POLICY

Research

25.0

Policies direct required organizational practice/behaviour

island health

Purpose:

- This Policy provides the principles and framework for research governance to ensure the integrity, quality and suitability of activities associated with research conducted across Island Health facilities.
- Articulates the authority, requisite processes, and requirements surrounding various aspects of research activity undertaken by, or in collaboration with Island Health.

Cultural Safety and Humility:

Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Kwakwaka'wakw, and Nuu-chah-nulth 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 workplace

Scope:

- **Audience:**
  - Internal individuals undertaking research under the auspices of Island Health or external individuals or entities undertaking research involving Island Health patients, staff, sites, data or systems regardless of location ("Researchers").
  - Island Health staff and medical staff, contractors, students, volunteers, or others who are under the supervision of a Researcher.
- **Environment:**
  - Island Health-wide
- **Exceptions:**
  - None

1.0 Policy

- All research conducted at Island Health shall:
  - a) Ensure protection of the rights and welfare of research participants;
  - b) Align with and advance commitments to Indigenous health and reconciliation including:
    - *Declaration on the Rights of Indigenous Peoples Act*
    - Calls to Action issued by the Truth and Reconciliation Commission of Canada
    - Recommendations made in the report In Plain Sight: Addressing Indigenous-specific Racism and Discrimination in B.C. Health Care
    - Indigenous data sovereignty and governance principles
  - c) Align with provincial legislation, regulation, and data standards including:
    - *Anti Racism Data Act*,
    - Gender Based Analysis Plus (GBA+)
    - Sex and Gender Data Standard
  - d) Ensure protection of Island Health, including Island Health staff and medical staff, as well as affiliated parties;

e) Encourage research that has relevance to Island Health and the populations and patients it serves;
f) Ensure the efficient use of available resources;
g) Provide an environment that facilitates dialogue on research; and
h) Promote the commitment to consider ethical and equity issues in all decision-making related to the research and knowledge translation programs.

- Research conducted at Island Health shall be in accordance with Island Health policies and relevant institutional documents including, but not limited to, those listed in the *Related Island Health Policy Documents* section of this policy.
- Research is an integral part of Island Health's purpose statement: to provide superior health care through innovation, teaching and learning, and research and a commitment to quality and safety.
- Island Health commits to maintaining academic freedom, freedom of inquiry and freedom of expression in all its research activities.
- All individuals who undertake, publish, and/or disseminate research findings must follow this policy.
- Island Health will comply with the *Tri-Agency Framework: Responsible Conduct of Research* and expects honest and thoughtful inquiry, rigorous analysis, commitment to the dissemination of research results and adherence to the use of professional standards by all Researchers.
- Island Health will comply with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and other regulations applicable to research that involves human participants living or deceased and/or human biological materials.
- Island Health endorses all principles of patient-oriented research. Island Health will actively engage patients, their Informal Caregivers and families as partners in the research process, to ensure that studies focus on patient-identified priorities.
- Research at Island Health shall foster a culture and practices that respect and promote equity, diversity, and inclusion.

1.1 Roles and Responsibilities

- **Island Health**
  - The President and the Chief Executive Officer (CEO) has overall responsibility for all research conducted at Island Health and oversight for research governance and operations at Island Health. Such responsibility may be delegated.
  - Work with Indigenous partners to uphold Indigenous data governance and to ensure that Island Health respects the First Nations principles of ownership, control, access, and possession and the Métis principles of ownership, control, access, and stewardship.
- **Researchers and Study Team Members**
  - Must inform themselves of and comply with all regulatory and Island Health policy requirements, training, and terms and conditions relevant to their research.
  - Island Health researchers shall list "Vancouver Island Health Authority" as the professional affiliation or institution on all publications resulting from research conducted under the auspices of Island Health.
  - Must ensure that research is compliant with applicable legal employment standards and the policies and procedures of Island Health Human Resources, including *Respectful Workplace*.

  - Must ensure that all research is conducted to the highest scientific, ethical and professional standards and in accordance with the Research Integrity Policy.
  - Must ensure that all research is conducted safely in accordance with the policies of Island Health including, without limitation, Island Health policies governing the safe use of equipment, bio-hazardous materials, radioactive materials, and certain chemical materials.

1.2 Research Governance and Services

- Island Health is committed to providing an environment that supports Researchers and fosters best research practices and external partnerships. In that regard, Island Health has established the Research Department, which provides the infrastructure to support research best practices.

