

# Island Health Research Ethics Board Annual Report

April 1, 2024 - March 31, 2025



*Before Canada and BC were formed, Indigenous peoples lived in balance and interconnectedness with the land and water in which the necessities of life are provided. Health disparities persist, which are due to the impacts of colonization and Indigenous-specific racism.*

*Healthy lands, healthy people.*

*Island Health acknowledges and recognizes these homelands and the stewardship of Indigenous peoples of this land; it is with humility we continue to work toward building our relationship.*

*The Research Ethics & Compliance Office and REB are grateful to work on the unceded and traditional lands of the Kwakwaka'wakw, Nuuchahnulth, and Coast Salish peoples.*



# REB Chairs' Message

*The need for good quality research in health has never been so important, with the rise of Artificial Intelligence, third-party apps and other technological innovations that are becoming used more frequently in research studies and in health care in general. Island Health depends upon the Research Ethics and Compliance Office (along with the Research Ethics Boards) to ensure that this type of research, when carried out within this health authority, follows the standards of Health Canada, the Tri-Council Policy Statement (TCPS2) requirements, and Good Clinical Practice requirements, as well as compliance with Island Health's Standard Operating Procedures. The skill, expertise and knowledge of the RECO staff is vital to the success of studies carried out within Island Health.*

*The two Research Ethics Boards (CREB and HREB) are composed of volunteers who willing give of their time to review studies and ensure that the rights and best interests of study participants are upheld and that the participants are giving truly informed consent to be in a study. Their interest and passion in the role as Board members is very much appreciated and honoured.*

*We have reviewed this annual report for 2024-2025 and endorse it fully.*

***Heather Fudge, BSN, MN***

***Chair, Health Research Ethics Board***

***Reginald Smith, BSc (Pharm) ACPR, Pharm.D.***

***Chair, Clinical Research Ethics Board***

# Introduction

The Island Health Research Ethics Boards (REBs) are established and empowered under the authority of the Chief Executive Officer (CEO), and delegated to the Vice Presidents) responsible for research review, to review and approve all research involving human participants within Island Health jurisdiction and under Island Health auspices as defined in Island Health Research and Research Ethics policies and procedures, prior to the initiation of any research related procedures.

The Island Health REB, composed of the Clinical Research Ethics Board (CREB) and the Health Research Ethics Board (HREB), are established to review all research involving human participants in Island Health facilities, involving Island Health programs, with Island Health staff and/or patients or their data, conducted by Island Health staff or medical staff or anyone conducting research or under the auspices of Island Health.

The REBs have the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants which will include:

- reviewing, require modifications to, approve or disapprove, any research activity that falls within its jurisdiction.
- conduct continuing ethical review as it deems necessary to protect the rights and welfare and privacy of research participants. Continuing review activities include, but are not limited to:
  - Suspend or terminate the ethics approval for the research.
  - Place restrictions on the research.
  - Take any actions considered reasonably necessary and, consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the REBs' jurisdiction.

In accordance with *the Agreement on the Administration of Agency Grants and Awards by Research Institutions* signed by Island Health, the REBs abide by the:

- [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#), referred to as 'The Policy' and 'TCPS2 2022' and is Canada's foundational ethics policy for research involving human participants, data, or biological materials.
- [Tri-Agency Framework: Responsible Conduct in Research](#), which describes Agency policies and requirements related to applying for and managing Agency funds, performing research, and disseminating results.

The REBs observe policies and standards for rights holders and Indigenous Peoples including:

- [The United Nations Declaration on the Rights of Indigenous People \(UNDRIP\)](#) is a non-binding, comprehensive international instrument adopted in 2007, outlining 46 articles that establish minimum standards for the survival, dignity, and well-being of indigenous peoples. In Canada, it was adopted into law in 2021 (Bill C-15) to ensure federal laws align with its principles.
- The First Nations Principles of ownership, control, access, and possession (more commonly known as [OCAP](#)) which asserts that First Nations' have control over data collection processes, and that they own and control how this information can be used
- [The BC Cultural Safety & Humility Assessment Standard](#) (HSO A75000:2022) which outlines the responsibilities of health authorities and health and social services organizations in BC to establish cultural safety and humility and a culture of anti-racism in their services and programs to better respond to the health and wellness priorities of First Nations, Métis, and Inuit Peoples, communities, and families served by those organizations.

