RESEARCH SUBMISSION REQUIREMENTS
SOP 537

PROCEDURE

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 describing the Research Ethics Board (REB) submission requirements including: initial review, amendments or changes to approved research and any new information.
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

Outcomes:	• Procedures that facilitate quality, completeness, adequate documentation, and regulatory compliance in the conduct of research through identifying the requirements of submissions to the REBs.

1 Responsibility

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

2 Procedure

REB members must rely on the documentation provided by Investigators, or other parties, for initial and continuing review. Therefore, this material submitted must provide REB members with sufficient information about a study to assess if it adequately meets the REB criteria to conduct the review and to make the required determinations. A submitted protocol will be scheduled for REB review only when the REB Office Personnel determines that the information and materials submitted present an adequate description of the proposed research.

The requirements for REB submissions are made available to all Researchers. The REB Office Personnel are responsible for maintaining and disseminating this information to Investigators and other parties.

Each Island Health REB requires that applications for initial and continuing review of human participant research be submitted using the online databases: The Research Portal for single jurisdiction research solely conducted at Island Health; and the Researcher Information System (RISe) for multi-jurisdictional research conducted at multiple institutions in British Columbia (BC).

2.1 Submission Requirements for Initial Review

a) Submission requirements for initial review are outlined in the REB Applications Forms and the accompanying Guidance Notes. Investigators applying for initial approval of proposed research must follow the guidance notes and complete the online application form as required by the applicable online database systems;

b) All applicable sections of the Application Form, including all required accompanying documentation, must be completed. Electronic signatures from the Principal Investigator/Qualified Investigator approving the study are required or the application will not be forwarded to research ethics administration for review and assignment;

c) REB Office Personnel will review each application for completeness. If there are elements missing, the Investigator will be notified by the REB Office Personnel, and applications will not be assigned for review or consideration at an REB meeting until all required documents are received;

d) The REB may request any additional documentation it deems necessary to the ethics review, or for research ethics oversight;

e) Research Requirements: The research question and methodology is written in sufficient detail to permit evaluation of the merit of the project. The research should include all of the required elements applicable to the research such as, but not limited to:

- Research rationale and objectives,
- Design and detailed description of methodology,
- Eligibility criteria, description of the population to be studied,
- Recruitment and consent process,
- Research interventions,
- Treatment allocation (if applicable),
- Primary and secondary outcome measures,
- Assessment of safety,
- Sample size justification,
- Data analysis,
- Data monitoring.

2.2 Submission Requirements for Continuing Review

During the term of the approval and the conduct of the research study, Investigators must submit documentation to inform the REB about changes in the status of the study. Submission requirements are outlined in the Post-Approval Activity (PAA) form for study Amendments. Revisions to documents such as consent forms must be tracked using track changes.

a) Submission Requirements for Requests for Acknowledgement

In some instances, Investigators require acknowledgement of certain study related details including the submission of unanticipated problems, protocol deviations, safety letters, notification that a study is on hold, off hold, closed to accrual/enrolment and other miscellaneous information. Submission requirements are outlined in the PAA- Request for Acknowledgment form. The Request for Acknowledgment form is used by the Investigator to report any incident, experience or outcome that could result in increased or different risks to the participants that were not anticipated/expected/and/or that were not described in the original application, including serious and unexpected adverse events. This includes any new information that might adversely affect the safety or well-being of the study participants, including new information or literature that has come out of other studies that could potentially adversely affect study participants or significantly impact trial design;

b) Unanticipated Problem Reporting

During the conduct of a study which is a clinical trial, all local adverse events that are deemed to be unanticipated problems must be reported to the REB in accordance with applicable regulations and guidelines. Submission requirements are outlined in the Research Portal in the Guidance Notes for Request for Acknowledgement, and the PAA – Request for Acknowledgement form on RISe;

c) Annual Renewal

Prior to the relevant REB approval expiration date, Investigators requesting renewal of an approved research project must submit an Annual Renewal Form in the Research Portal, or a completed PAA – Annual Renewal on RISe. All of the submission requirements are outlined in the applicable forms.

Both online systems send out reminders.

It is the Principal Investigator/Qualified Investigator's responsibility to submit the application for annual renewal to the REB office in a timely manner.

2.3 Documentation is not Adequate or Additional Information is Required

a) If the REB or REB Office Personnel determines that the submitted documents are not adequate, Investigators may be required to submit additional information, or their presence may be required to answer questions to explain the details for the study. No substantively incomplete submission will be reviewed by the REB.

2.4 Deadlines and Timelines

a) Application deadlines may vary depending on which Island Health REB will be reviewing the application. Timelines are provided in the REB Guidance Notes and on the REB webpages.

2.5 REB Administration Fee

a) An administration fee of $4000 shall be levied for all private, industry-sponsored research projects submitted for REB review. All new studies submitted for initial ethics review to an REB will be subject to an annual renewal fee of $750 when they are submitted for annual renewal. Amendments do not have a fee.

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.

5 Definitions

- Refer to the Glossary – Research Ethics

6 Related Island Health Documents

- SOP 523 Research Ethics Review Fees

7 References

- Network of Networks (N2), SOP 301 REB Submission Requirements and Administrative Review
- University of British Columbia, SOP 301 Research Submission Requirements
- Island Health Research Services Portal
- UBC Research Information Services (RISe) online system
- The Tri-Council Policy Statement:Ethical Conduct for Research Involving Humans, Article 6.14

8 Summary of Changes

Version	Effective Date	Change Description
1.0	05 DEC 2022	New procedure