Interior Health
RESEARCH ETHICS OFFICE

Community Health and Services Centre
3rd Floor 505 Doyle Avenue
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Phone: 250-870-4602
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Frequently Asked Questions

Q: Does my project require research ethics review?

If your research involves Interior Health (IH) in any way, it must be reviewed by the IH Research Ethics Board. This includes:

- All research involving *human participants conducted by individuals from outside IH but involving IH employees, patients, institutions or programs in any aspect of the research. This includes using IH resources to promote research and distributing or displaying recruitment materials in IH facilities.

- All research involving humans and conducted by IH employees, students, or privileged staff.

*Human participants include human biological materials, human embryos, fetuses, fetal tissue, reproductive materials and stem cells derived from either living or deceased individuals.

Q: Why do I need to submit a research protocol? Isn't the REB application form enough?

A research protocol serves a different purpose from an REB application. The protocol is a document that outlines the research question and how it will be answered, regardless of the sites or institutions where the research will be done. At a minimum, it should include the:

- Background and scientific justification
- Research question, hypothesis and objectives
- Methodology including study design, study population, outcomes or endpoints, study procedures, data collection points, data management plan
- Statistical Analysis or Data Analysis plan
- Limitations
- References

In contrast, the IH REB Application form is used to explain how the protocol will be implemented at the IH site(s), so it requires site-specific information. For example, who specifically will recruit IH participants? What are the anticipated start and end dates for the IH sites? If existing IH data will be used for research purposes, list the specific data sources (Meditech, Omnicell, hard copy charts from a specific hospital or unit, etc), who will access them, and how permission to access them for research purposes will be obtained. Who is the local investigator that IH participants can call in case of a research-related injury?

Q: I am an IH employee as well as a graduate student. I am submitting to my university's REB. Do I also need to submit my project to the IH REB for review?

If your research involves Interior Health in any way, you will require IH REB review. For example, if you are recruiting IH patients, residents, staff/colleagues, or physicians; if you are posting recruiting materials in your workplace or sharing them via your work email address and work contacts; if you are using any work time or other IH resources for your research.

If you are an IH employee that is doing research in your role as a university student and the research will not intersect with IH under any circumstances, you may submit solely to your university's REB.

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Q: I am a member of a research team that involves investigators from another Health Authority or Agency of a Health Authority or University as well as Interior Health. To which REB do I submit my application for ethical review package?

If your study involves any two or more of the following institutions, you must submit your application for ethical review via the provincial research ethics platform housed by UBC, known as RISe. Use this platform even if UBC is not involved.

The institutions are: IH, Fraser Health Authority, Northern Health Authority, Vancouver Island Health Authority, University of BC, Simon Fraser University, University of Victoria, and University of Northern British Columbia. Institutions included under the UBC umbrella include UBC Okanagan, BC Cancer, BC Centre for Disease Control, BC Children's Hospital, BC Women's Hospital, Providence Health Care, and Vancouver Coastal Health Authority.

I am the only researcher on a project. My primary professional role is as an IH employee, physician or midwife, but I also have a UBC appointment. Do I need to apply for harmonized ethical review?

Yes. UBC policy states that if you have a faculty appointment (clinical, adjunct, etc) and you publish or present any part of your research under the UBC name, you must have ethical review from one of the UBC REBs. If you do not apply to a UBC REB, you are responsible for ensuring that there is no mention of UBC in connection with the research, including none in any publications or presentations.

Q. How do I distinguish research from quality improvement?

According to the Secretariat on Responsible Conduct of Research, authors of our primary guidance in research ethics (TCPS2), ***the primary purpose of the project is the key determining factor in whether a project is research or quality improvement*.** Just because an activity uses research methodology does not make it research, for example Quality Improvement and Evaluation projects often use research *techniques,* but QI and Evaluation projects do not require REB review.

To help determine if your project requires REB review, first determine the primary use of results. For example, is the intention:

- To inform ***local*** decision-making or develop a better practice within an organization? This is more likely to be QI.
- To contribute to the existing body of knowledge on a topic (e.g., publish generalizable results in a widely-distributed format such as a journal)?

Some characteristics that help distinguish research from quality improvement:

- Applicability of project results: site-specific or generalizable
- Language of project: site-specific or general
- Beneficiaries: project participants or broader

For further information, see the IH Project Ethics policy.

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Q: How do I get a Waiver of Consent? I just want to look at charts that I already have access to as part of my job.

