

Type of Project	Description	Ethical and/or Operational Approval Requirements
Research	Research is defined as "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation" (TCPS2). Research proposals/components include: Background and justification Purpose, hypothesis, & objectives Research design and statistical and/or narrative analysis plan Procedures Ethical considerations Knowledge translation or dissemination plan References Please note that pilot studies fall within the definition of research requiring REB review as per TCPS2 Articles 6.11 and 10.1, where pilot studies are smaller versions of the main study (e.g., fewer participants, shorter duration). The purpose of pilot studies is to assess the feasibility and/or inform the design of a subsequent study intended to address a research question.	 Ethics: All research involving human participants at Island Health requires approval by a Research Ethics Board (REB). For more information on how to submit an ethics application to an Island Health REB, please visit this page of the Research Ethics & Compliance website. Operational: A separate operational application is required to seek institutional approval for the research use of Island Health employees, sites, patients, and data. The department or program concerned will review research study application and evaluate for resource impact. For information on how to submit an operational application, please visit this page of the Research Ethics & Compliance website. Educational: All members of the research team, including medical staff, students, residents, and research staff, are required to complete the TCPS2: CORE-2022 (Course on Research Ethics), an online tutorial on the Tri-Council Policy Statement. For more information on other educational requirements that may apply, please review the Guidance for Research Training Requirements.
Quality Improvement	Quality improvement (QI) is a continuous and ongoing effort to systematically improve local and internal processes and systems by applying a scientific framework where the benefits and risks of interventions are already known. These projects seek to utilize best practices & evidence to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes. Essential components of QI include: Set SMART goals (Institute for Healthcare Improvement - Quadruple Aim framework) Established set measures & metrics for process, outcome and balance A predefined scope of intervention/change Plan-Do-Study-Act cycles Ethical considerations & consultation to respond to impact	 Operational approval from departmental/area leadership. Submission of the project to the Island Health QI Ethics Screening Tool & Registry is required. If low risk, and no additional flags (e.g. privacy concerns, data linkages, data leaving the institution, data leaving the country), no further consult is necessary. If flagged or high risk, the QI Ethics team will offer a consultation with mitigation strategies and recommendations. qiethics@islandhealth.ca More information about the QI Ethics team can be found on the QI Ethics website.



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Quality Assurance, Quality Control	Quality assurance (QA) is defined as a part of quality management focused on providing confidence that quality requirements will be fulfilled. QA consists of the collection of management processes and technical activities designed to guarantee that the defined standards of quality for data are met. Examples: process checklists, project audits and methodology and standards development, employee performance reviews. Quality control (QC) is defined as a part of quality management focused on fulfilling quality requirements, i.e. a corrective tool focused on the quality of output. Examples: peer reviews, inspection, or validation.	 There is no requirement that quality assurance projects receive REB approval, as projects that meet this criteria are exempt from REB review under TCPS2 Article 2.5. Quality assurance and control projects are welcome to seek the support of the QI Ethics team if they think there are ethical pieces worthy of consideration, but this is optional and not required. Approval not applicable unless artificial intelligences being used or related to the work, then refer to AI section below.
Evaluation	Evaluation is the <i>systematic</i> assessment of the design, implementation and/or results of a project, program, or initiative against its design and objectives for the purposes of learning and decision-making. (Canadian Evaluation Society, 2025) Evaluation requires a minimum level of rigor and impartiality to prevent bias, beliefs or conflated data interpretation from affecting true findings and conclusions. Appropriate approaches for DEI, intersectionality, Indigenous populations respecting OCAP, and cultural safety/Indigenous interpretation should embed in all evaluations. Ethical considerations for all evaluations should include potential for harm and meeting	 There is no formalized process in Island Health to ensure ethical standards for evaluation projects. The responsibility/accountability is currently held by the Evaluation Lead. Evaluation projects are welcome to seek the support of the QI Ethics team if they think there are ethical pieces worthy of consideration, but this is optional and not required. The evaluation project should have Operational approval by program/department.
Innovation	evaluation ethics standards (e.g. informed, anonymity). Innovation (and commercialization) refers to the processes by which research is	Submission of the project to the Island Health QI Ethics Screening Tool & Registry or
	translated through knowledge, expertise and skilled people between the science base and its user communities contributing to the economic competitiveness, effectiveness of public services and policy, and quality of life of Canadians ¹ . This leads to value creation in the health system in a safe and sustainable manner.	 for REB review (if applicable) is required. Submission of the project to the <u>Clinical Governance Innovation Intake</u> is required. If low risk, and no additional flags (e.g. privacy concerns, data linkages, data leaving the institution, data leaving the country), no further consult is necessary.

¹https://www.cihr-irsc.gc.ca/e/30162.html



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		 If flagged or high risk, the QI Ethics team will offer a consultation with mitigation strategies and recommendations. More information about the QI Ethics team can be found on the QI Ethics website. Approval from Departmental/area leadership.
Artificial Intelligence	Artificial intelligence (AI) is a broad term for a category of algorithms and models that perform tasks and exhibit behaviours such as learning and making decisions and predictions.	 Phase 1: If an AI system or algorithm is being designed or developed, but not tested, please submit the project to the Island Health QI Ethics Screening Tool & Registry; Phase 2: If an AI product has been purchased by Island Health and requires quality assurance or "silent" testing before deployment at a specific site or with a specific patient population, please submit the project to the QI Ethics Screening Tool; Phase 3: If an AI system is to be trialed or integrated within clinical care, trialed against real patient encounters, and/or impacting clinical decision-making, it requires review by a research ethics board (REB). Please reach out to researchethics@islandhealth.ca
Other Projects	A project has two key characteristics: 1) Any temporary, structured endeavor with a definite beginning and end. 2) It is undertaken to create a product, service, or result that is unique (Project Management Institute). This category includes projects that do not fall under the definition of research, quality improvement, quality assurance or evaluation.	 Please check with Departmental /area leadership regarding requirement of any approvals. Please note that REB review is not required for the initial exploratory phase of a research study, which is intended to establish research partnerships or to inform the design of a research proposal and may involve contact with individuals or communities. For more information see TCPS2 Articles 6.11 and 10.1
Projects involving Animals	Any research, evaluation, or exploratory project involving the use of animals, live or deceased.	 No work involving animals is permitted at Island Health, as our institution does not have an active or licensed Animal Care Committee (ACC). For more information, please visit the Canadian Council on Animal Care (CCAC) website.

• If there is doubt as to whether a project requires research ethics review, the researcher or project lead shall consult with the REB before proceeding with the project. The REB makes decisions on exemption from research ethics review².

² Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2022, Retrieved on 21 March 2025, page 16.



- The implications of engaging in activities that qualify as research, including thesis or dissertations, and/or quality improvement without obtaining appropriate ethics review are significant.
 - o Results from such studies may not be published unless ethics review/ approval was obtained prior to data collection.
 - Conducting research without REB approval can constitute research misconduct in accordance with the provisions of Island Health Research Ethics policies. Please review and become familiar with Island Health Research and Island Health Research Ethics policies Research & Capacity Building | Island Health
- If you have any questions, please contact Island Health Research Ethics at ResearchEthics@islandhealth.ca