

SOP 513-2

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



Purpose:	To provide Island Health a standardized approach to outline the ethical review and approval tasks delegated by the Island Health Research Ethics Board (REB) Chairs and members to Island Health REB Office Personnel.				
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				
Scope:	 Affected Roles REB Chairs REB Members REB Office Personnel Environment Research Ethics Boards Research Ethics and Compliance Office This Standard Operating Procedure (SOP) addresses the need to expedite the flow of requests for ethical review, approval of certain categories of proviso responses, requests for acknowledgements, and post approval activities submitted to the Research Ethics Boards and delegated by the REB Chairs and members to the REB Office Personnel. Some tasks are delegated to qualified staff, who are appointed as non-voting members of the REBs. 				
Outcomes:	 Expedited or delegated flow of requests for ethical review, and approval of certain categories of responses submitted to the REBs that may completed by the REB Office Personnel. 				

1 Responsibility

1.1 All REB Chairs, Members and Office Personnel are responsible for the procedures outlined in this SOP.

2 Delegated Tasks

The following are tasks delegated for approval/acknowledgement to REB Office Personnel.

2.1 Response to Provisos

a) If the REB Chair/Member reviewer has documented approval of a study pending receipt of an item or administrative changes completed, REB Office Personnel may issue an approval upon receipt of the item or administrative changes completed (e.g. typo corrections in a consent form). When issuing their

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decision and provisos, the REB Chair/Member reviewer should use the following wording to indicate this delegation: "Provisos – DTS [delegated to staff]".

b) If the REB Chair/Member reviewer has documented clear prescriptive provisos that are not administrative changes but can be handled by qualified staff, qualified REB Office Personnel may issue approval upon a satisfactory response to the provisos. The REB Chair/Member reviewer should use the following wording to indicate this delegation: "Provisos – DTNS [delegated to REB non-voting- member staff]".

2.2 Acknowledgement of Study Completion

a) REB Office Personnel may issue an acknowledgement of notification of study completion. If there is any question or concern regarding the Researcher's compliance with study closure guidelines, the REB Coordinator will ask the Researcher for clarification and/or refer the application to the REB Chairs.

2.3 Annual Renewals

a) The REB Office Personnel may issue an Annual Renewal approval without review by the REB Chair.

2.4 Amendments

REB Office Personnel may review and approve an amendment without review by the REB Chair if restricted to the following:

- a) Administrative changes (e.g. changes in study personnel, research funding, editorial changes to the study title or documents): *Provisos DTS [delegated to staff]*.
- b) Changes in recruitment procedures that do not change the broad type of recruitment strategy (e.g. changing from third party to direct recruitment would not qualify) or what prospective participants are told about the study (e.g. changing from posters to newspaper advertisements): *Provisos DTNS* [delegated non-voting-member staff].
- c) Changes in the study procedures that do not affect the level of risk for participants (e.g. changing from face-to-face to phone interviews): *Provisos DTNS [delegated to non-voting-member staff]*.
- d) Changes in the study population of minimal risk studies that do not involve any heightened risk for the new population (e.g. addition of men to a previously all-women study): *Provisos DTNS [delegated to non-voting member staff]*.
- e) Adding a research site that is equivalent to the research sites already included in the study (e.g. adding further cafés as field sites to a naturalistic observation study on coffee shops, adding a site that is equivalent to the local study sites already approved): *Provisos DTS [delegated to staff]*.

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2.5 New Applications

a) Where a minimal risk application has been reviewed and approved by another Tri-Council Policy Statement (TCPS2)-compliant, Canadian REB and has come through the REB streamlined review process as a truncated application (on RISe) or has been submitted into Romeo with all approvals in place (including approval letter, and listed documents), qualified office personnel may review and approve the application as *Provisos – DTNS* [delegated to non-voting member staff].

2.6 Harmonized Applications

- a) Where a minimal risk application has been submitted on Provincial Research Ethics Platform (PREP), and the Island Health REB is the Board of Record, qualified staff may review and coordinate the review with partner REBs following the agreed-upon Research Ethics BC (REBC) model. The above delegated authority tasks, outlined in section 2 Delegated Tasks, may be applied for approval.
- b) Where an above minimal risk application has been submitted on PREP, and the Island Health REB is the Board of Record, qualified office personnel may review and coordinate the review with partner REBs following the agreed-upon Research Ethics British Columbia (REBC) model for Full Board review. The above delegated authority tasks, outlined in section 2 Delegated Tasks, may be applied for approval.

3 Exceptions

In all cases of delegated acknowledgement or approval, if REB Office Personnel have any concern about the application, they will either consult the REB Chairs and Member reviewers or immediately assign the submission to the REB Chairs and Member reviewers. Consultations with the REB Chairs and Member reviewers will be documented under the Communications tab on the Research Services Portal or Correspondence tab on PREP.

4 Processing

Certificates of Approval will be issued by delegated REB Office Personnel under the following statement: **The above** approval has been provided by the Full REB or by an authorized delegated reviewer.

5 Training

5.1 Review of the SOP.

6 Compliance Monitoring

- 6.1 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.
- 6.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.
- 6.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

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7 Definitions

• See Glossary of Terms – Research Ethics

8 References

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Chapter 6, Article 6.4
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS 2 (2018), Chapter 6, Article 6.12

9 Summary of Changes

Version	Effective Date	Change Description
2.0	09 JAN 2023	New procedure. Versioning of 513-2 will start at V 2.0 to align with revised SOP 513 Delegated Review.

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