RESEARCH ETHICS BOARD REVIEW DECISIONS
SOP 544

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

Purpose:	To provide Island Health a standardized approach for describing the decisions that the Research Ethics Boards (REBs) may make resulting from its review of proposed research for ethical acceptability. This standard operating procedure (SOP) also describes knowledge generating projects that do not require REB review because the activity does not constitute human research.
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 All REB Chairs and members
	  o All REB Office Personnel
	• Environment
	  o Research Environment

Outcomes:	• Describes REB decision making outcomes from its ethical review of research and other types of knowledge generating projects that do not require REB review.

1 Responsibility

All Island Health Research Ethics Board (REB) members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

2 Procedure

All research involving human participants must be submitted for REB review according to the specified application format and process, otherwise the Researcher will be notified that the REB will not review the research activity until all required elements are submitted.

No intervention or interaction with human participants in research, including recruitment, may begin until the REB has reviewed and approved the research protocol, consent documentation, recruitment materials, and any other relevant study documentation submitted upon initial review.

As a result of its review, an REB has the authority to approve, disapprove, or to require modifications to submitted project/proposal/documents. Except when the delegated review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with REB conflict of interest policies.

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When reviewed via delegated review, the REB Chair or their designee can take any of the actions outlined below, except to disapprove a study.

REB members with a conflict of interest in the research under review must not participate in the deliberations or in the vote of the REB (if applicable), in accordance with the REB and organization's conflict of interest policies.

When the delegated review procedure is used, the REB Chair and/or REB member(s) who are assigned to the review can decide to approve the research or to request revisions to the research; the decision to disapprove the research must be made by the Full Board.

Researchers have the right to request reconsideration of the REB's decisions and to appeal the decision of the REB.

2.1 Activities Requiring REB Review

Research is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. The following requires ethics review and approval by an REB before the research commences:

- Research involving living human participants;
- Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

For research funded or supported by the United States (U.S.) government, human research is any activity that either: 1) meets the Department of Health & Human Services (HHS) definition of "research" and involves "human participants" as defined by the HHS regulations or 2) meets the Food and Drug Administration (FDA) definition of "clinical investigation" and involves "human participants'" as defined by the FDA regulation.

2.2 Activities Not Requiring REB Review

Some research does not require REB review and certain projects are exempt from REB review. Determination of exemption is based on regulatory and institutional criteria. The Island Health **Quality Improvement Ethics** process provides guidance for determining whether a project constitutes a quality improvement/ quality assurance / program evaluation activity that is exempt from REB review.

REB review is not required for:

a) REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;

b) Quality improvement and quality assurance studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment,

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management or improvement purposes, do not constitute research for the purposes of this SOP, and do not fall within the scope of REB review;

c) Creative practice activities, in and of themselves. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review;

d) Observations of behaviour within a public gathering which cannot be associated with any particular individual or group of individuals (random people or an anonymous group with no known, identifiable membership); and

e) Information which is already in the public domain (e.g. autobiographies, diaries or public archives).

2.3 **The Application Process**

a) REB Office Personnel will review each application for completeness. If there are elements missing, the Researcher will be notified.

b) Initial applications are pre-screened for completeness and assessment of the level of risk. If the application does not meet the criteria for delegated review, it will be reviewed by the REB at a Full Board REB meeting in accordance with the following procedures:

- REB Office Personnel will assign the study to two primary reviewers who will review the study and the application and all relevant documentation in detail. If the study involves a medical intervention, at least one of the reviewers must be a medical professional. An external peer review is required for all clinical research submissions to the Full Board; the peer review must be attached by Researchers prior to the Full Board meeting date;
- The protocol may also be assigned to an additional expert (external reviewer) who is not a member of the REB if the nature of the protocol warrants the need for additional expertise;
- All materials and relevant documents are accessible by all REB members. The primary reviewers will receive notification of their assignments vie e-mail or via the online database system approximately one to two weeks prior to the REB meeting at which the study is scheduled to be reviewed;
- For protocols reviewed by the full REB, the Principal/Qualified (PI/QI) Investigator may be requested to attend the meeting of the REB and if so, they will be given an appointment time. If the PI/QI is requested to attend but cannot represent the project on the specified date and cannot delegate this responsibility to a Sub-Investigator, the project may be deferred to the next scheduled REB meeting;
- Discussion of the protocol at the REB meeting is led by the primary reviewers. By unanimous consensus or by majority vote in accordance with SOP 506 Research Ethics Boards Meeting, section 3. The REB may make any of the determinations outlined below in section 2.4.

