obsolete HREB membership rosters, including alternate HREB members; and
  - CVs and training/qualification documentation of current and past HREB members;
- Signed conflict of interest and confidentiality agreements;
- Current and obsolete SOPs;
- Current and obsolete documentation of the HREB Chairperson or designee's delegation of authority, responsibilities, or specific functions; and
- Current Records of registration of the HREB with the US Office of Human Research Protection (OHRP), if applicable, and HREB membership updates.
  - The roster of HREB members must be submitted to the Office for Human Research Protections (OHRP) to maintain the Federal Wide Assurances of the HREB. Any changes in HREB membership must be reported to the OHRP.

4.3 Document Access, Storage and Archiving

4.3.1 Access to individual research projects and related documents is role-based in the Researcher Portal online system to ensure that users only have access to documents and activities that are required by their role.

4.3.2 HREB records will be housed securely with back-up, disaster and recovery systems in place.

4.4 Confidentiality and Document Destruction

4.4.1 All submissions received by the HREB are considered confidential and are accessible only to HREB members (including the HREB Chairperson) and the REO Personnel. Documents related to research projects will not be stored on HREB members or REO personnel computers/personal devices.

4.4.2 Relevant research projects and associated documents may be made accessible to organizational officials, as well as to sponsor or CRO representatives, if the Researcher or their research team submits a request for access to the research.

4.4.3 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.

4.4.4 The HREB will retain required records (e.g., research-related or HREB administrative documents, as applicable) for a minimum of 3 years after completion/termination of the research, or for the maximum amount of time stipulated in any applicable governing regulation(s) e.g., 15years for Health Canada regulated research.

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

5.0 REFERENCES

Health Canada Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects (Schedule 1024): Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (GUI-0100) - Canada.ca

Health Canada Natural and Non-prescription Health Products Directorate, Part 4: Clinical Trials For Natural Health Products - Canada.ca

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.103 & 46.115): Electronic Code of Federal Regulations (eCFR)

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.115): CFR - Code of Federal Regulations Title 21 (fda.gov)