Purpose:	To provide a standardized approach to state the Research Ethics Board's (REB) commitment to maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles regarding the conduct of research with human participants. Standard Operating Procedures (SOP) or policies provide the framework to promote ethical standards in the review, oversight, and conduct of research involving human participants is of the highest quality and integrity.
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; REB Chairs, and members
	• Environment
	  o Research Environment
	• This Standard Operating Procedure (SOP) applies to the REBs operating under the direct authority of Island Health that review human participant research in compliance with applicable regulations and guidelines.

Outcomes:	• Procedures that facilitate quality, completeness, adequate documentation, and regulatory compliance in the conduct of research.

1 Responsibility

1.1 The REB Chairs, members of the REB and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

2 Procedure

Procedures that follow the regulations and guidance of Health Canada's Food and Drugs Act, International Council for Harmonisation (ICH) Good Clinical Practice, (where applicable) United States (U.S.) Federal Regulations, Tri-Council Policy Statement, and are supported by institutional policies, assures that the rights and welfare of human research participants will be overseen and protected in a uniform manner, regardless of changes in personnel.

2.1 Development, Review, Revision, and Approval of Policies & Procedures

a) Policies and SOPs will be reviewed by the appropriate Institutional Official(s) at intervals established by the Manager, Research Ethics & Compliance in consultation with the Chairs of the REBs. The qualified REB Office Personnel will review the policies and SOPs at least every two years. Applicable policies and SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new policies or SOPs;

b) Changes to regulations, federal or international ethical guidelines, or research practice as well as changes to REB or administrative policies and procedures of Island Health may require a new policy or SOP or a revision to a previously issued policy or SOP;

c) The qualified REB Office Personnel will make the necessary modifications to existing policies or SOPs, or draft a new policy (ies) or SOP(s). Policies and SOPs are controlled documents and new drafts will be indicated by the addition of "DRAFT version date" and removal of the previous "Final Version Date";

d) The revised policy (ies) or SOP(s) will be circulated to the REB Office Personnel and REB Chairs or designee, as well as REB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;

e) Once the policy or SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the "Final Version Date". The history of revisions will be recorded in the 'Last Revised' section of each policy or SOP;

f) Signatures on the policy or SOP, as determined by organizational standards and practice, will denote approval. A new final version of the policy or SOP supersedes any previous versions.

2.2 Distribution and Communication

a) New or revised policy (ies) or SOPs and associated guidance documents will be communicated and disseminated to the appropriate individuals, departments, and all individuals identified in the 'Responsibilities' section of each policy or SOP;

b) Policies and SOPs will be available to Researchers and researcher sites, Sponsors and Regulatory Authorities as required;

c) Qualified REB Office Personnel will train members of the REB and the REB Office Personnel on any new or revised policy and or relevant procedure, as applicable;

d) Each new REB member must review the applicable policies and procedures prior to undertaking their responsibilities as an REB member;

e) Each new REB Office Personnel must review the applicable policies and procedures prior to undertaking their responsibilities with the REB office;

f) Evidence of training must be documented;

g) The Research Ethics & Compliance office shall maintain all documentation of policy and SOP training.

2.3 Forms, Memos, and Guidance Documents

Forms are used to:

- Ensure that policies and SOPs are integrated into the daily operations of research and review throughout the Island Health research environment;
- Enable Research Ethics & Compliance Office Personnel to manage, review, tracking, and notification functions consistently.

Standardized online database forms are used by all Island Health REBs, including the REB application forms, and all post-approval activity forms such as; notices of completion, renewals, amendments, and acknowledgements. Changes to these forms are reviewed and approved by the Manager, Research Ethics & Compliance, in consultation with Island Health REB Chairs, and/or REB Office Personnel, where appropriate.

a) Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;

b) Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;

c) Memos and guidance documents will be made available to the Researchers and researcher sites as applicable;

d) The qualified REB Office Personnel and/or REB Chair or designee will evaluate the need for new or revised forms, memos or guidance documents.

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 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 (CAPA) implementation.

5 Definitions

5.1 See Glossary of Terms – Research Ethics

6 References

- Network of Networks and Canadian Association of Research Ethics Board (CAREB) - Research Ethics Board Standard Operating Procedures, V 3.0
- Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonised Guideline, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, E6(R2), November 9, 2016
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46):
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.108(a))

7 Summary of Changes

Version	Effective Date	Change Description
1.0	05 DEC 2022	New procedure