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2.4 REB Decisions

a) REB decisions are made either by consensus or a majority vote of the REB members present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies. The REB Chair abstains from voting except to break a tie vote;

b) The REB should reach one of the following decisions as a result of its review of research submitted for initial or for continuing review:

- **Approval** (approve the application as submitted, including the consent form):
  - When an acceptable risk/benefit ratio exists, the regulatory criteria required for approval are satisfied (including Institutional Approvals) and the approval to proceed is not withdrawn by the Vice-President, Quality, Research and Chief Nursing & Allied Health Officer, or the Chief Executive Officer (CEO), the research may be approved as submitted;
  - For studies reviewed by the Full Board, the approval date is defined according to the date of the Full Board REB meeting review;
  - For studies reviewed via delegated review, the approval date is defined according to the date the reviewer confirms approval via the online database system and the Certificate of Approval is released;
  - Studies will expire within one (1) year of the date in which the study was approved.

- **Conditional Approval** (ethics requirements have been satisfied):
  - When a study has been reviewed and approved by the REB, but other regulatory criteria have not been met (e.g. School Board approval), the REB will issue a letter indicating the study has met all ethics requirements and a Certificate of Approval will be issued once other regulatory requirements have been met.

- **Approval with Modifications/Clarifications** (Provisos):
  - When an acceptable risk/benefit ratio exists, and the regulatory criteria required for approval are satisfied, but the REB members require modification to any aspect of the application or clarification or further information to secure approval, the REB may recommend “Approval with Modifications/Clarifications” or “Provisos”;
  - A written explanation of the conditions and/or modifications is sent to the Researcher by the REB Chair through the REB Office Personnel, via the online database system;
  - When the REB recommends “Approval with Modifications/Clarifications” or “Provisos”, the REB Chair or designee should ensure that the additional information, modifications, or clarifications required are identified at the REB meeting and that the procedures for reviewing the additional information and issuing the approval are clear. The responsibilities for additional review and the decision regarding approval conditions should be delegated to one of the following:
    - The REB Chair alone;
    - The REB Chair and one or more named REB members that were present at the REB meeting or who submitted written comments on the application;

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        - A sub-group of the REB members designated by the REB Chair or designee or by the REB;
        - A designated REB member or members with sufficient knowledge and experience regarding the research and the regulations;
        - Qualified REB Office Personnel following SOP 513.2 Delegated Review – Delegated Responsibility to Research Ethics Board Office Personnel.
    - In deciding the procedures to be followed, the REB should consider the significance of the requested additional information or modifications and the expertise necessary to assess it. Where the information or modifications are straightforward, it is acceptable to delegate the consideration of that material to the REB Chair or designee alone;
    - Where the additional information/modification is technical (e.g. statistical clarifications), the REB Chair or designee should review the information with consideration given to involving other REB members, such as the lead reviewer(s) or relevant expert member(s);
    - When the Investigator provides the REB with proof that the conditions have been met and the documents have been amended, (as confirmed by the REB Chair or designee), the Certificate of Approval will be sent to the Researcher;
    - If the Researcher's response is incomplete and does not fully address the matters raised, requests for further information, modifications or clarification should be sent to the Researcher;
    - The reviewers may decide upon reviewing the Researcher's response that the decision should be deferred and that the application and the Researcher's response materials should be reviewed at a subsequent Full Board meeting (see 'Deferral' process below);
    - The approval date is defined according to procedures listed under the "Approval" above. The expiry date of the REB approval is calculated from this date; however, the Approval Letter is not issued until all of the conditions for approval have been met.

