

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

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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:

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Have a question about what you see here? Notice something that needs to be updated? Let us know! We will continue to edit this document as new information is received.

### KEY CONTACT

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## First Nations Health Authority

### *Research Initiatives*

The First Nations Health Authority (FNHA) does not currently possess a Research Ethics Board (REB). It requires the use of an external REB for all research projects. For FNHA-led or co-led initiatives, a number of FNHA staff members are adjunct professors at universities within the province and as such some are eligible to obtain ethics approval from the Office of Research Ethics at the associated University. Research proposals that involve a linkage to the First Nations Client File 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, although all major projects undergo review at the Data Champions Committee (DCC), an internal senior Executive Committee on policy and governance of research and data in First Nations health in BC.

A formalized Research Ethics Framework is in development. This framework will serve as the foundation for the First Nations Health Authority (FNHA) research ethics approval process and will include a structure for reviewing QI projects as well. Several First Nations in BC already have their own research ethics policies and committees in place. The FNHA Research Ethics Framework, once formalized, will not replace or supersede these policies; rather, a project requiring community approval would require both community approval (if relevant) and FNHA approval.

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 has been first and foremost Community-driven.

#### OCAP –

FNHA is adherent to the Ownership, Control, Access and Possession (OCAP) principles, as originally formulated by the First Nations Information Governance Council. These principles guide how information and data is collected, shared, stored, 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 and Evaluation

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### *Links of Interest*

- FNHA 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 (FH) has an internal Research Ethics Board (REB), which is overseen by the Department of Evaluation and Research Services. All research projects are required to receive approval from the FHREB before initiating any research-related activities. FH participates in the BC Ethics Harmonization Initiative, a provincial model that aims to make the ethics review process more timely and 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 FH do not require formal ethical review or approval. While the FH REB 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*

- FH Research and Evaluation website: <http://www.fraserhealth.ca/health-professionals/research-and-evaluation/>
- Differentiation of Research, Quality Improvement and Program Evaluation table: <http://research.fraserhealth.ca/about-us/research,-program-evaluation-&-quality-improvement/>
- BC Ethics Harmonization Initiative: <https://bcethics.ca>

## 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 more timely and 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*

Island Health has an internal Research Ethics Board (REB). In order to conduct research, principal investigators must first obtain approval both from the REB as well as from the Island Health Operational Review & Approvals, as applicable. Island Health participates in the BC Ethics Harmonization Initiative, a provincial model that aims to make the ethics review process more timely and 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, the use of the ARECCI© screening tool is encouraged. There is a QI Registry database managed by Quality and Patient Safety, and plans are in place to link the ARECCI© tool to this database including the ARECCI © score. 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: <http://www.aihealthsolutions.ca/initiatives-partnerships/ARECCI©-a-project-ethics-community-consensus-initiative/tools-and-resources/>
- Island Health research ethics: [http://www.viha.ca/rnd/research\\_ethics/](http://www.viha.ca/rnd/research_ethics/)
- BC Ethics Harmonization Initiative: <https://bcethics.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 more timely and 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 more timely and 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](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 Agency 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 more timely and 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 via email will be sent stating that 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 Agency REB inquiries:  
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For BCEHS quality improvement inquiries:  
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For research process and resource inquiries:  
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PHSA Information Access and Privacy Department  
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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](http://www.phsa.ca/researcher/Documents/Visio-Approvals%20and%20certification%20flowchart_2015.pdf)
- ARECCI© ethics guideline and screening tool: <http://www.aihealthsolutions.ca/initiatives-partnerships/ARECCI©-a-project-ethics-community-consensus-initiative/tools-and-resources/>
- PHSA research ethics: <http://www.phsa.ca/researcher/ethics-approvals/research-ethics-approval>
- 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 more timely and 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 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, 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.

### *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](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>