

Summary of Ethical Review & Oversight Requirements for Quality Improvement Projects in BC

This document is intended to support those leading improvement efforts that involve people or their information within British Columbia's health authorities to navigate the ethical considerations pertaining to their work. It contains a summary of current organizational-specific requirements for ethical review and oversight of quality improvement projects (QI), including key contacts and links for additional information. For the purposes of this document, please note that QI also encompasses program evaluation and quality assurance projects.

You're invited to scroll through the pages below, or else click on the name of your health authority to be brought directly to the relevant section:

[First Nations Health Authority](#)

[Fraser Health](#)

[Interior Health](#)

[Island Health](#)

[Northern Health](#)

[Providence Health Care](#)

[Provincial Health Services Authority](#)

[Vancouver Coastal Health](#)

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KEY CONTACT

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First Nations Health Authority

Research Initiatives

The First Nations Health Authority (FNHA) participates in the BC Ethics Harmonization Initiative, now named Research Ethics BC (REBC), funded by the BC Academic Health Science Network. REBC provides streamlined, provincial research ethics review that aims to make the ethics review process timelier and more efficient by allowing researchers to submit a single ethics application, regardless of the number of participating BC jurisdictions involved in a project.

While FNHA does not currently possess an independent Research Ethics Board (REB), an interim ethics review process is carried out by the Research Executive Committee (REC). This Committee of five FNHA Executives provides ethical review, feedback and approval (or denial) for research that FNHA is leading, partnered on, or participating in. Research proposals that involve a linkage to the First Nations Client File require Data Access Requests and are also reviewed by the Data and Information Planning Committee.

Quality Improvement Initiatives

FNHA does not currently have a formal review process for QI projects. Individuals involved in QI projects with FNHA may contact the FNHA Research and Knowledge Exchange (RKE) team for input, but should look to leadership within their team if they have any questions relating to ethical considerations pertaining to the work.

A FNHA Research Ethics Framework is in development which will be finalized through engagement with First Nations communities in BC. This framework will eventually serve as the foundation for the FNHA research ethics approval process and may include a structure for reviewing QI projects. Several First Nations in BC already have their own research ethics policies and committees in place. The FNHA Research Ethics Framework, once formalized, will complement community-based and led review processes rather than replace or supersede them.

FNHA currently approaches ethical review of both research and QI projects according to the following:

7 Directives –

Guided by its [7 Directives](#), which were developed for FNHA by First Nations leadership, the development of a Research Ethics Framework will be “Community-driven and Nation-based”.

OCAP® –

FNHA adheres to the First Nations principles of Ownership, Control, Access and Possession ([OCAP®](#)), as originally formulated by the First Nations Information Governance Centre. These principles guide how information and data are collected, shared, stored, accessed and protected when a First Nations community is involved. It applies to all levels of First Nations data and information governance.

Key Contact

Research, Knowledge Exchange

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Links of Interest

- FNHA – RKE team website: <http://www.fnha.ca/what-we-do/research-knowledge-exchange-and-evaluation>
- 7 Directives: <http://www.fnha.ca/about/fnha-overview/directives>
- Ownership, Control, Access and Possession (OCAP®) principles: <http://fnigc.ca/ocap.html>

Fraser Health

Research Initiatives

Fraser Health has an internal Research Ethics Board (FHREB), which is overseen by the Department of Evaluation and Research Services. All research projects involving humans are required to receive approval from the FHREB as well as Institutional Approval from the Fraser Health Department of Evaluation and Research Services before initiating any research-related activities. Fraser Health participates in the Research Ethics BC, a provincial model that aims to make the ethics review process timelier and more efficient by allowing researchers to submit a single ethics application, regardless of the number of participating BC jurisdictions involved in a project.

Quality Improvement Initiatives

QI projects within Fraser Health do not require formal ethical review or approval. While the FHREB does not review or approve QI studies, those leading projects should always have the approval of their relevant supervisor before proceeding. QI projects that contain an element of research do require review for those particular components. A decision-making tool is available to help project leads differentiate between research and QI. Project leads are welcome to reach out to Department of Evaluation and Research Services with outstanding questions pertaining to their work. Upon request, the department can provide a letter acknowledging that a particular QI or evaluation project does not require REB approval in accordance with both Fraser Health Research Policy Article 3.3 (Excluded Studies) and the current Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans, Article 2.5.

Key Contact

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Links of Interest

- Fraser Health Research and Evaluation website: <https://www.fraserhealth.ca/employees/research-and-evaluation#.XTs8gvlKiUk>

Interior Health

Research Initiatives

All projects involving people and their private information require ethics review using the ARECCI© process according to Interior Health policy. If a project is determined to involve research, before initiating any activities all research projects are required to receive two approvals: REB and Interior Health Operational Approval. Interior Health has an internal Research Ethics Board (REB). It also participates in the BC Ethics Harmonization Initiative, a provincial model that aims to make the ethics review process timelier and more efficient by allowing researchers to submit a single ethics application, regardless of the number of participating BC jurisdictions involved in a project.