- **Deferral** (defer decision-making on the application and continue the deliberation of the application at a future Full Board meeting):
    - The REB may defer a decision on any submitted research application if it does not have sufficient information to arrive at a determination, or if the REB requires extensive revisions to any part of the research;
    - The REB will defer its decision to a subsequent Full Board meeting when significant questions are raised during its review of the research and/or when the criteria required for approval have not been met;
    - The REB Chair or designee should ensure that all additional information, modifications or clarifications that are required are specifically identified at the Full Board meeting;
    - The research and the Researcher's response materials shall be reviewed at a Full Board meeting;
    - Upon consideration of the research along with the response from the Researcher, at the Full Board meeting, the REB should issue its final decision (approved, approved with modifications, deferral or disapproval);
    - Researcher responses must be received and reviewed at a Full Board meeting. The approval date is defined according to the REB procedures listed under "Approval" above. The expiry

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date of the REB approval is calculated from this date; however, the Approval Letter is not issued until all the conditions for approval have been met.

- **Disapproval:**
  - The REB may disapprove the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the REB to reach a positive determination;
  - Disapproval cannot be decided through the delegated review mechanism. If the recommendation under delegated review is to disapprove the research, a final decision must be made by the REB at a Full Board meeting;
  - The REB Chair or designee should ensure that the reasons for the disapproval are identified at the Full Board meeting for communication to the Researcher;
  - If the research is disapproved, the reasons for disapproval will be communicated to the Researcher and the Researcher will be given an opportunity to respond in person or in writing.

2.5 **Delegated Reviews:**

a) When the research qualifies for delegated review, the reviewer(s) has the authority to approve the application, to require modifications to any aspect of the application, or to request clarification or further information before considering it eligible for ethics approval. The reviewer(s) may also refer the applications as submitted for a review at a Full Board meeting,

b) When delegated review procedures are followed, approval is considered as the day the research is approved by the REB Chair or designee as well as all other designated reviewer(s), if applicable. The expiry date of the REB approval is calculated from this date; however, the approval letter is not issued until all of the conditions for approval have been met,

c) If the research cannot be approved through the delegated review mechanism, it must be reviewed at a Full Board meeting.

2.6 **Reconsideration and Appeal of REB Decisions**

a) A Researcher may appeal the decision of the REB, pursuant to SOP 546 Reconsiderations of REB Decisions and Appeal Process if the disagreement between the Researcher and the REB cannot be resolved through

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a reconsideration process at a Full Board meeting at which the Researcher/ applicant shall have the right to be heard;

b) The Researcher must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched only for procedural or substantive reasons, and a final decision after reconsideration must be issued by the REB prior to the initiation of an appeal process;

c) Appeals are conducted in accordance with SOP 546 Reconsiderations of Research Ethics Board Decisions and Appeal Process. The organization at which the appeal will take place will be determined on a case-by-case basis by the REB in consultation with the Researcher (and their affiliated organization);

d) The appeal committee shall have the authority to review negative decisions made by the REB and in so doing it may approve, disapprove, or request modifications to the research proposal. Its decision shall be final and shall be communicated to the Researcher and the REB in writing.

2.7 **Documenting REB Decisions**

a) The REB meetings minutes will satisfy the applicable requirements;

b) The REB shall notify the Researcher via the online database system of its decision to approve or disapprove the proposed research, or of modifications/clarifications required to secure approval of the research;

c) If the REB defers its decision, the letter to the Researcher should include the issues of concern and what further information is required;

d) The final approval letter should include standard conditions of approval to which the Researcher must adhere;

e) When the decision to approve a submission is recorded on behalf of the Full Board, or when a delegated reviewer electronically signs off on a decision (under delegated review procedures), the notification or correspondence to the Researcher may be issued by the REB Office Personnel.

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 implementation.

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5 Definitions

- Refer to the Glossary - Research Ethics

6 References

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.1
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Articles 2.3 & 2.4
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.5 & 2.6
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.102(d), (f)
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 50 (21 CFR 50.3(c) (g))
- 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)

7 Summary of Changes

Version	Effective Date	Change Description
1.0	13 MAR 2023	Information found in SOP 502, V 1.0 incorporated into this document per current national policy and guidelines; updated per changes to TCPS 2 and applicable regulations.

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