PROCEDURE

Research Ethics Board: Communication – Researcher

25.5.540

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

island health

Purpose:	The purpose of this Standard Operating Procedure is to describe the Research Ethics Board's (REB's) actions that must be communicated to the Researcher and the importance of open communications among REBs, researchers, staff, and Island Health committees and officials.
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:	• **Audience:**
	  o REB Office Personnel.
	  o REB Chairs and Members.
	• **Environment:**
	  o Research Ethics Environment.
	• **Indications (when this document is to be used):** For communication between the REBs, researchers, staff and Island Health committees and officials.
	• **Exceptions (when this docment is NOT to be used):** Communication that is not the above.

Outcomes:	• Define the paths for communicating with those involved in the research processes under review by the REB.

1.0 Responsibility

- All Island Health Research Ethics Board Office Personnel, Chairs, and REB members are responsible for the review and implementation of these procedures

2.0 Procedures

- In the interest of enhancing human research participant protection, it is important for the REB to foster collaboration and open communication between and among the REB, Researcher, research staff, and organizational representatives. This applies not only to communication related to a specific research project, but also to communication related to ethical issues and REB processes, policies, and procedures.
- All Researchers participating in REB approved research shall be informed, in writing, of all determinations made by the REB regarding specific research.
- Feedback from Researchers should be encouraged and should be considered as an opportunity to review and improve the function of the REB and of the REB office procedures.
- In order to facilitate clear and accurate communication with Researchers and research staff, the REB will follow standardized notification and documentation procedures.

2.1 Notification of REB Decisions

- Island Health REBs use electronic secure web-based REB document management systems. Researchers will be notified of REB decisions via an email automatically generated by the applicable systems.

a) The online system will be used to notify the Researcher and/or their research staff of the REB's decision in a timely manner, following the review (e.g., from the REB meeting or delegated review date) of new research, modifications, or amendments to currently approved research, applications for continuing review or reportable events;

b) The determinations of the REB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);

c) If the research does not receive initial approval or is denied re-approval (for continuing review), the REB Chair or designee will notify the Researcher of the REB's decision as soon as possible following the REB meeting. Formal written notification will follow;

d) The REB Chair or designee will review the draft REB review letter, or deferral notice, make revisions as necessary, and will indicate their approval;

e) The REB review letter or deferral notice will be issued to the Researcher(s) via the online system;

f) The Researcher will be asked to include the REB number or equivalent designation assigned to the research in all subsequent correspondence with the REB;

g) Upon receipt of the Researcher response to the REB review letter, or deferral notice, the REB will follow-up with the Researcher and/or their staff to request any additional clarifications as needed, or as requested by the REB Chair or designee, or the reviewers;

h) Once all of the REB conditions are satisfied, the REB will issue a Certificate of Approval. Included in the Certificate of Approval is the study title and REB number, name of the Principal Investigator and any co-investigator(s), funding agency, study sites, and a list of the approved documents. The document titles, version numbers, and dates listed in the Certificate of Approval correspond to the information entered on page 9 (RISe) and in Documentation) (the Portal) of the application form in the online system.

2.2 Researcher Appeal of REB Decision

a) A Researcher may request a reconsideration or appeal the decision of the REB and/or any of the revisions to the research requested by the REB;

b) Appeals are conducted in accordance with established Island Health SOP 546 Reconsiderations of Research Ethics Board Decisions and Appeal Process;

c) Only a full-board meeting of the REB may lift a restriction or re-review previously disapproved research. Delegated review procedures may not be used.

2.3 Communications Concerning Non-compliance

- Research non-compliance may be the result of communication difficulties. The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the study, especially if the rights and welfare of participants may be jeopardized.
    - However, if it appears that a Researcher is intentially non-compliant with the protocol, SOPs, TCPS2, REB, and/or other applicable requirements, the REB, through the REB Chair or their designee, will notify the Researcher in writing, detailing the alleged non-compliance, specifying corrective action, and stating the consequences. Such actions may be the result of an onsite audit conducted by the Research Ethics & Compliance office at Island Health. When appropriate, copies of such correspondence shall also be sent to the Researcher's supervisor and/or Department Head, study SponsorSenior Research Leadership.

3.0 Training

3.1 Review of the SOP Communication – Researcher.

4.0 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.

5.0 Definitions

- **Research Ethics Board Chair:** is responsible for ensuring that the REB review process conforms to the requirements of this Policy.
- **Research Ethics Board Members:** Current members of the Research Ethics Boards according to the roster.
- **Research Ethics Office Personnel:** Current employees of Island Health that make up the supporting structure for administration of Research Ethics Board(s).
- **Non-compliance:** failure to follow applicable guidelines and regulations governing human participant research; failure to follow the protocol approved by the Research Ethics Board (REB), or failure to follow stipulations imposed by the REB as a condition of approval.
- **Appeal:** A process that allows a researcher to request a review of a research ethics board (REB) decision when, after reconsideration, the REB has refused ethics approval of the research.

6.0 Related Island Health Policy Documents

- Reconsiderations of Research Ethics Board Decisions and Appeal Process

7.0 References

- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. (2022). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2022). (Chapter 6, Articile 6.19).
- 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).(2016). (3.3.9).
- IRB review of research, 21 C.F.R. § 56.109e (2024).
- IRB functions and operations, 21 C.F.R § 56.108a (2024).
- IRB records 21 C.F.R. § 56.115a(6) (2024).
- IRB functions and operations, 45 C.F.R. § 46.108 (2024).
- IRB review of research, 45 C.F.R. § 46.109 (2024).
- IRB records, 45 C.F.R. § 46.115 (2024).

8.0 Resources

- Glossary of Terms – Research Ethics

9.0 Summary of Changes

Version	Effective Date	Change Description
1.0	2024-MAR-01	New Procedure