# Island Health Research Ethics Boards Annual Report

*April 1, 2021 – March 31, 2022*

*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 REBs are grateful to work on the unceded and traditional lands of the Kwakawaka'wakw, Nuu-chah-nulth, and Coast Salish peoples.*

Research Ethics & Compliance Office

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## Fast Facts

- 130+ NEW study reviews of research involving humans conducted by Research Ethics Boards and staff.
- 324 Active Studies on ROMEO and for this fiscal year 64 studies were closed or withdrawn.
- We are associated with 321 Active Studies on RISe[1], comprised of:
  - 73 new studies,
  - 69 we manage on RISe as Board of Record
- 56% of total reviews were harmonized studies
- 45% of new projects reviewed were funded research
- 2 Research Ethics Boards (Clinical and Health) with 34 members
- 39 Researchers completed the TCPS online course on research ethics.
- 56 completed Good Clinical Practice training for clinical research.
- Only REB in Canada with proportionate representation from Indigenous identifying members
- First REB in Canada to mandate formal cultural safety training for staff and members via San'yas
- First in community REB review at Cowichan Tribes in partnership with First Nations Health Authority, Island Health, and University of British Columbia

## Executive Summary

> Thanks for all your support and encouragement. As you can imagine, taking time out to look at outcomes when there is exciting and pressing clinical work, is at best a bore. Your ever willingness to help has kept the project going.
>
> Thank you!

This report highlights the activities of the Island Health Research Ethics Boards (REBs) at Island Health. The REBs are supported by the Research Ethics & Compliance office (RECO) within the department of Research & Capacity Building (Research). In addition to supporting ethical review of research, RECO tracks data to help the organization better understand what sort of research is occurring, where it is occurring, and who is leading it.

Research Ethics staff include two full-time permanent Coordinators, one permanent part time (.69 FTE) and one temporary part-time (.05 FTE) Ethics Assistants. A full-time Administrative Coordinator role offers part-time support to the REBs, provides operational review and prepares institutional approvals as well as Finance, reporting and support for the RECO Manager. A Manager (1.0 FTE) supports research ethics and staff, as well as the Compliance role of the office along side the Research Compliance Facilitator, another full time role.

[1] The online database platform at UBC which hosts the Provinical Research Ethics Platform, PREP.

In total, there were seven office personnel in the office with four full-time positions in total to support research ethics specifically. These staff coordinate and support the work of two Research Ethics Boards: Clinical and Health. There were 6 Health Research Ethics Board (HREB) meetings scheduled and 20 members; as well as 12 Clinical Research Ethics Board (CREB) meetings scheduled and 14 members. Due to workload, the CREB had an extra meeting in September 2021. The Research Ethics Boards and staff conducted over 1032 reviews of submitted research review requests comprising new applications, and post-approval activities. The office also supported 67 QI Ethics consults in order to determine whether the project could be exempted from formal research ethics review at Island Health.

This report offers an overview of the activity of Research Ethics for the period of April 1, 2021 to March 31, 2022.

# Introduction

The Research Ethics Boards (REB) provide independent ethical review of research that involves human participants, and is conducted within the jurisdiction and under the auspices of Island Health. This includes: research that occurs in an Island Health facility; involves an Island Health staff member, medical staff, or student as a researcher; or involves Island Health patients, clients, residents, staff, medical staff, volunteers, students, or their information as participants. The REBs are established by Island Health's CEO, and delegated to the Vice President – Professional Practice, Research and Chief Nursing and Allied Health Officer. The REB Chairs are appointed by the Vice President, Quality, Research and Chief Nursing and Allied Health Officer and via delegation report to the Executive Medical Director, Research. Members are appointed by the Chair of the REB to which they serve.

The REBs abide by the national standard for research ethics, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018)*, commonly known as TCPS2 or 'The Policy'. In addition, the REBs observe applicable Health Canada, and US federal regulations, national and provincial privacy legislation, and institutional procedures and policies. The Research Ethics &Compliance Office (RECO) work to provide thoughtful interpretation of these standards in order 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 RECO.

This report encompasses the work of the Research Ethics & Compliance Office and the Island Health REBs. Under TCPS 2, public reports may be provided which should summarize activities and initiatives relevant to the ethical review research involving humans, its research ethics administration, and relevant research ethics education and training[2]. As the first annual report issued by this office, the report will provide an update based on the past fiscal year, and provide some historical information from the past 10 years for context.

## The Island Health Research Ethics Boards

In 2021-2022 the REBs received 174 new initial applications for ethical review. This includes where Island Health was added via an amendment to a previously approved study at another institution (see Section: Research Ethics Harmonization). This number is higher than the ten-year moving average of 108 per year.

