Interior Health
RESEARCH ETHICS OFFICE

220 – 1815 Kirschner Road
Kelowna, BC V1Y 4N7
Phone: 250-870-4602
Email: researchethics@interiorhealth.ca

Research Ethics - Frequently Asked Questions

Question: Does my project require research ethics review?

Answer: Projects that require research ethics review by the Interior Health Research Ethics Board (IH REB) include:

- All research that involves human participants* conducted under the auspices of Interior Health (IH); in IH facilities or programs, by IH staff or physicians, or with IH staff and/or patients** or their data
  The exception is when the researcher's role is completely separate from his/her role as an IH employee or physician, e.g. research conducted wholly in a private medical practice with no overlap with IH
- Distribution or display of recruitment materials in IH facilities for research projects that are occurring outside of Interior Health

*Human participant is defined to include human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

**Participants includes patients, clients and residents (persons in care) receiving health services in IH facilities and programs. Participants also includes "data participants" for studies where patient/resident data is used but no direct contact with patients or residents occurs, for example, chart reviews.

Examples of the types of research that require ethical review include:

- Clinical interventions, such as the testing of drugs, medical devices, and other diagnostic or therapeutic initiatives
- Administering interviews, questionnaires, tests, or conducting observations that research participants would not encounter in everyday life
- Use of secondary or non-public data in the custody or control of IH, where data can be linked to individuals, such as medical records
- A project that has the intent to publish broadly and/or create knowledge that can be generalized, including graduate theses and dissertations

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

Answer: If your research intersects with IH 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 wholly outside of IH, your project may not require IH REB review.

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If in doubt, please contact the Research Ethics Office at 250-870-4602 or email researchethics@interiorhealth.ca to discuss your project.

Question: I am a member of a research team that involves investigators from a university as well as IH. Which REB do I submit my application package to for ethical review?

Answer: If your project involves two or more of the BC Ethics Harmonization partners, you only need to submit one application for ethical review by all of the involved parties.

BCEHI parties include: Interior Health Authority, Fraser Health Authority, Northern Health Authority, Vancouver Island Health Authority, Simon Fraser University, the University of British Columbia, the University of Northern British Columbia, and the University of Victoria.

Start the process by completing a Cover Sheet for Harmonized Ethical Review, available here, and submitting it to researchethics@interiorhealth.ca or to your primary institution's Research Ethics Board. You will be advised which application package to complete.

Question: How do I distinguish research from quality improvement?

Answer: According to the Secretariat on Responsible Conduct of Research, *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 (QI) and Evaluation projects often use research *techniques,* but QI and Evaluation projects do not require REB review.

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

To determine if your project is research or QI, identify the primary use of the results. Is the purpose:

- To inform ***local*** decision-making or develop a better practice within an organization?
- To contribute to the existing body of knowledge on a topic (e.g., publish in a research journal)?

Use the ARECCI Decision Support Tools to screen your project to determine the ethical risk and review requirements. You can find the tools at http://www.aihealthsolutions.ca/arecci/screening/15484/8db27175117f4c13912abc9e4d71d801

Question: How do I obtain operational approval to conduct my research project in IH?

Answer: All research projects that have an impact on IH resources require the prior approval of the appropriate IH Administrator(s) who has the authority to assess and authorize the use of those resources for your research project. Complex research projects may require approval from Administrators for several facilities, departments or services.

Examples include:

- You will need operational approval from the facility Administrator if you are planning to recruit participants, including IH staff, visitors, residents, patients and clients, in an IH facility.

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- You will need operational approval from the Manager, Information Privacy & Access to access a database for research purposes (even if you regularly access this database for your IH employee role).
- You will need operational approval from Health Records if you want to review patient charts, either electronic or hard copy, for research purposes.
- You will need operational approval from your supervisor or manager if you are an IH employee and you are conducting research on IH paid time.
- You will need operational approval from the IH Administrator responsible for any IH employees who contribute to a research project while on IH paid time.

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

Answer: The IH REB will determine whether applications for research ethics review require a full board or delegated review. The Board uses the following criteria:

Projects require full REB review if:

- The research interventions are biomedical in nature; *or*
- The research procedures pose greater than minimal risk* to human participants
- The research population is considered vulnerable

*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.

Projects required delegated review if:

- The research does not use biomedical interventions
- The research poses minimal risk to human participants

The IH REB reserves the right to decide whether an application requires full or delegated research ethics review. If substantial ethical concerns are identified during a delegated review, the project will be forwarded for a full REB review at the next scheduled REB meeting.

Question: How long will it take for my research project to undergo ethical review?

Answer: For projects requiring **delegated** review, please allow four weeks from the time the complete application package is received to announcement of the REB decision.

For projects requiring **full Board review**, please allow at least one week following the REB meeting to receive a Report of Review from the Board. Total time to the announcement of the REB decision depends upon the outcome of the review.

Question: What are the possible outcomes of the ethical review process?

Answer: Upon completion of the initial ethical review, the REB will recommend one of the following levels of approval:

- Approved
- Provisionally Approved, subject to clarification or modification as noted
- Deferred, pending additional information or major revisions as noted
- Not Approved

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Question: How do I apply for ethical review of my research project?

Answer: Please follow these instructions to prepare your application for the IH REB:

1. Read the schedule of deadlines for ethics review applications. Note that research projects that qualify for delegated review are accepted on a continuous basis.
2. Download and complete the application form.
3. Send your application package to: researchethics@interiorhealth.ca

Applications that are incomplete and/or unsigned and/or not accompanied by the required documents will be sent back.

Question: Who should sign the Application for Ethical Review form under the "Department Head Signature" on page two?

Answer: The person to who you report for the research project is the person who should sign.

If you are an IH employee or privileged staff: your IH department head should 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.

Question: Do I need to put the IH logo on my consent form and recruiting materials?

Answer: If you are an IH employee or privileged staff, please use the IH logo on all recruitment and consent materials for participants. The logo may be downloaded from the InsideNet.

If IH is funding the research project, the IH logo should be used on all recruitment and consent materials for participants.

If there is no IH employee as an investigator on the project, use of the IH logo is not required.