Quality Improvement Initiatives

All projects involving people and their private information require ethics review using the ARECCI© Decision Support Tools according to Interior Health policy. Unless they contain research components, REB review is not required for QI projects (the ARECCI© process will help determine this). If a QI project yields a self-assessed score above minimal risk, a second opinion reviewer group is available to meet to discuss mitigation strategies within 7-10 days of receiving a request and additional information. This second opinion review will make recommendations for the project team, though it is not a formal approval body.

QI projects that self-assess a high risk score should undergo organizational required review, which includes sign-off by the relevant VP or designate. Further policy around this is under development.

Key Contact

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Links of Interest

- ARECCI© ethics guideline and screening tool: <http://www.aihealthsolutions.ca/initiatives-partnerships/ARECCI©-a-project-ethics-community-consensus-initiative/tools-and-resources/>
- Interior Health general ethics information: <https://www.interiorhealth.ca/AboutUs/Accountability/ethics/Pages/default.aspx>
- Overview of Interior Health activity requiring ethics review: <https://www.interiorhealth.ca/AboutUs/Policies/Documents/Activities%20Requiring%20Research%20Ethics%20Review.pdf>
- Interior Health Ethics Framework: <https://www.interiorhealth.ca/AboutUs/Accountability/ethics/Documents/Ethics%20in%20IH%20framework.pdf>
- Interior Health Project Ethics Policy: <https://www.interiorhealth.ca/AboutUs/Policies/Documents/Project%20Ethics.pdf>
- BC Ethics Harmonization Initiative: <https://bcethics.ca>

Island Health

Research Initiatives

In order to conduct research, principal investigators must first obtain approval both from the Island Health REB as well as from the impacted departments through the Island Health Operational Review process. Island Health also participates in the Research Ethics BC harmonization model that aims to make the ethics review process timelier and more efficient by allowing researchers to submit a single ethics application, regardless of the number of participating BC jurisdictions involved in a project.

Quality Improvement Initiatives

QI projects within Island Health do not require formal ethical review or approval in order to proceed. However, they should be registered in the QI Registry database managed by Quality, Safety and Improvement which includes an Island Health version of the ARECCI© tool. Upon completion of the registration including the ARECCI© tool, the project lead will be contacted by an Island Health Quality Associate to engage and discuss the risks and mitigation strategies (as required depending on the ARECCI© score).

Key Contacts

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Links of Interest

- ARECCI© ethics guideline and screening tool: <https://albertainnovates.ca/our-health-innovation-focus/a-project-ethics-community-consensus-initiative/arecci-ethics-guideline-and-screening-tools/>
- Island Health research ethics: <https://www.islandhealth.ca/research-capacity-building/research-ethics-approvals>
- Research Ethics BC: <https://researchethicsbc.ca/>

Northern Health

Research Initiatives

Northern Health (NH) has an internal Research Ethics Board (REB). Before initiating any research-related activities, all research projects are required to receive two approvals: REB and NH Operational Approval. Research ethics and operational approvals can be pursued simultaneously. NH participates in the BC Ethics Harmonization Initiative, a provincial model that aims to make the ethics review process timelier and more efficient by allowing researchers to submit a single ethics application, regardless of the number of participating BC jurisdictions involved in a project.

Quality Improvement Initiatives

QI projects within NH do not require formal ethical review or approval in order to proceed. However, the use of the ARECCI© screening tool and guidelines is encouraged. The improvement charter template includes a space for an ARECCI© score, and teams that engage with NH QI support staff for assistance with their improvement work are guided through the ARECCI© process as part of their project. If a project scores above minimal risk, any project lead is welcome to contact NH QI staff to engage and discuss the risks and mitigation strategies.

Key Contacts

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Links of Interest

- ARECCI© ethics guideline and screening tool: <http://www.aihealthsolutions.ca/initiatives-partnerships/ARECCI©-a-project-ethics-community-consensus-initiative/tools-and-resources/>
- NH research ethics: <https://northernhealth.ca/YourHealth/Research/NHResearchReviewCommittee.aspx>
- BC Ethics Harmonization Initiative: <https://bcethics.ca>

Providence Health Care

Research Initiatives

Providence Health Care (PHC) employs a University of British Columbia (UBC) affiliated Research Ethics Board (REB) through which all research projects are required to receive approval before initiating any research-related activities. It participates in the BC Ethics Harmonization Initiative, a provincial model that aims to make the ethics review process timelier and more efficient by allowing researchers to submit a single ethics application, regardless of the number of participating BC jurisdictions involved in a project.