The REBs observe the following in addition to any applicable international laws, regulations, and guidances for the conduct of clinical trials at Island Health:

- Health Canada Part C, Division 5 of the Food and Drug Regulations for clinical trials using drugs in humans. The [Regulations](#) came into force on September 1, 2001 and set out the federal requirements for the sale and importation of drugs used in human clinical trials in Canada, and include the requirement to comply with good clinical practices (GCP).
- [ICH E6\(R3\)](#), an international ethical and scientific quality standard for designing, recording, and reporting trials involving human subjects. It ensures participant rights, safety, and well-being are protected while guaranteeing, the credibility and reliability of trial data.

The REBs observe privacy legislation for research involving public bodies:

- In British Columbia governed by the [\*Freedom of Information and Protection of Privacy Act\*](#) (FOIPPA).
- Federally by the [Privacy Act](#).

Island Health's REBs work to provide thoughtful interpretation of applicable resources to promote the highest ethical conduct of research involving human participants. The REBs take an 'ethics-first' approach in all their work, as does the office which supports their work, the RECO Team.

# 2024-2025 RECO Team

The RECO team is organizationally situated within Research Services under Island Health's Research Department. The RECO team coordinated three distinct research processes:

- **Research Ethics** review and the services we provide the research ethics boards in their administration and decision-making;
  - Karen Medler, Clinical Research Ethics Board Coordinator
  - Victoria Philibert, Human Research Ethics Board Coordinator
  - Joey Pearson, Administrative Coordinator
  - Jordan Beck, Administrative Coordinator
- **Research Compliance** related to supporting the rights and interests of research participants, ensuring institutional research standards & quality, aligning policies with the responsible conduct of research and scholastic integrity, and leading education efforts for our researchers and research administrators;
  - Tracy Wong, Research, Quality Assurance Specialist
- **Research Operational review** for all research studies that involve Island Health property and facilities; services, staff; health records and data; participant recruitment through/at Island Health; team member affiliation or other resources;
  - Julita Traylen, Research Administrative Coordinator

**RECO Manager:** Sarah Bennett

**Director, Research Services:** Dawn Waterhouse, PhD

# REB Meetings and Reviews

Full board meetings, typically hosted using Zoom as the REB members are geographically dispersed throughout the region, primarily evaluate initial applications and major amendment requests that represent greater than minimal risk to research participants. For the review of initial applications, the applicant may be invited to the REB meeting (whether full board or delegated review) to give a brief presentation about the proposal and to answer any questions from the REB members. Full board meetings also can include guest presentations from researchers both internal and external to the institution, in addition to educational activities and the review of new policies and procedures.

Per Island Health's SOP 501, quorum is achieved for reviews requiring a full board decision when all five members required by section 2.2 of TCPS2 2022 (one member each with expertise in ethics and in law, one community member, and two researcher members) and at least 50% + 1 of the voting members of the REB participate.

By contrast, minimal risk applications are generally sent to delegated review, along with submissions for continuing ethics review (i.e., annual renewals, study amendments, protocol deviations, and adverse event reports). REB members attend delegated review meetings as needed. Delegated review meetings are normally attended by the Chair, one other REB member, and one of the non-voting members of the RECO staff.

Members from CREB and HREB strive to meet once-a-year in person, and remotely as required, for intensive educational sessions and presentations from researchers.

# Clinical Research Ethics Board

The CREB held 9 Full board meetings during the year and members, including staff and the Chair, attended 1 harmonized full REB meeting.

