

# 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 personal information within British Columbia's health authorities to navigate the ethical considerations pertaining to their project. It contains a summary of current organizational-specific requirements for ethical review and oversight of quality improvement projects (QI), including contact links and links for additional information. For the purposes of this document, please note that QI also encompasses program evaluation and quality assurance projects.

Scroll through the pages below, or click on the health authority:

First Nations Health Authority

Fraser Health

Interior Health

Island Health

Northern Health

Providence Health Care

**Provincial Health Services Authority** 

Vancouver Coastal Health

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 (FNHA) Research and Knowledge Exchange

#### 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 own 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 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 have their own research ethics policies and committees in place. The FNHA Research Ethics Framework, once formalized, will complement community-based and community-led review processes rather than replace them.

#### RESEARCH INITIATIVES

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 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 reviewed by the Data and Information Planning Committee.

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

- Guided by its <u>7 Directives</u>, 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.

## CONTACT:

Research, Knowledge Exchange



# Fraser Health Authority Research and Evaluation

#### QUALITY IMPROVEMENT INITIATIVES

QI projects within Fraser Health do not require formal ethical review or approval. While the Fraser Health Research Ethics Board (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 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.

## **RESEARCH INITIATIVES**

The 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.

#### **CONTACT:**

Research, evaluation, and library services team



#### Interior Health Research

# 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.

## **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.

## **CONTACT:**

**Quality Improvement and Patient Safety** 

## LINKS OF INTEREST:

ARECCI© ethics guideline and screening tool

Interior Health Ethics Framework

Interior Health Project Ethics Policy



# Island Health Research Ethics & Compliance Office

# QUALITY IMPROVEMENT INITIATIVES

QI projects within Island Health do not require formal ethical review or approval in order to proceed as per TCPS2, Article 2.5. However, such projects may raise ethical issues that would benefit from careful consideration by an individual or group, capable of providing some independent guidance. The Island Health QI Ethics Decision—Making Tool is now a single fluid process that upon confirmation of the project as QI, directly leads to a registry so the project can be entered. Upon completion of the registration including tool, the project lead will be contacted by an Island Health QI Ethics team member to engage and discuss the risks and mitigation strategies (as required depending on the score).

#### RESEARCH INITIATIVES

To conduct research, principal investigators must first obtain approval both from an 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.

## **CONTACT:**

Research Ethics and Compliance Office



# Northern Health (NH) Research

## QUALITY IMPROVEMENT INITIATIVES

QI projects within NH do not require formal ethical review or approval to proceed. However, the use of the <u>ARECCI©</u> 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.

## **RESEARCH INITIATIVES**

Northern Health has an internal Research Ethics Board (REB), which is responsible for reviewing the ethical acceptability of all studies conducted under the jurisdiction of NH. 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. Find out more information about this process at NH Research Review Committee | Northern Health.

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.

CONTACT:

**Quality Improvement projects** 

Research projects



# **Providence Health Care Research Ethics**

#### 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 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 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.

## **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.

**CONTACT:** 

Research Ethics General inquires

LINKS OF INTEREST:

Tool for determining nature of project



# Provincial Health Services Authority - Conducting Research at PHSA

# QUALITY IMPROVEMENT INITIATIVES

Quality improvement initiatives are "assessments of the performance of an organization or its employees or students (or patients), within the mandate of the organization, and is carried out according to the terms/conditions of employment or training" (TCPS2, 2018). The primary purpose of QI is to inform local decision-making or develop a better practice within an organization. The applicability of results is aimed to be site specific, and the beneficiaries are generally restricted to project participants (i.e. the results are generally meant to stay internally within the organization). QI projects do not require research ethics oversight, and if a project is determined to be QI, confirmation will be sent stating it falls outside the scope of research ethics review and oversight. It is important to note that while QI projects do not require research ethics oversight, these types of projects still raise ethical issues that may benefit from careful consideration by an individual or a body capable of providing ethical guidance.

Project leads are encouraged to contact the relevant REB if they have any questions prior to submitting their projects for review or initiating any work to ensure current processes and procedures are followed. Decision-support tools may also assist such as the PHSA approvals and certification flowchart and the ARECCI© ethics guideline and screening tool. 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.

## **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.

All human research projects undertaken at Provincial Health Services Authority must be reviewed and approved by an appropriate Research Ethics Board "REB" (considerations include your research site and your affiliation/appointment). The BC Cancer Research Ethics Board (BCC REB) has oversight of all clinical and behavioral adult oncology research projects undertaken at BC Cancer or by affiliated researchers. The Children's and Women's Research Ethics Board (C&W REB) oversees clinical and behavioral research projects conducted at BC Children's Hospital and Sunny Hill Health Centre; BC Mental Health & Addiction Services; BC Women's Hospital & Health Centre; BC Children's Hospital Research Institute; and Women's Health Research Institute.

**CONTACT:** Ethics services

LINKS OF INTEREST:

PHSA sorting tool



# Vancouver Coastal Health Research Institute

# 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 <a href="VCHRI-UBC tool">VCHRI-UBC tool</a> 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 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.

#### 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.

# **CONTACT:**

**Ethics services** 

#### LINKS OF INTEREST:

Tool for determining nature of project

VCH Operational Research Approval