DOCUMENTATION AND DOCUMENT MANAGEMENT SOP 507

Procedures are a series of required steps to complete a task, activity or action

island health

Purpose:	To provide Island Health a standardized approach for the Research Ethics Board (REB) and office to define the documentation, including retention periods and archiving required.
Context:	Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples. As a signatory to the 2015 Declaration of Commitment to Cultural Safety and Cultural Humility, Island Health is committed to addressing the ongoing impacts of colonialism and Indigenous-specific racism in order to provide a culturally safe, inclusive, healthy and respectful environment. The organization is committed to strengthening diversity, equity and inclusion to enable excellence in health and care for everyone, everywhere, every time. Through these commitments, Island Health strives to deliver the highest possible standard of care and to promote safe workplaces.

Scope:	• Affected Roles
	  o REB Office Personnel
	  o REB Chairs, and members
	• Environment
	  o Research Environment

Outcomes:	• Requirements for documentation and retention of documents related to REB review.

1 Responsibility

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

2 Procedure

The Research Ethics and Compliance Office must retain REB files in a manner that contains a complete history of all REB actions related to the REB review and approval of a protocol.This includes scientific reviews, approved sample consent documents, progress reports submitted by Researchers, and reports of injuries to participants. The Research Ethics and Compliance Office must also retain all relevant records respecting REB activities, including minutes as described in SOP 506 Research Ethics Boards Meeting, records of continuing review activities, copies of all correspondence between the REB and Researchers, REB membership lists as described in REB SOP 535 Management of the Research Ethics Boards, written procedures relating to review and reporting (as described in REB SOPs 508 Ongoing Research Ethics board Review Activities and 511 Research Ethics Boards – Reportable Events and Reporting), and statements of significant new findings. 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.

2.1 Research-Related Documents

a) The Research Ethics and Compliance Office retains the submission materials for all research that have been submitted for REB review and have been either approved, acknowledged, or disapproved;

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

- Signed 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's Brochures;
- Continuing review applications;
- Copies of correspondence between the REB and regulatory agencies;
- Reports of any complaints received by the REB and their resolution.

2.2 REB Administrative Documents

a) The Research Ethics and Compliance Office retains all administrative records related to the REB review activities;

b) REBs must retain all records regarding a project or protocol application (regardless of whether it is approved) for at least five (5) years and for fifteen (15) years or the time as required by Health Canada regulations if the project is subject to Health Canada regulations (e.g. a drug, device or natural health product clinical trial). For all applications that are approved and the research initiated, the REB must retain all records regarding that research for at least five (5) years after completion of the research or termination of REB approval.

c) 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 (OHRP), and REB membership updates;
    - The roster of REB members must be submitted to the OHRP to maintain the Federal Wide Assurance of Island Health. Any change in REB membership must be reported to the OHRP.

2.3 Document Access, Storage and Archiving

a) Access to individual research projects and related documents, and the institutional and Researcher profiles, is role-based in the online database systems to ensure that users only have access to documents and activities that are required by their role;

b) The REB records are housed securely with back-up, disaster, and recovery systems in place.

2.4 Confidentiality and Document Destruction

a) All submissions received by the REB are considered confidential and are accessible only to REB members (including the REB Chair and Co-Chair), and the Research Ethics & Compliance Office Personnel, as well as to organizational official(s);

b) Relevant research projects and associated documents may be made accessible to organizational officials, as well as to Sponsor or contract research organizations (CRO) representatives, if the Researcher or their research team submits a request for access to the research;

c) Relevant research projects and associated documents may be made accessible to members of regulatory agencies, or representatives of a Sponsor or Researcher for review. Access is limited to the applicable research and research-related submissions;

d) The REB will retain required records (e.g., research-related or REB administrative documents, as applicable) for a minimum of five (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 or time required for Health Canada regulated research;

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

3 Training

3.1 Review of the SOP.

4 Compliance Monitoring

4.1 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for ongoing monitoring of Island Health operations, where applicable, to verify compliance with this SOP.

4.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.

4.3 Deviations from this SOP will be addressed through corrective and preventative action implementation (CAPA).

5 Related Island Health Documents

- SOP 506 Research Ethics Boards Meeting
- SOP 508 Ongoing Research Ethics Board Review Activities
- SOP 535 Management of the Research Ethics Boards

6 Definitions

- Refer to The Glossary of Terms – Research Ethics

7 References

- Network of Networks (N2), SOP 303.003 Document Management
- University of British Columbia, SOP 304: Documentation and Document Management
- Health Canada Food and Drug Regulations: Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects (Schedule 1024)
- Health Canada Natural and Non-prescription Health Products Directorate, Part 4, Clinical Trials Involving Human Subjects
- ICH GCP International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R2), 3.4
- Health Canada Food and Drug Regulations Part C, Division 5, Records, C.05.012
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.115):
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.115)
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.103(b)

8 Summary of Changes

Version	Effective Date	Change Description
1.0	15 JUN 2013	New procedure
2.0	05 DEC 2022	Updated to current national standards; updated language referring to regulations; changed Issuing Authority.