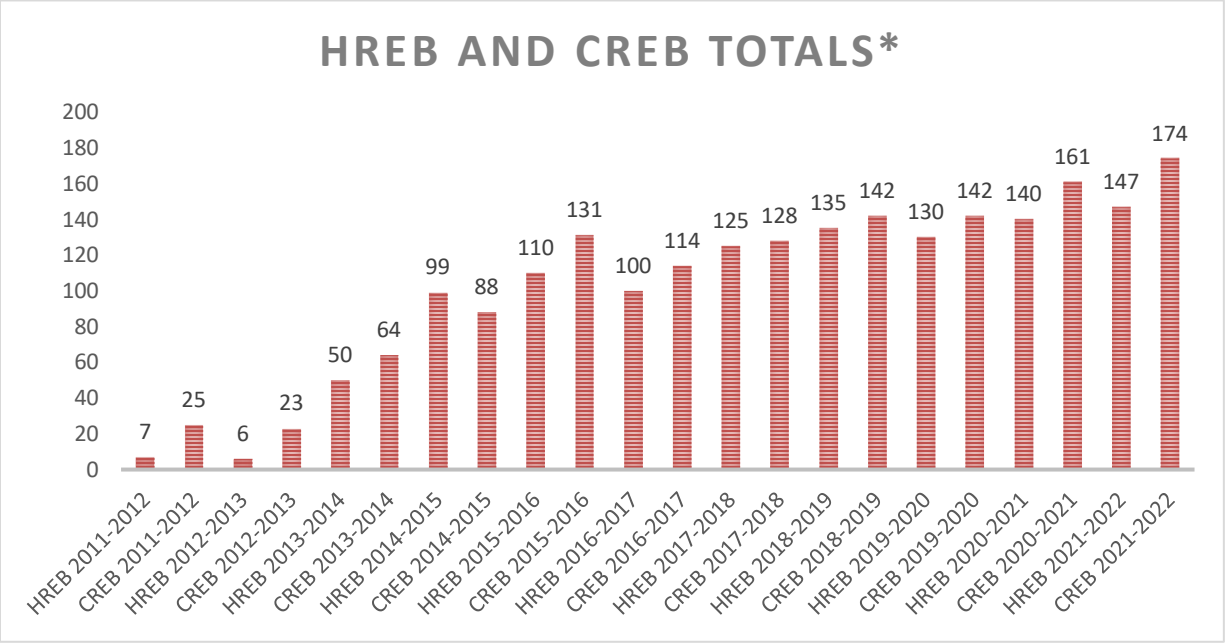
Approximately 56% of the new applications were submitted on PReP (on RISe), as part of the harmonized review system. Of these submissions, the Island Health REBs served as Board of Record (e.g. primary board responsible for the administration of the harmonized review) for 69 studies.

Post-approval submissions also accounted for a significant portion of the demand for review. The REBs received 575 requests for amendments, 221 requests for renewal, and 62 requests for study closures. The total number of review requests is 858, which is higher than the previous fiscal year where a notable increase occurred due to COVID-19, but in keeping with previous fiscal year trends.

In total, there are approximately 324 active applications within the databases.

[2] TCPS 2, Article 6.1, https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html

Figure 1:




Average CREB Studies over 10 years: 108.36
Average HREB Studies over 10 years: 95.36

# The Clinical Research Ethics Board (CREB)

## Composition of the Board

As of the end of the fiscal year, the CREB included 14 regular members, three alternate members, and the Chair. The credentials, roles, affiliations and terms of office for each member are described in the table below.

**CREB Membership List – February 2022**

Voting Members*

| Name | Date of Appointment | Highest Degree | Primary Specialty | Role | VIHA Affiliate |
|---|---|---|---|---|---|
| Fudge, Heather | July 2018 | MN | Seniors Health | Community | N |
| Davenport, Lesley | January 2017 | MSc | Marine Biology | Community | N |
| Godfrey, Nelson | February 2019 | JD | Law | Legal | N |
| Hasselback, Paul (Dr) | November 2021 | MD | Epidemiology/Public Health & Preventive Medicine | Scientific | N |
| Jackson, Heather (Dr) | January 2010 | PhD | Kinesiology | Scientific, Community | N |
| Patterson, Caitlin | February 2022 | BSc | Cardiac Research | Scientific | N |
| Pirani, Sarah (Dr.) | February 2022 | DNP | Primary Healthcare/Internal Medicine | Scientific | N |
| Pollock, Lynn | November 2020 | BSc | Pharmacy | Scientific | N |
| Shanner, Laura (Dr) | August 2021 | PhD | Bioethics | Ethics, Community | N |
| Smith, Reginald (Dr) (Chair) | June 2015 | PhD | Pharmacy/Cardiology | Scientific | Y |

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

Alternate Members

| Name | Date of Appointment | Highest Degree | Primary Specialty | Role | VIHA Affiliate |
|---|---|---|---|---|---|
| Francis, Hannah | August 2021 | RN | Nursing Science | Scientific | Y |
| Patel, Anika | January 2022 | BSN | Nursing Science/Ethics | Scientific, Ethics | N |
| Schichter, Brittney | December 2020 | JD | Law | Legal | N |

Non-voting Members (Staff)

| Name | Date of Appointment | Title |
|---|---|---|
| Karen Medler | November 2011 | Research Ethics Coordinator |
| Joey Pearson | August 2014 | Research Ethics Administrative Assistant |
| Simon Munn | November 2021 | Research Privacy Specialist |

## Responsibilities of the CREB

The CREB is responsible for review, approval and ongoing oversight of all clinical research studies including clinical trials involving humans conducted by Island Health researchers at all Island Health sites. These researchers include Island Health employees, privileged physicians, affiliated academic researchers and clinical or medical student or resident who is completing or participating as a research team member in the health authority as part of their academic requirements.

The CREB reviews research that involves surgery, clinical interventions (the administration or testing of drugs, medical devices, medical imaging or diagnostic techniques, and the taking of blood or other specimens), and the analysis of clinical data. The CREB will also review clinical studies involving registries and/or the linkage of databases.

The CREB operates according to the principles and standards detailed in TCPS2. In addition, the CREB complies with Health Canada regulations and guidelines concerning the ethical review of clinical drug, device, and natural health project trials, and with United States (U.S.) government legislation governing the ethical review of studies funded by their government agencies and/or regulated by the U.S. Food and Drug Administration. As such it has a U.S. Federal Wide Assurance (FWA) which designates it as compliant. The CREB ensures that any other Canadian legislation that is applicable to the conduct of research by a public institution is adhered to by Island Health researchers.

An additional role is assigned to the CREB Chair who conducts the delegated review of studies that meet the criteria for minimal risk as defined by the TCPS2 and Island Health REB policy. The delegated review process is also used to review:

1) Applications for amendment and renewal of previously approved studies that do not required full board review;
2) Local and international serious adverse events and protocol deviations;
3) Principal investigator responses to provisos arising from full board or delegated reviews, and;
4) Any other study-related correspondence.