Everyone owns their own personal information, so although IH is the custodian of personal information, under BC law that information cannot be used for research unless the person who owns the information grants consent to use it. Access to the personal information of others, e.g. patients or employees, is granted to IH employees strictly for the purposes of carrying out their responsibilities as employees. This does not include access for research purposes.

Under certain specific criteria listed in the TCPS2 Article 5.5A, the IH REB can grant access to personal information for research purposes on behalf of the people who own the information, but the standards that must be met are high. The one that is generally most difficult for people to meet is 5.5.A(e), *it is impossible or impracticable* to seek consent from individuals to whom the information relates. Impracticable is a much higher standard than impractical. The two are often confused but are dissimilar. Impracticable means there is such a great degree of onerousness or hardship involved with obtaining consent that it is, for all intents and purposes, impossible to do. If obtaining consent is merely impractical or inconvenient, your study will not qualify for a waiver of consent.

Q: What other approvals are needed before I can start my research in Interior Health?

All research studies involving IH must undergo an Operational Review. This process is facilitated by the IH Research Department and initiated with the online study intake form.

Q: How do I determine if my research project requires full-board review vs. delegated review?

The IH Research Ethics Board uses the TCPS2 criteria for minimal risk to determine if studies qualify for delegated review (i.e. they are minimal risk) or if they must undergo full board review.

Minimal risk is defined as *those risks that would be encountered in normal, everyday life*. Risks can be physical, psychological, emotional, social, cultural, or related to employment.

Any study that does not meet the above definition requires full board review. This includes all research involving biomedical interventions.

The IH REB Chair reserves the right to forward any application package for full board review based on the level of risk to participants and/or the level of vulnerability of the participants as it applies to the research.

Q: How long does it take for my study to undergo ethical review?

For **delegated** reviews, please allow four weeks from the time the complete application package is received to the awarding of the approval status.

For studies requiring **full board review**, please allow at least one week following the REB meeting to receive a Report of Review from the REB. Total time to the awarding of approval status depends upon the outcome of the review and completeness of responses.

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Q: What are the possible outcomes of the Ethical Review process?

The REB will reach one of four possible decisions after review of your application for ethical review: Approved, Provisionally Approved, Deferred, or Not Approved. For more information, please see IH REB policy Initial Review of Research.

Q: Who signs my Research Application Form under the "Department Head Signature" line?

If you are an IH employee or privileged staff, please have your IH department head sign the application.

If you are not formally affiliated with IH as an employee or privileged staff, please have your department head at your primary institution sign the application. For students, this would be your thesis supervisor or program head.

By signing your application, your Department Head is confirming that the principal investigator has the qualifications, experience and facilities to carry out this research project.

Q: Do I need to put the IH logo on my consent form, recruiting materials, etc?

If you are an IH employee or privileged staff, please use the IH logo on documents used with participants such as recruitment posters and consent forms. The logo may be downloaded from the InsideNet.

If there is no IH staff member as an investigator in the study, use of the IH logo is ***not*** recommended.

All use of the IH logo must conform to IH policy AC0100, Visual Identity policy.

Q: The Consent Form template used for this international study comes from the United States. Do I have to change the language?

Yes, Canadian terminology must be used for all documents used with participants at Canadian research sites. Common vocabulary differences are listed below.

Do Use:	**Do Not Use:**
REB or Research Ethics Board	IRB or IEC
participant	Subject or patient
Health Canada	FDA
FIPPA	HIPPA
Invited (to participate)	Asked (to participate)

When can I close the study with the IH REB?

When all contact with participants, including any use of their personal information or source data derived from them, is completed, then you may submit a Closure Report to the IH REB. Research Ethics approval is not required during the final phases of research, including data analysis, manuscript preparation and publication or presentation, so long as all contact with participants and all use of their source data has ceased.

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Q: What else do I need to know in order to do research at Interior Health?

All personnel involved in the conduct of the research are responsible for adhering to all applicable policies, regulations and laws. This includes, but is not limited to:

- The IH Research Ethics Board policies, which are found at www.interiorhealth.ca.
- Applicable privacy legislation including the Freedom of Information and Protection of Privacy Act (FIPPA)
- IH employees must follow all IH Administrative Policies including Standards of Conduct and Acceptable Use of Information Systems
- Your application will be reviewed against the standards outlined in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2014). Completion of the TCPS2 tutorial is recommended for all researchers and is required for those leading above minimal risk research.