1.3 Safe Reporting of Concerns

- Researchers, study participants and other relevant parties must report, in good faith, any information pertaining to possible non-compliance with this Policy per applicable Research policies, the *Tri-Agency Framework: Responsible Conduct of Research* and the Island Health Safe Reporting Policy and Safe Reporting Procedure.
- Allegations of non-compliance will be reviewed and, where appropriate, investigated.

2.0 Monitoring and Evaluation

- This policy and its content will be reviewed by Research Ethics & Compliance every two (2) years or earlier dependent on the importance of the change(s).
- Review will be based upon the Research Department's review schedule of controlled documents.

3.0 Definitions

- **Affiliated Researcher:** An individual who does not have a direct relationship with Island Health by virtue of employment or being engaged as a privileged healthcare practitioner but who has met specific requirements for applying for this status and who has been granted this status by delegated authority through negotiated agreement or memorandum of understanding.
- **Distinction-based Approach:** An approach that acknowledges that First Nations, Métis and Inuit Peoples have unique cultures, territories, histories, strengths to build on and challenges to face. A distinctions-based approach means working with First Nations, Métis and Inuit together and independently in recognition of their distinctions and rights as affirmed under section 35 of the *Constitution Act* and the *Declaration on the Rights of Indigenous Peoples Act*. This approach recognizes that collaborations with First Nations, Métis and Inuit Peoples must occur from the outset when developing legislation, standards, policies, or programs to ensure that services are inclusive, and respect and meet the diverse priorities of each group.
- **Family**: Person or persons who are related in any way (biologically, legally, or emotionally), including immediate relatives and other individuals in the client's support network. Family includes a client's extended family, partners, friends, advocates, guardians and other individuals. The client defines the makeup of their family and has the right to include or not include family members in their care and redefine the makeup of their family over time.
- **First Nations:** The preferred terminology for Indigenous peoples of what is now Canada, and their descendants, who are neither Métis nor Inuit. First Nations people who are legally registered as Indian under the *Indian Act* are considered "status," while those who are not are considered "non status." A First Nations person's status can have many implications, including on their health and wellness.

- **Funding Terms:** The policies, rules and regulations that govern the use of research funds. They may come from various sources including Island Health policies, the provisions of a contract for research funds, or the policies of the organization providing the research funds.
- **Gender Based Analysis Plus (GBA+):** GBA+ is an analytical tool used to assess the potential impacts of policies, programs, services, and other initiatives on diverse groups of people, taking into account sex, gender and other intersecting identity factors (such as age, culture, language, education, sexual orientation, ability, faith, etc.). Application and use of GBA+ is a national, provincial and organizational commitment.
- **Indigenous Peoples:** Inclusive of First Nations (status and non-status), Métis and Inuit Peoples as defined under Section 35 of the *Constitution Act, 1982*.
- **Informal Caregiver**: A person who provides unpaid (informal) care to another person such as a family member or friend.
- **Métis:** A person who self-identifies as Métis, is of historic Métis ancestry, is distinct from other Indigenous Peoples and is accepted by the Métis Nation.
- **Non-Research Activities**: Quality assurance and quality improvement initiatives, program evaluation activities and system performance reviews, or testing within normal educational requirements when undertaken for Island Health’s internal assessment, management or improvement purposes ("Internal Assessment"). Other projects which fall outside of the scope of ‘research’. Ethical concerns must be considered within these activities as they would benefit from careful consideration by an individual, or a body other than the Research Ethics Boards (REBs), capable of providing independent guidance (i.e. in professional or disciplinary associations). When in doubt about the applicability of Tri-Council Policy Statement 2 (TCPS2) articles to a particular project, researchers shall seek the opinion of the applicable REB for a final determination.
- **OCAP® Principles/First Nations OCAP® Principles:** The First Nations principles of ownership, control, access, and possession (OCAP®) are a set of standards that establish how First Nations data and information should be collected, protected, used, or shared.
    - Ownership: Refers to the relationship of First Nations to their cultural knowledge, data, and information. This principle states that a community or group owns information collectively in the same way that an individual owns their personal information.
    - Control: Affirms that First Nations, their communities, and representative bodies are within their rights to seek control over all aspects of research and information management processes that impact them. First Nations control of research can include all stages of a particular research project-from start to finish. The principle extends to the control of resources and review processes, the planning process, management of the information, and so on.
    - Access: Refers to the fact that First Nations must have access to information and data about themselves and their communities regardless of where it is held. The principle of access also refers to the right of First Nations’ communities and organizations to manage and make decisions regarding access to their collective information. This may be achieved, in practice, through standardized, formal protocols.
    - Possession: While ownership identifies the relationship between a people and their information in principle, possession or stewardship is more concrete: it refers to the physical control of data. Possession is the mechanism by which ownership can be asserted and protected.

