INITIAL RESEARCH ETHICS BOARD REVIEW – CRITERIA FOR APPROVAL

SOP 545

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

Purpose:	To provide a standardized approach for describing the minimal requirements that research proposals involving human participation must meet in order to be approved by the Research Ethics Board (REB), independent of the review pathway (i.e. Full Board or delegated review), for conduct at or under the auspices of Island Health.
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
	  ○ All REB Chairs
	  ○ REB Members
	  ○ REB Office Personnel
	• Environment
	  ○ Research Environment

Outcomes:	• To describe minimal requirements required of research to be approved by an Island Health REB.

1 Responsibility

1.1 All REB members and REB Office Personnel are responsible for ensuring that the requirements of this standard operating procedure (SOP) are met.

1.2 The REB members are responsible for determining whether the research meets the criteria for approval.

2 Procedure

2.1 All research proposals that intend to enroll human participants must meet certain criteria before REB approval may be granted. Initial REB approval of the research is based on assessment of a complete submission to the REB.

2.2 The REB and/or REB Office Personnel may consult the Researcher for additional information as necessary. The criteria are based on the guiding ethical principles of the Tri-Council Policy Statement 2 and are specified below.

2.3 Following initial review of the research, the REB should be prepared to make a determination as to the approvability of the research.

2.4 In addition to REB approval, certain other criteria unique to the institution (e.g. Operational Approval), such as the provisions of Research policies, department approvals, adequate resources, etc. must also be met before Institutional Approval to commence the research is granted.

3 Minimal Criteria for Approval of Research

In order for the research to receive REB approval, the REB will take the following into consideration:

3.1 The research application has been submitted via the online database system and electronically signed or attested to by the Researcher;

3.2 The Researcher has the qualifications, including where applicable the medical scope of practice required, to conduct the research;

3.3 Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data;

3.4 There is a state of clinical equipoise when there is a comparison of two or more treatment arms;

3.5 The research will generate knowledge that could be generalized and lead to improvements in health or well-being;

3.6 The methodology is scientifically sound and capable of answering the research question;

3.7 The risks to participants are minimized by:

- Using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk; and
- By using procedures already being performed on the participants for diagnostic or treatment purposes whenever appropriate;

3.8 The risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated;

3.9 The selection of participants is equitable. In making this assessment, the REB will take into account the purpose of the research and the research setting. The REB will consider the scientific and ethical reasons for including vulnerable populations, if applicable;

3.10 There are sound scientific and ethical reasons for excluding groups of persons who might benefit from the research;

3.11 When some or all of the participants are likely to be in vulnerable circumstances or have those circumstances increased in the context of the research, additional safeguards have been included in the research, and in the REB review process to uphold the rights and welfare of these participants;

3.12 Recruitment methods which respect the privacy of individual participants must be followed. Except under unusual circumstances, it is preferred that members of the patient's healthcare team may approach the patient regarding potential participation in a research study;

3.13 The amount and method of payment to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding payment to participants including method, amounts, and schedule is provided to participants when applicable;

3.14 Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by appropriate local, provincial, or national guidelines or regulations;

3.15 The informed consent form (or documentation) will accurately explain the research and contain the required elements of consent;

3.16 The informed consent process will be appropriately documented as required by local, provincial, and federal regulations;

3.17 Any waiver or alteration of the informed consent process will be properly justified and documented;

3.18 Where applicable, there will be provisions for on-going data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research. The REB may recommend the use of a Data and Safety Monitoring Board (DSMB) to enhance participant protection;

3.19 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

3.20 There will be adequate provisions for continued access to the agent or device or adequate replacement of the test agent after the research is complete, when appropriate;

3.21 There will be adequate provisions for the timely publication and dissemination of the research results;

3.22 The resources required for successful completion of the study are committed (e.g. funding, space, personnel, etc.);

3.23 If applicable, evidence that the research has been or will be registered via an internationally recognized clinical trial registry.

4 Additional Criteria

4.1 The REB may require verification of information submitted by an Investigator. The need to verify any information will be determined by the REB at a convened meeting. The purpose of the verification will be to provide necessary protection to participants when deemed appropriate by the REB. Sources of external verification are detailed in SOP 508 Ongoing REB Review Activities and criteria for considering external verification are detailed in SOP 509 Research Ethics Boards - Continuing Review.

4.2 Studies proposing access to or collection of personal information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether appropriate privacy legislation is adhered to;

4.3 Additional criteria for research involving specific populations shall be applied when applicable in accordance with governing principles and/or regulations.

5 Cooperative Research Arrangements

5.1 The Vice-President, Quality, Research and Chief Nursing & Allied Health Officer or their delegate may enter into joint review arrangements, rely upon the review of another qualified REB, or make similar arrangements to avoid duplication of effort as allowed. Where necessary, the Institutional Federal Wide Assurance (FWA) will be appropriately modified, and REB Authorization Agreements will be entered into.

6 U.S. Federally Funded Research

6.1 For research that is subject to the provisions of Title 45 Code of Federal Regulations Part 46 or Title 21 Code of Federal Regulations Part 56, the REB shall consider the listed criteria in the applicable regulations, to the extent that they differ from or vary the criteria noted in 3.1 and 3.2 above;

6.2 REB members are provided with an REB reviewer form to ensure that these criteria are considered in the review process. For U.S. regulated studies, consideration of the eight (8) required elements is discussed and documented in the meeting minutes in addition to 3.1 and 3.2 above:

- Risks to subjects are minimized by use of sound research design and that wherever appropriate; procedures that are already being performed for diagnostic reasons are being used in the research;
- Risks to subjects are reasonable in relation to anticipated benefits;
- Selection of subjects is equitable;
- Informed consent will be appropriately sought;
- Informed consent will be appropriately documented;
- There are adequate provisions for monitoring;
- There are adequate privacy protections;
- Vulnerable persons are protected through the use of additional safeguards.

7 Length of Approval Period

7.1 The REB shall review research at periods appropriate to the degree of risk and at least annually;

7.2 The REB may require review more often than annually as deemed appropriate by the REB;

7.3 The REB may consider reviewing the research more often than annually as required by the continuing review procedure;

7.4 In instances where the research project has been continually renewed and modified over several years, the REB may request a new application be submitted.

8 Training

8.1 Review of the SOP

9 Compliance Monitoring

9.1 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.

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

9.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

10 Definitions

- Refer to The Glossary – Research Ethics

11 References

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 7: Conflicts of Interest, Article 7.4
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 1, Part B, Core Principles:
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 2, Article 2.6
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 4.1
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 3: The Consent Process, Article 3.9
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 4: Fairness and Equity in Research, Article 4.6
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 8 – Multi-Jurisdictional Research, Articles 8.3 & 8.4:
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 3: The Consent Process, Articles 3.1 & 3.2
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 3: The Consent Process, Article 3.9
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 5 – Privacy and Confidentiality, Part A, Key Concepts
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 3: The Consent Process, Article 3.3
- 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) ,4.1.1
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111)
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111)

- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(1))
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(1)):
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(2))
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(2))
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(3)
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(3
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (b))
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (b)
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(7)
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(7)
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(4)
  & (a)(5)
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(4)
  & (a)(5)
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(6)
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(6)
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(7)
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(7)

12 Summary of Changes

Version	Effective Date	Change Description
1.0	19 DEC 2022	New procedure