Quality Improvement Initiatives

QI projects within PHC do not require formal ethical review or approval. However, QI projects that contain an element of research do require review. Project leads who are unclear as to the nature of the work should complete the jointly created VCHRI-PHC-UBC tool designed to assist researchers to decide whether or not their project constitutes research requiring review, or whether it is QI and does not. If after completion of the tool someone is still unsure as to whether or not the project constitutes research, the Ethics Office suggests the use of the ARECCI© screening tool for further clarification and/or consultation with the REB office as required. If the project is determined not to require REB review, a memo from the REB office can be provided to the project lead upon request. The Ethics office will connect the project team with the PHC Privacy Leader (Janet Scott) around how to obtain access to information for QI purposes.

Key Contact

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Links of Interest

- Tool for determining nature of project: http://www.vchri.ca/sites/default/files/Guideline%20-%20Guidance_ResearchEthicsBoard_Jan2012.pdf
- ARECCI© ethics guideline and screening tool: <http://www.aihealthsolutions.ca/initiatives-partnerships/ARECCI©-a-project-ethics-community-consensus-initiative/tools-and-resources/>
- PHC research ethics: <http://www.providenceresearch.ca/research-ethics>
- BC Ethics Harmonization Initiative: <https://bcethics.ca>

Provincial Health Services Authority

Research Initiatives

Provincial Health Services Authority (PHSA) and its agencies generally employ a University of British Columbia (UBC) affiliated Research Ethics Board (REB) through which all research projects are required to receive approval before initiating any research-related activities (BC Cancer REB and Children's and Women's REB). Both participate in the BC Ethics Harmonization Initiative, a provincial model that aims to make the ethics review process timelier and more efficient by allowing researchers to submit a single ethics application, regardless of the number of participating BC jurisdictions involved in a project. Researchers are encouraged to reach out to PHSA's Research Privacy Advisor prior to applying for REB review and approval.

Quality Improvement Initiatives

QI projects within PHSA do not require formal ethical review or approval. However, QI projects that contain an element of research do require review. Project leads who are unclear as to the nature of the work are offered decision-support tools: a PHSA approvals and certification flowchart and the ARECCI© ethics guideline and screening tool. Project leads are encouraged to contact the relevant REB office if they have further questions before initiating any work. If a QI project is submitted to the REB and does not include any research components, confirmation will be sent stating it falls outside the scope of review. QI initiatives involving the use of personal information require privacy review and approval. It is recommended that project leads connect with PHSA's Information Access and Privacy Department early in the project planning stages.

Key Contacts

For PHSA & BCCA quality improvement inquiries:
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For BC Cancer REB inquiries:
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For BC Children's and Women's REB inquiries:
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For research process and resource inquiries:
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For research-related privacy inquiries:
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Links of Interest

- PHSA approvals and certification flowchart: http://www.phsa.ca/researcher/Documents/Visio-Approvals%20and%20certification%20flowchart_2015.pdf
- ARECCI© ethics guideline and screening tool: <http://www.aihealthsolutions.ca/arecci/screening/>
- PHSA research ethics: <https://researchethicsbc.ca/>
- BC Ethics Harmonization Initiative: <https://bcethics.ca>

Vancouver Coastal Health

Research Initiatives

Vancouver Coastal Health (VCH) employs a University of British Columbia (UBC) affiliated Research Ethics Board (REB) through which all research projects are required to receive approval before initiating any research-related activities. It participates in the BC Ethics Harmonization Initiative, a provincial model that aims to make the ethics review process timelier and more efficient by allowing researchers to submit a single ethics application, regardless of the number of participating BC jurisdictions involved in a project. Additionally, researchers must also receive “Operational Research Approval” from VCH before proceeding.

Quality Improvement Initiatives

QI projects within VCH do not require formal ethical review or approval. However, QI projects that contain an element of research do require review. Project leads who are unclear as to the nature of the work should complete the jointly created VCHRI-UBC tool designed to assist researchers to decide whether their project constitutes research requiring review, or whether it is QI and does not. If after completion of the tool someone is still unsure as to whether or not the project constitutes research, they are welcome to consult with the REB administration.

An intention to publish QI results does not necessarily mean that the project needs REB review. If an academic journal specifically requires REB oversight or review for publication, however, consultation with the appropriate UBC REB prior to commencing the project is highly recommended.

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Links of Interest

- Tool for determining nature of project: [http://www.vchri.ca/sites/default/files/Guideline%20-%20Guidance ResearchEthicsBoard Jan2012.pdf](http://www.vchri.ca/sites/default/files/Guideline%20-%20Guidance%20ResearchEthicsBoard%20Jan2012.pdf)
- VCH Operational Research Approval: <http://www.vchri.ca/services/operational-research-approval>
- UBC Research ethics information: <https://ethics.research.ubc.ca/clinical-research-ethics>
- BC Ethics Harmonization Initiative: <https://bcethics.ca>