- **OCAS® Principles/Métis OCAS® Principles:** The Métis principles of ownership, control, access, and stewardship (OCAS®) are a set of standards that establish how Métis data and information should be collected, protected, used, or shared.
    - Ownership: legal possession of data (e.g., the Métis Population Data-Base in Manitoba)
    - Control: the "power to make decisions about something and decide what should happen"
    - Access: the "right or opportunity to use something that will bring benefit"
    - Stewardship: "responsible planning and management of resource" so research that is completed is in the best interests of Métis health, and will improve health and health services delivery"
- **Patient**: Refers to patient, client, resident or person in receipt of healthcare services within Island Health.
- **Patient Oriented Research (POR):** Grounded in the Canadian Institutes for Health Research Strategy for Patient Oriented Research, POR engages Patients, their Informal Caregivers and families and friends (people with lived and living experience) as partners in the research process. This engagement helps to ensure that studies focus on patient-identified priorities, which ultimately leads to better patient outcomes.
- **Research**: Any disciplined inquiry or systematic investigation intended to extend knowledge or to establish facts or principles that is conducted by Island Health employees, contractors or privileged healthcare practitioner acting in their Island Health capacity. This includes the use of Island Health services articulated in agreements. At Island Health, knowledge translation (evidence to practice) activities are also supported by the Research Department.
- **Researcher**: The leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. Examples include, but, are not limited to: "Qualified/Principal Investigator/Principal Applicant".

4.0 Related Island Health Policy Documents

- Conflict of Interest
- Research Finance
- Research Integrity
- Safe Reporting Policy
- Safe Reporting Procedure

5.0 References

- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Agency Framework: Responsible Conduct of Research, 2021.
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.
- First Nations Information Governance Centre. The First Nations Principles of OCAP®. Retrieved from: https://fnigc.ca/
- Fraser Health Authority. (2024). *Policy Research (Fraser Health Authority Publication).* https://www.fraserhealth.ca/-/media/Project/FraserHealth/FraserHealth/Health-Professionals/Research-and-Evaluation-Services/Research-Policy.pdf

- Island Health Authority. (2023). *Research Data Management Strategy* (Island Health Authority Publication). https://www.islandhealth.ca/sites/default/files/research/documents/island-health-rdm-strategy-jan-2023.pdf
- University of British Columbia. (2019). *Research Involving Human Participants – Human Research Policy.* (University of British Columbia Publication). https://universitycounsel.ubc.ca/files/2022/05/Human-Research-Policy_LR9.pdf

6.0 Resources

- British Columbia, Anti-Racism Data Act
- British Columbia, Declaration on the Rights of Indigenous Peoples Act (DRIPA)
- British Columbia, Gender and Sex Data Standard
- British Columbia Network Environment of Indigenous Health Research
- British Columbia, Provincial Data Plan
- British Columbia Support Unit, Indigenous Knowledges for Decolonized Research and Evaluation Practices
- Canadian Institutes of Health Research's Strategy for Patient-Oriented Research
- First Nations Health Authority. 7 Directives. Health Canada, Food and Drugs Act
- The Fundamentals of OCAP® Health Canada, Food and Drug Regulations, Part C, Division 5
- Government of Canada, Gender-based Analysis Plus (GBA Plus)
- Government of Canada, Policy on Sensitive Technology Research and Affiliations of Concern (STRAC)
- Guiding Inuit Qaujimajatuqangit Principles
- Indigenous Communities, Collectives and Organizations
- In Plain Sight: Addressing Indigenous-specific Racism and Discrimination in B.C. Health Care, November 2020
- International Council for Harmonisation of Technical Requirement for Pharmaceuticals for Human Use Good Clinical Practice Guidelines, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice (E6R2)
- Strategy for Patient-Oriented Research
- Truth and Reconciliation Commission of Canada
- United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)
- US Department of Health and Human Services, Protection of Human Subjects, 45 CFR Part 46, sub-part A
- US Department of Health and Human Services, Protection of Human Subjects, 21 CFR Part 50

7.0 Summary of Changes

Version	Effective Date	Comments
1.0	2025-JUL-02	New policy