

	RESEARCH ETHICS BOARD	
	STANDARD OPERATING PROCEDURES	
	SOP Number	303
	Document Management	
Date of Issue	2006 03 01	
Date of Revision	2010 08 17	
	2017 06 09	
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<p>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.</p> <p>Directive: Fraser Health Policy “The Ethical Conduct of Research and Other Studies Involving Human Participants”</p> <p>References: 2019 10 08 CAREB SOP 303.002, Health Canada Food and Drug Act Regulations Part C – Division 5, Natural Health Products Regulations – Part 4 Clinical Trials Involving Human Subjects, The International Conference on Harmonization Guidelines for Good Clinical Practice E6(R2), Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.115, US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.115.</p> <p>Responsibility: All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.</p>		

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 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.

1.0 Research-Related Documents

- 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;
- 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.

2.0 REB Administrative Documents

- 2.1 The REB Office retains all administrative records related to the REB review activities;
- 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 registration of the REB with the US Office of Human Research Protection, if applicable, and REB membership updates.

3.0 Document Access, Storage & Archiving

- 3.1 Access to individual research projects and related documents, is role-based to ensure that users only have access to documents and activities that are required by their role;
- 3.2 The REB records are housed securely with back-up, disaster and recovery systems in place.

4.0 Confidentiality and Document Destruction

- 4.1 All submissions received by the REB are considered confidential and are accessible only to REB members (including the REB Chair/co-Chairs), the REB Office Personnel, and Fraser Health administrative staff supporting research operational approvals and who have signed a confidentiality agreement;
- 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;
- 4.3 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 The REB will retain required records (e.g., research-related or REB administrative documents, as applicable) for a minimum of 5 years after completion/termination of the trial, or for the maximum amount of time stipulated in any applicable governing regulation(s) e.g., 15 years for Health Canada regulated research;
- 4.5 Any confidential materials in paper format in excess of the required documentation will be shredded.