The CREB held 12 Full Board meetings during this period. Typically, the CREB meetings 10 times in a year. Additional meetings were needed to address workload due to the COVID-19 pandemic.

# The Health Research Ethics Board (HREB)

## Composition of the Board

As of the end of the fiscal year, the HREB had 18 regular members, and the Chair. The credentials roles, affiliations and terms of office for each member are described in the table below.

### HREB Membership List – February 2022

**Voting Members***

| Name | Date of Appointment | Highest Degree | Primary Specialty | Role | Island Health Affiliate |
|---|---|---|---|---|---|
| Fudge, Heather (Chair) | July 2018 | MN | Seniors Health, Nursing Science | Community | N |
| Brewster, Paul Dr. | January 2019 | PhD | Neuropsychology | Scientific | Y |
| Cheek, Joanna Dr. | January 2022 | PhD | Psychiatry | Scientific | Y |
| Chenery, Jessica | January 2016 | MSc | Aboriginal Health | Community, Scientific | N |
| Costello, Louise Dr. | September 2016 | PhD | Psychology | Community, Scientific | N |
| Gillis, Amanda | January 2019 | GDip | Learning Support | Community | N |
| Godfrey, Nelson | January 2019 | JD | Law | Community, Legal | N |
| Hansen, Vaneysa | January 2010 | MSc | Speech Language Pathology | Scientific | Y |
| Hasselback, Paul Dr. | September 2012 | MD | Epidemiology, Public Health, Preventative Medicine | Community, Scientific | Y |
| Hastings, Heather | September 2011 | MA | Public Health Nursing, Health Administration | Community, Scientific | N |
| Lencar, Cornel | September 2019 | MA | Epidemiology, Population Health | Scientific | Y |
| Schau, Torben | September 2021 | MA | Health System Planning | Non-Scientific | Y |
| Shanner, Laura Dr. | September 2021 | PhD | Bioethics, Ethicist | Ethics | N |
| Tolloczko, Barbara Dr. | December 2019 | PhD | Biology, Research | Community | N |
| White, Crystal | January 2011 | MA | Dispute Resolution | Non-Scientific | N |

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

**Non-Voting Members**

| Name | Date of Appointment | Title |
|---|---|---|
| Vacant | | Research Ethics Coordinator |
| Traylen, Julita | June 2021 | Research Ethics Administrative Assistant |
| Simon Munn | November 2021 | Research Privacy Specialist |

## Responsibilities of the HREB

The HREB is responsible for the review, approval and ongoing oversight of all reviews research that is predominantly behavioural or social sciences related. Studies may involve the study of patients or healthcare providers and retrospective chart reviews. Studies also may involve interviews, focus groups, observations, the administration of questionnaires or tests, or retrospective chart review (where no clinical interventions are performed as part of the study).

The HREB operates according to the principles and standards detailed in TCPS2. In addition, the HREB complies with Health Canada regulations and guidelines where applicable. The HREB ensures that any other Canadian legislation that is applicable to the conduct of research by a public institution is adhered to by Island Health researchers.

An additional role is assigned to the HREB Chair who conducts the delegated review of the studies that meet the criteria for minimal risk as defined by the TCPS2 and Island Health REB policy. The delegated review process for the HREB follows the CREB as outlined above. The HREB Chair is also a member of the CREB.

Please refer to Appendices for a complete description of the REB Chair role.

The HREB held six Full Board meetings during this period.

## Conflict of Interest

All REB members are required to complete a conflict of interest and commitment disclosure form at their appointment. Any members found to have a conflict are excused from the review of the applicable research study.

## REB Compensation

The REB members are each paid per meeting attended and per study reviewed ($100 per meeting, and $50 per study). REB Chairs are contracted annually at a rate of $25, 000 per year. The amounts for members are funded by the fees paid by industry sponsors for research studies conducted in Island Health. Chairs are paid from the same fees, and partly through the Research Ethics & Compliance Operational budget.

## REB Education

The COVID-19 pandemic limited in-person education sessions, and due to workload, such events were limited even virtually. However, the following virtual education activities were provided and attended by REB members and staff:

- Research Ethics BC (REBC): Indigenous Cultural Safety and Humility Workshop, March 3, 2022
- REBC and University of British Columbia (UBC): Clinical Research Ethics Symposium, October 21-22, 2021
- CAREB-ACCER National Conference on Research Ethics: May 5-7, 2021

Ongoing education both attended and provided by RECO office personnel are tracked. Professional development and learning is a necessity as the research ethics landscape grows, and is a requirement by TCPS2 for staff and members alike. It ensures that staff are able to provide that learning on to Island Health's research community.