## Composition & Administrative Supports

### Voting Members

Name	Date of Appointment	Highest Degree	Primary Specialty	Role	Island Health Affiliate
Boxall, Jan (Dr)	Feb, 2023	MD	Family Medicine	Scientific, Community	N
Davenport, Lesley	Jan, 2017	MSc	Marine Biology	Community	N
Fudge, Heather	Jul, 2018	MN	Seniors Health	Community	N
Godfrey, Nelson	Feb, 2019	JD	Law	Legal	N
Hasselback, Paul (Dr)	Nov, 2021	MD	Epidemiology/Public Health & Preventive Medicine	Scientific	N
Kerr, Susan	Nov, 2022	MN	Cardiac Nursing	Community	N
Patel, Anika	Feb, 2024	MSc	Nursing Science/Ethics	Scientific, Ethics	N
Pirani, Sarah (Dr)	Feb, 2022	DNP	Primary Healthcare/Internal Medicine	Scientific	N
Pollock, Lynn	Nov, 2020	BSc	Pharmacy	Scientific	N
Robinson, Jill (Dr)	May, 2023	PhD	Clinical Psychology	Scientific	N
Shanner, Laura (Dr)	Aug, 2021	PhD	Bioethics	Ethics, Community	N
Smith, Reginald (Dr) <b>(Chair)</b>	Jun, 2015	PhD	Pharmacy/Cardiology	Scientific	Y

### Alternate Members

Name	Date of Appointment	Highest Degree	Primary Specialty	Role	ISLH Affiliate
Francis, Hannah	Aug, 2021	RN	Nursing Science	Scientific	Y
Patterson, Caitlin	Sep, 2022	BSc	Cardiac Research	Scientific	N
Schichter, Brittney	Dec, 2020	JD	Law	Legal	N

*All voting members are Canadian citizens or permanent residents of Canada.*

### Non-voting Members (Staff)

Name	Date of Appointment	Title
Karen Medler	Nov, 2011	Research Ethics Coordinator
Joey Pearson	Aug, 2014	Research Ethics Administrative Assistant

# Health Research Ethics Board

The HREB met 11 times with 1 full Board review meeting. The HREB added two Indigenous REB members through the aid of the BC Network Environment for Indigenous Health Research ([BC NEIHR](#)), and one board member retired.

## Composition & Administrative Supports

Name	Date of Appointment	Highest Degree	Primary Specialty	Role	Island Health Affiliate
Anderson, Sheldon	Sep, 2024	BSW	Social Work	Community, Non-Scientific	N
Boxall, Janice Dr.	Jan, 2024	MD	Family Medicine	Community, Scientific	N
Costello, Louise Dr.	Sep, 2016	PhD	Psychology	Community, Scientific	N
Fudge, Heather ( <b>Chair</b> )	Jul, 2018	MN	Seniors Health, Nursing Science	Community	N
Godfrey, Nelson	Jan, 2019	JD	Law	Community, Legal	N
Hasselback, Paul Dr.	Sep, 2012	MD	Epidemiology, Public Health	Community, Scientific	Y
Kesten, Cyril Dr.	Jun, 2023	PhD	Mental Health, Community Care	Patient Partner	N
Kottova, Alena Dr.	Jan, 2023	PhD	Cybersecurity, Physics	Scientific	N
Lencar, Cornel	Sep, 2019	MA	Epidemiology, Population Health	Scientific	Y
Litchfield, Michael	Jun, 2023	JD, LLM	Law, Drug and Alcohol Policy	Community, Legal	N
Obeidat, Samer	Mar, 2024	MA	Artificial Intelligence, Deep Learning	Scientific	N
Premji, Zahra Dr.	Jan, 2023	PhD	Chemistry, Health Research Libraries & Data	Non-Scientific	N
Schau, Torben	Sep, 2021	MA	Health System Planning	Non-Scientific	Y
Shanner, Laura Dr.	Sep, 2021	PhD	Bioethics, Ethicist	Ethics	N
Turcotte, Kara Dr.	Sep, 2024	PhD	Psychology, First Nations Health Equity	Community, Scientific	N
Udy, Vanessa	Jun, 2023	LLM	Indigenous Property Law	Community, Legal	N
White, Crystal	Jan, 2011	MA	Dispute Resolution	Non-Scientific	N
Yoo, Laura	Jul, 2024	PharmD	Pharmacy	Scientific	Y

*All voting members are Canadian citizens or permanent residents of Canada.*

## Non-Voting Members (Staff)

Name	Date of Appointment	Title
Philibert, Victoria	Apr, 2022	Research Ethics Coordinator
Beck, Jordan	Jun, 2023	Research Ethics Administrative Assistant

# Boards' Activity

In the fiscal year, the REBs received 100 new initial applications for ethical review. Including post-approval activities such as amendments, renewals and closures, the team processed ~1250 submissions through the online database systems, another new record for the team.