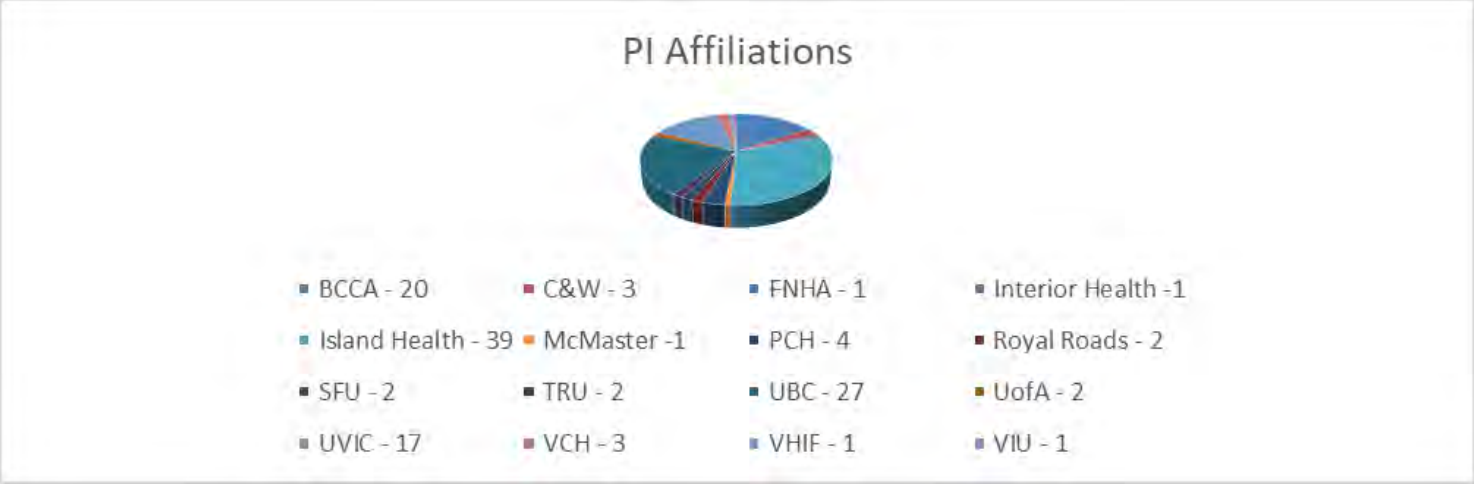
| **Professional Development and Training – Attended by RECO staff** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Year** | **External Presentation** | **VIHA Course/ Workshop** | **Conference Attendance** | **COVID-19** | **Education Event** | **Other** | **Total** |
| 2019 | 3 | 24 | 10 | 0 | 12 | 0 | 49 |
| 2020 | 8 | 8 | 0 | 3 | 16 | 0 | 35 |
| 2021 | 5 | 6 | 9 | 0 | 47 | 0 | 67 |
| 2022 | 26 | 120 | 0 | 0 | 0 | 29 | 175 |
| Total | 42 | 158 | 19 | 3 | 75 | 29 | 326 |

| Outreach – Provided by RECO staff | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Year** | **External Presentation** | **Face-to-Face Meeting** | **Internal Presentation** | **COVID-19** | **Tele - conference** | **Other** | **Total** |
| 2019 | 13 | 41 | 13 | 0 | 72 | 34 | 173 |
| 2020 | 1 | 8 | 2 | 48 | 102 | 5 | 166 |
| 2021 | 1 | 0 | 3 | 0 | 115 | 30 | 149 |
| 2022 | 2 | 0 | 3 | 0 | 88 | 1 | 94 |
| Total | 17 | 49 | 21 | 48 | 377 | 70 | 582 |

## Research Ethics Harmonization

Multi-jurisdictional research and research in partnership with academic institutions, health authorities, and clinical research groups in BC compose the majority of research submitted for review to the REBs. Research Ethics BC (REBC) provides supports for the provincial, harmonized system for research ethics review of multi-jurisdictional studies involving humans from more than one BC institution. This includes facilitating the Provincial Research Ethics Platform (PReP) hosted on UBC's online database system, RISe. Island Health's REBs are active participants and partners in this initiative. Staff participate in various committees, and Communities of Practice, with the Manager, E. Sarah Bennett, as Past Chair and ongoing member of the Advisory Council.

Principal Investigators of research at Island Health demonstrate the wide variety of affiliations that are represented.



# Achievements and Successes

## REB Standard Requirements

Since 2019, a substantial review of the Island Health REB Standard Operating Procedures (SOPs), institutional policies related to research, application forms, templates and guidance has been ongoing by the Research Ethics & Compliance Office. This past fiscal year, the updating of the RECO webpages ensured information is aligned with current regulations, best practices, and ethics guidance. Refer to Appendix X for a complete list of updated documents.

## Research Ethics and Research Privacy Supports

The REBs are served by the role of the Research Privacy Specialist. This role is central to ensuring that research studies at Island Health address privacy concerns during the initial submission review. These can then be dealt with via the privacy office or within the Operational Review processes. In 2021-2022, Privacy reviewed approximately 20 studies for privacy concerns. This role also supports the occasional review of QI Ethics projects.

## REB Standard Operating Procedures

The SOPs specifically applicable to the work of research ethics have been extensively updated. There were 24 new SOPs adopted based on national templates provided by the Network of Networks (N2). This aligns our REBs provincially and nationally to enable harmonized research ethics approvals, and improve consistency of review and organization for the REBs and staff.

## QI Ethics Program

Projects that are "quality assurance and quality improvement, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research"[2] and are exempt from formal research ethics review. Where this exemption is applied, institutions should offer a method to ensure ethical issues that may arise are addressed. Since 2017, Island Health Research Ethics and Quality offices have supported the QI Ethics tool for this purpose. In 2020, the tool was revised to streamline the survey and registry components, and update the tool to comply with current TCPS2. The registry creates an understanding of the QI work happening in different areas of the organization. Proportionate consults for QI projects with higher scores (above minimal risk) offer mitigation and address to potential ethical issues. The QI Ethics team continues to be a collaboration between Research Ethics, and Patient Safety, with leadership support from both departments, Research, and Quality. The team is grateful for this support, and the valuable contribution made by the participating members in QI Ethics work. A biannual report, *QI for You and I*, provides metrics to the larger leadership community at Island Health.

The QI Ethics tool held 146 projects as of end of fiscal 2022; of these 59 were entered into the registry during this period. The total number of projects in the current tool now stands at approximately 190.

[2] TCPS 2, Article 2.5, https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#5

# Administrative Operations

## Research Ethics Education

A total of 139 research ethics outreach and education opportunities were presented to both Island Health researchers and external groups (Refer to table in Section: REB Education). Presentations were given at national conferences, local institutions including UBC Family Practice Residents, and Pharmacy Residents, Royal Roads University Masters in Leadership students, and those entering Physician Quality Improvement cohorts. All of these were virtual due to the pandemic.

## Research Ethics Website

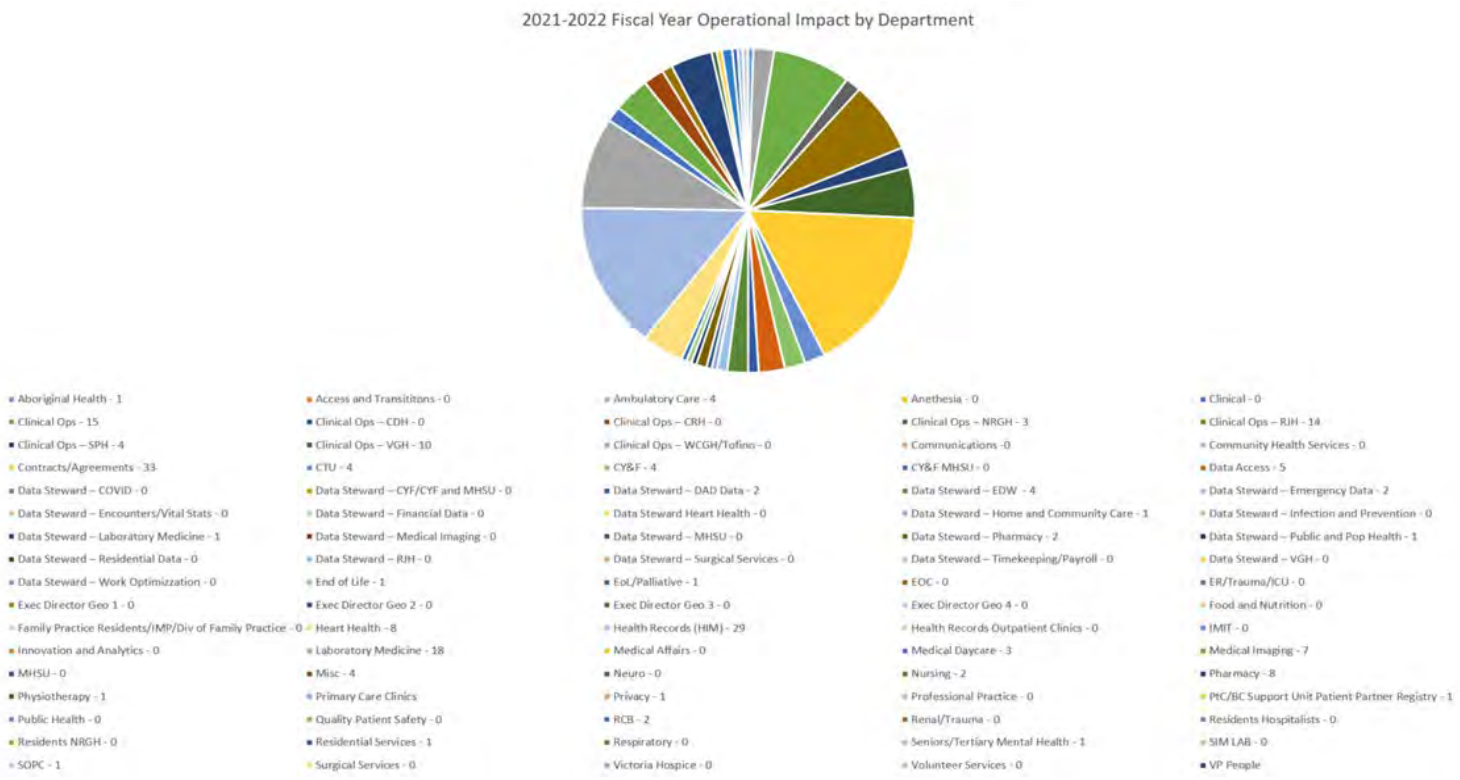
All ethics review procedures, including meeting schedules, and applicable guidance, forms, and templates are posted and updated on an ongoing basis to the RECO webpages: https://www.islandhealth.ca/research-capacity-building/research-ethics-compliance-office. The work to update and refresh these pages was completed in the beginning of 2022. In addition, RECO staff are now trained to complete updates in real-time which supports compliance. The office is grateful for the support of Web Communications for this, and the updates necessary during the COVID-19 response.

## Operational Review

**Research Operational Review and Institutional Approval**
The Research Ethics Office includes one full-time (1.0 FTE) permanent Research Administrative Coordinator who reviews research studies and amendments for operational impact at Island Health.
The role includes:

- Training support for Operational Reviewers – Directors and Delegates
- The maintenance of the Clinical Research Ethics Board, Health Research Ethics Board and Operational Applications
- Designated "super-user" of the Research Services Portal (commonly referred to as ROMEO)
- Presentations, Support and Training to our Provincial Partners including co-leading the Research Operational Administrators Community of Practice
- Maintenance of metrics and delivery of reports to Research and Capacity Building and Departmental Directors, and the Ministry of Health
- Finance support to the Manager, Research Ethics and Compliance
- Back up of Administrative positions

| Total Studies Reviewed for Operational Impact | Total Amendments reviewed for Operational Impact | Meetings to gain approval from Directors/Delegates | Training Sessions Completed for new Directors/Delegates | Training Sessions for RAC role |
|---|---|---|---|---|
| 174 | 686 | 99 | 23 | 43 |




## Challenges Ahead

Coming challenges for the Operational Review and Institutional Approval include:

- The complexity and number of studies that are coming to Island Health are increasing.
- The number of staff changes in Island Health has been a concern for effective timelines. It is hopeful that this is more settled and that long-term, meaningful and productive relationships with the 23 new roles trained this year.
- The delay in researcher access to data, time to completed contracts, and privacy review (when applicable) is an ongoing concern.
- Anticipated updates to the ROMEO Portal may present issues; however, changes should improve the overall experience for reviewers, staff, and the research community.