Of 100 new applications, 89 were submitted in RISE, the provincial platform hosted by UBC for harmonized review. The Island Health REBs acted as Board of Record for 45 of these applications and participated in the review of 27 others. Not all studies directly involve the Island Health REBs due to policies related to single ethics review for BC Cancer and Children's and Women's REBs reviewing. Direct reciprocity aimed at a single ethics review continues to be supported at Island Health.

Post-approval activity submissions make up a significant demand for review by the REBs. Together, the Boards received 598 requests for Amendments, 314 renewal applications, and 89 closures reports.

## Average Timelines

Measures improved across almost all indicators for ethical review and operational review. When compared to the previous year, from the date of new research study being received by Island Health to issuance of institutional approval (ethical review + operational review), the length of time improved to just over 4 months (128 days).

Fiscal Year	Days between received & REBC assigned	Days between REBC & first REB reviewer	Days between assigned to OpR & final OpR	Days between initial response from PI & Island Health approval	Days between from PI & Ethical CofA	Days between Final OpR & Institutional Approval	Days between received & Institutional Approval	Days between Final OpR & Contract complete	Days between received & Contract complete	Total Days with Data	Additional Days Taken with Contracts	Total Days with Contracts	Days Taken
2024/2025	5.1	4.5	89	32	33	18	128	40	98	98*	NA	NA	100
2023/2024	6.4	7.8	97	35	35	7	141	39	123	98	NA	NA	109
2022/2023	<1	9	37	73	31	27	39	44	98	98	NA	NA	95
2021/2022	1	7	38	16	20	60	101	44	63	98	40	56	116

\*less than 6 studies requested data services during this FY.

\*These are calendar days

### Legend

REBC – Research Ethics Coordinator, OpR – Operational Review, PI – Principal Investigator, CofA – Certificate of Approval (Ethics Approval)

# Operational Review

Institutional Approval Certificates were issued for 97 studies during the year. To ensure the timeliness of operational review, the Research Administrative Coordinator meets regularly with department reviewers.

# Research Compliance

Research Compliance staff includes one full-time permanent Research Quality Assurance Specialist and a part-time role filled by one of the Ethics Assistant roles. At the end of March 2025, this part-time role was surrendered and remains unfilled due to fiscal restraints. The RECO Manager provides support. Through research related training, quality assessments, auditing, inspection support, consults and investigations, Research Compliance supports Island Health Researchers to deliver quality research.

Investigations	4
Training	18
Audits	0
Regulatory Inspections	1
Standard Operating Procedures (SOPs) Support	24
Consults	15
External Presentations	3
Internal Presentations	12
Good Clinical Practice (GCP) course completion	50
Health Canada Division 5 course completion	51
Tri Council Policy Statement 2 course completion	38

# Education and Outreach

An ongoing priority for RECO and the REBs continues to be education, including outreach and professional development. Some notable events included:

- Attendance by invitation to the BC SUPPORT Unit & BC NEIHR Indigenous Health Research Ethics in Clinical Research Symposium (April 16, 2024, Vancouver)
- CAREB-ACCER National Conference on Research Ethics: “Impact and Effect: Connecting to Community Through Research Ethics” (April 30 – May 2, 2024, virtual)
- REBC Clinical Research Ethics Symposium (December 3-4, 2024, virtual)

Staff participated in multiple events providing education, which is valued and appreciated by those receiving it. Outreach, including that which is in person, has increased. This has fostered greater connections across not only Island Health but across the domains RECO represents professionally at a national level.

# Research Ethics Harmonization

The REBs and staff continue to make significant contributions enabling and supporting a wide variety of research and researchers to optimize their research service experience at Island Health.

The Research Approvals Processes Project (RAPP) led by the Ministry of Health and Michael Smith Health Research BC continues to address the need for infrastructure and processes related to research ethics and operational review as well as other key components of research administration. RECO staff and REB Chairs participated in several meetings as subject matter experts. The work continues into the foreseeable future.



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