## Research Ethics Office

The Research Ethics Boards are supported by the Research Ethics office personnel.

E. Sarah Bennett is the Manager, Research Ethics & Compliance with responsibility for developing, implementing, and monitoring ethical review processes and standards for Island Health, providing policy guidance to the Island Health REBs, ensuring Island Health is compliant with all applicable international, Canadian, and provincial legislation, guidelines, and standards, and for overseeing the administration of the Island Health REBs. All RECO staff conducts workshops on the overall conduct of research for Island Health employees, and clinical staff. In addition, the Manager is a member of the Advisory Council for the Research Ethics BC harmonization initiative.

The REBs are each staffed by two full-time Research Ethics Coordinators (Karen Medler, and Victoria Philibert), and two part-time Research Ethics Administrative Assistants (Julita Traylen, and Joey Pearson). The Coordinators perform the essential function of ensuring that the Board runs efficiently, and effectively. This includes providing support to individual researchers, processing all applications for, and decision of the Full Boards, and delegated review, providing assistance to the REB Chairs, participating in developing and presenting workshops on ethical review, and updating forms, templates, guidance notes, standard operating procedures and policies. In addition to this, and as a strategy to improve and sustain the consistency of ethical review, a pre-review or analysis of all initial and renewal applications, consent forms and other documentation submitted for Full Board and delegated review is conducted to ensure standard requirements are met. This information is including in the study documents sent to the Board members prior to their attendance at meetings and upon assignment of a study application by a reviewer.

Due to volume and increased post-approval activities related to the pandemic, updated SOPs documented the delegation of authority and review to the REB Coordinators formally. REB staff now may review and approve minimal risk studies for the following types of submissions:

a. new minimal risk studies (input from Chairs/REB members solicited as needed at the discretion of the REB Coordinators);
b. responses to provisos (if minor);
c. annual renewal applications that do not require Full Board review;
d. study close-out applications;
e. minor amendment applications that do not constitute a change in the risk-benefit ratio (e.g. addition of study site, submission of new recruitment material, consent form language, change in REB contact information); amendments of a clinical nature would usually require review by the clinical REB Co-Chair, and;
f. acknowledgements of administrative letters, e.g. data safety monitoring board reports.

The addition of an annual day long retreat for RECO staff enhanced the ability to identify priorities fitting within the overall Island Health and Research department strategies. The publication of the priority plans provides transparency and clarity for the team around performance goals, and accountability, as well as connecting with the larger research community (See Appendices).

This past year also saw the hiring of a new Coordinator for the HREB, Victoria Philibert. Past Coordinator, Dawn Pollon, resigned at the end of January 2021.

The office of the unit remains at Queen Alexandra Centre for Children's Health, with safe, flexible working spaces established, and all staff equipped with the appropriate tools to enable work from home agreements.

# Research Compliance

Research Compliance staff includes one full-time permanent Research Quality Assurance Specialist along with the support of the RECO Manager. Through research related training, quality assessments, auditing, consults and investigations, Research Compliance supports Island Health Researchers to deliver quality research.

This report offers an overview of the activity of Research Compliance for the period of April 1, 2021 to March 31, 2022.

| Investigations | Training | Audits | Regulatory Inspections | Standard Operating Procedure (SOP) Support | External Presentation(s) | Internal Presentation(s) |
|---|---|---|---|---|---|---|
| 3 | 34 | 0 | 0 | 15 | 3 | 1 |

## Challenges Ahead

For the coming year, we will continue our work to build a quality culture within research, shaping Research Compliance's role as supportive, non-punitive. The message that we all have a common goal to offer safe, accessible, quality research must be at the forefront when building and/or maintaining relationships.

Research Compliance's role, authority and autonomy is not well defined and many Researchers use historical experiences to define Research Compliance. Research Compliance's role needs to be defined through policy, standard operating procedures, guidance and reporting structure to support Researchers understanding. For role in particular, Research Compliance acts on behalf of the institution to provide objective review of research systems and practice. Identifying the role in this way helps to address the ongoing and challenging relationships of scope between Research Compliance and Researchers.

With one FTE dedicated to Research Compliance for Island Health, resource management, priority scheduling, communication and leadership support are requirements for a successful year.

## Summary

At the end of the fiscal year, RECO and REB operations were stable both administratively, and strategically. These successes illustrate the importance of having local research ethics review that can address immediate challenges in the healthcare systems in order to support the delivery of excellence in care for the Island Health communities. After the challenges of COVID-19, the increase in workload volume and complexity for this office is apparent.

The following operational challenges remain to be addressed in the coming year:

- Establish and document clear reporting parameters for review timelines;
- Increase REB membership especially for physician members;
- Ensure permanent funding lines for the Research Compliance Facilitator (1.0 FTE) and Research Ethics Administrative Assistant (0.5 FTE).

# DUTIES OF RESEARCH ETHICS BOARD MEMBERS
# SOP 534

PROCEDURE

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

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| | |
|---|---|
| **Purpose:** | To provide Island Health a standardized approach to describe the management and oversight of the Research Ethics Board (REB) to ensure continuity of membership and expertise to meet guidelines, regulations, and institutional mandates. |
| **Context:** | Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples.<br><br>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.<br><br>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<br>  o Vice-President, Quality, Research and Chief Nursing & Allied Health Office<br>  o Executive Medical Director, Medical and Academic Affairs<br>  o REB Office Personnel<br>  o REB Chairs, and members<br>• Environment<br>  o Research Environment<br>• This Standard Operating Procedure (SOP) applies to the activities of the Research Ethics Boards operating under the direct authority of Island Health. |
| **Outcomes:** | • Describes and ensures REB membership and expertise for compliance with all requirements. |

## 1 Responsibility

- All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.
- The REB Chair or designee is responsible for clearly articulating all required duties associated with membership to the REB to potential and current REB members.
- REB members and alternates are responsible for fulfilling their duties as specified in this SOP.

## 2 Procedure

Each REB member's primary duty is the protection of the rights and welfare of the individual human beings that are serving as the participants of research. The reviewer must understand that they are not serving on the Board to expedite the approval of research, but to serve as a link between the Investigator, and the research participants. In order to fulfill their duties, REB members are expected to be knowledgeable of the guidelines and regulations governing human participants' protection and research ethics, and the policies of Island Health germane to human participant protection.

The REB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The REBs operate under the direct authority of Vancouver Island Health Authority. As such, REB members serve the health authority as whole, rather than a particular site, department or hospital. Therefore, members must not allow their own interests or that of their departments to supersede their duty to protect their rights and welfare of research participants.

### 2.1 Attendance

a) Regular REB members are expected to attend the regularly scheduled REB meetings. REB Members may be asked to step down if they consistently miss more than 75% of the scheduled REB meetings;

b) REB members must notify the REB office if they will be absent for an REB meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in their place;

c) Alternate REB members are expected to attend the identified REB meetings for which they have confirmed their availability to replace a regular REB member;

d) REB members are expected to be available for the entire REB meeting, not just the sections for which they have been assigned as reviewers.

### 2.2 Terms of Duty

a) REB members are expected to commit to a minimum one year term and during that time, fulfill certain duties. These duties will be described prior to appointment and each REB member will be aware of their responsibilities as an REB member prior to accepting appointment to the REB.

b) Any employee of Island Health is automatically covered by Island Health's liability insurance. For non-employees, Island Health's liability coverage is also extended to include:

- "members of medical and other advisory boards and committees, and medical staff and professional staff committees while acting in their capacity as committee members."
- "physicians, interns, residents, dentists, or midwives, but only in the performance of their administrative duties on behalf of (Island Health)."

c) All members will have a responsibility to participate in an appeal process, depending on the level of review required (i.e. office, executive, delegated, or full board). Any appeal of a decision made by another health authority, such as Fraser Health Authority, would be assessed proportionately for risk as with reviews originated by Island Health, thereby determining the level of review required.

### 2.3 Duties

a) All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review or consideration by the REB, to submit comments in advance of the REB meeting, and to be prepared to discuss each agenda item and provide input at the Full Board meeting;

b) Each REB member is expected to fulfill specific duties based on the role as outlined below. More than one REB member may fulfill each role;

c) **Scientific members**: Scientific members are expected to contribute to the evaluation of the research on its ethical, scientific and statistical merits. These members should also advise the Board if additional expertise in a scientific or non-scientific area is required to assess if the protocol adequately protects the rights and welfare of human participants;

d) **Non-scientific members**: Non-scientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or provincial requirements regarding consent. Non-scientific members should advise the Board if additional experience in a non-scientific area is required to assess whether the protocol adequately protects the rights and welfare of participants and to comment on the comprehension of the consent document;

e) **Community member(s)**: Community members, including Patient Partner members, are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective. The role of the Community members on the REBs is unique and arm's length from the institution to ensure review is fair and impartial. Their primary role is to reflect the perspective of the participant. This is particularly important when participants may be vulnerable and risks to participants are high.

f) **Member(s) knowledgeable in relevant law**: Members knowledgeable in relevant law are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the REB;

g) **Member(s) knowledgeable in ethics**: Members knowledgeable in ethics are expected to guide the REB in identifying and addressing ethics issues related to the research under review;

h) **Ad hoc advisors**: Individuals with competence in special areas may be required to provide input on issues that require expertise beyond or in addition to that available on the REB. The ad hoc advisor may be

required to submit a written report and to participate via teleconference or to attend the REB meeting to lend their expertise to the discussions;

i) **REB Chair**: The role of the REB Chair is to provide overall leadership for the REB:

- The REB Chair and the Manager, Research Ethics & Compliance in consultation with the REB Coordinators, may recommend to the Vice-President, Quality, Research and Chief Nursing & Allied Health Office or their delegate, the Executive Medical Director, Medical and Academic Affairs the appointment of one or more Chairs to assist or act on behalf of the chairperson in particular REB matters and at REB meetings, either as a general procedure, or case-by-case basis. The REB Chair also may delegate any of their responsibilities, as appropriate to other qualified individual(s);
- Any responsibilities that are designated by the REB Chair must be documented;
- The REB Chair facilitates the review process based on Island Health policies and procedures, and the TCPS 2. The REB Chair monitors the REB's decisions for consistency and ensures these decisions are recorded accurately and communicated to Researchers in writing in a timely fashion;
- The REB Chair ensures that all REB members are free to participate in discussions during the REB meetings. The REB Chair can ask an additional expert REB member to attend a REB meeting in order to draw their expertise in an area that may be relevant to the REB's review and deliberations of the research;
- The REB Chair in consultation with REB Office Personnel, or other voting members of the REB, determines level of risk and the appropriateness of an application for REB Review for delegated or full REB review. The REB Chair may delegate this function to another REB member, or to REB Office Personnel as appropriate;
- The REB Chair or designee performs or delegates authority to (an) REB member(s) to perform a delegated review;
- The REB Chair or designee signs off on all REB decisions with an electronic signature via the online database;
- For REB approval of clinical trials approved by Health Canada, the REB approval letter is electronically signed by the REB Chair or designee via the online database. The REB Certificate of Approval by an online database contains required elements of the REB attestation;
- The REB Chair is empowered to suspend the conduct of a research project or clinical trial deemed to place participants at unacceptable risk pending discussion by the Full Board. The REB Chair is empowered to suspend the conduct of a study if they determine that a Researcher is not following the REB's policies or procedures;
- The Manager, Research Ethics & Compliance will provide a report on the activities of the Island Health affiliated REBs to the Director, Research, and the Executive Medical Director, Medical and Academic Affairs on an annual basis;
- The REB Chair, in conjunction with the Manager, Research Ethics & Compliance, and such other institutional representatives as are appropriate, is responsible for ensuring that REB members are informed of all new legislation, regulations and guidelines which bear on REB review;
- The REB Chair, in conjunction with the REB Office Personnel, shall assess the educational and training needs of the REB members and REB Office Personnel, and will address any gaps identified;

- The REB Chair or designee reviews and approves REB policies and procedures at set intervals, to ensure the REB SOPs meet all current standards;
- In addition to the above responsibilities (germane to the members' capacity), this person chairs meetings of the REB. Ensures that the total number of votes cast regarding any matter being considered by the REB will not exceed the number of members present. The Chair will vote if the vote is tied.

j) **REB Co-Chair**: The REB Co-Chair or equivalent is responsible for performing the responsibilities of the REB Chair when the REB Chair is unable to do so:
- The REB Co-Chair performs all responsibilities assigned by the REB Chair;
- The REB Co-Chair assists with the overall operation of the REB.

**2.4 Primary and Secondary Reviewers**:

a) In addition to the duties described in section 2.2.a., each regular (or alternate) member is expected to act as a primary and/or secondary reviewer for assigned studies at convened meetings. The primary and secondary reviewers present their findings resulting from detailed review of all of the application materials and provide an assessment of the soundness and safety of the protocol and recommend specific actions to the Board. They may lead the discussion of the study by the convened REB. The primary and secondary reviewers are required to review the entire submission, be familiar with it, and be prepared to conduct an in depth review of all materials;

b) Primary and secondary reviewers are provided with a protocol review checklist for their reference when reviewing all new studies assigned to Full Board. Reviewers are to post their comments, discussion points and provisos via the online database. The elements within the checklist will be discussed during the Full board meeting and posted to the study with the relevant minutes in the online database. The primary and secondary reviewers are expected to contact the REB Chair or Coordinator in advance of the convened meeting if further clarification of the Investigator is required prior to review of the submission.

**2.5 Training and Education**

a) All members must adhere to Island Health policies in the discharge of their duties including the following policies:
- 25.2 Free & Informed Consent in Research
- 25.3 Research Integrity
- 5.5.2P Respectful Workplace Policy
- 1.5.1 Confidential Information – Privacy Rights of Personal Information Policy
- 1.5.2 Confidential Information – Third Party, Island Health Business and other Non-personal Information Policy
- 5.5.1P Conflict of Interest Policy

b) Education
- Tri Council Policy Statement 2 (TCPS2)
- San'yas Anti-Racism Indigenous Cultural Safety Training Program – Core Health
- Collaborative Institutional Training Initiative (CITI) Good Clinical Practice (GCP)
- SOP 501 Research Ethics Board Terms Of Reference
- SOP 502 Activities Requiring Research Ethics Board Review
- SOP 534 Duties of REB Members

**2.6 Conflict of Interest**

a) REB members are expected to follow specific REB related conflict of interest procedures.

## 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 References

- Network of Networks and Canadian Association of Research Ethics Board - Research Ethics Board Standard Operating Procedures, V 3.0
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.4:
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.8:

## 7 Summary of Changes

| Version | Effective Date | Change Description |
|---|---|---|
| 1.0 | 05 DEC 2022 | New procedure |

# Research Ethics & Compliance Office (RECO)
## 2021 - 2022 Priorities Plan

We oversee the ethical conduct and decision-making in clinical and health research projects that use human participants, materials and information. Together with the REBs, Operational Review, and Research Compliance, we aim to build capacity in ethics, integrity, and compliance through educating, advising, research, policy/guidance development, and administration. Since March 1, 2020, our office and REBs have reviewed almost 1600 research study events and activities[1].

**APPROACH:** Our work is grounded in a commitment that '*Research is Care*', which speaks to Island Health values, articulated within ethically driven research that centers participants who come from communities served by our institution.

**ALIGNMENT:** Island Health's Five Year Strategic Framework

**Goal 1**: Improve the Experience, Quality and Outcomes of Health and Care Services for Patients, Clients and Families

**Objective 1.4:** Care will be driven by best practice, evidence and data to achieve the highest level of quality and safety

**Goal 3:** Increase Health System Value and Ensure the Sustainability of Health and Care Services

**Objective 3.2:** Island Health will drive innovation and research to improve outcomes for people, care teams and communities

**ASSIGNMENT:** To identify and enact the below priorities in alignment with the goals and objectives of the above framework, our work will focus on:

### COMMUNICATIONS

Share regular research study reports by developing a dedicated delivery schedule.

Ensure information on the RECO website is a clear and compliant with current requirements and regulations.

Enhance external communication offerings through newsletter items distributed through known channels (e.g. The Weekly).

Standardize language for all communications with the REB and office services by creating templates, forms and review related documents.

### POLICIES & PROCEDURES

Increase accessibility to current policies and procedures.

Develop process structure for creating new guidance from REBs.

Improve participant complaint process including the completion of the CAPAs resulting from reviews.

Ensure procedures (e.g. SOPs) review effective and efficient.

### TRAINING & EDUCATION

Deliver comprehensive training for REB and research administrative staff at regular intervals throughout the year.

Develop and book online database systems training for researchers and teams including research staff.

Create REB member manual for onboarding and streamline the processes for this using a DEI lens.

Improve access to research ethics knowledge and expertise across Island Health.

Provide and enable opportunities for the REB and RECO staff to access, attend and provide training in order to bring comprehensive expertise to our areas of specialty within the institution: research ethics, quality assurance and operational review.

[1] *Study events and activities refers to new initial research study applications and post-approval activities including amendments, acknowledgments, renewals, closures for both Island Health only research AND multijurisdictional or harmonized provincial research studies submitted up until August 31, 2021.*