Research Ethics Board
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250-870-4602
researchethics@interiorhealth.ca

Frequently Asked Questions

Q1. Does my project require IH Research Ethics Board 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[1] conducted by IH employees, students, or medical staff.
- All research involving human participants conducted by individuals from outside IH but involving IH employees or medical staff, patients, or persons in care either as study team members or as participants.
- Use of IH resources to promote or conduct the research, including distribution or display of recruitment materials in IH facilities or via IH Communications or distribution lists; use of any IH facility or involvement of any IH program in the conduct or facilitation of the research..
- All research involving **data** derived from humans and held in the custody of IH. This includes data pertaining to patients, persons in care, employees, and medical staff.

Whether or not the researchers have direct contact with participants is **not** a consideration for whether REB review is required. If the data is derived from humans, TPCS2 considers the research to involve human participants and REB review is required.

Q2. 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:

- Literature review, 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 purpose of an REB Application form is 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 source data held in IH custody? How will permission to access data in IH custody be obtained? Who is the local investigator that IH participants can call in case of a research-related injury?

[1] Human participants include human biological materials, human embryos, fetuses, fetal tissue, reproductive materials and stem cells derived from either living or deceased individuals (TCPS2 2018).

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Q3. 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, persons in care, employees or medical staff; 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.

Q4. I am a member of a research team that involves investigators from another BC 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 Research Ethics BC partner institutions, 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 partner institutions and instructions for how to apply are found on the REBC website: https://researchethicsbc.ca. See also the REBC tutorial on YouTube; the search term is Navigating Harmonized Research Ethics.

Q5. I have a UBC appointment, but I am involved in this research project wearing only my IH "hat". Do I still need to submit via the RISe platform?

UBC policy states that if you have a faculty appointment or are a UBC student, any research you do must have approval from one of the UBC REBs. To obtain approval from one of the UBC REBs, submit your application for ethical review via the RISe platform.

If you choose not to apply to a UBC REB, you are responsible for ensuring that UBC is not cited in connection with the research and no UBC resources are used to support it. This includes:

- No use of UBC email
- No use of UBC resources (Qualtrics, OneDrive, physical or human resources, etc.)
- No use of your UBC credentials in anything connected to the research (study documents, correspondence, etc.)
- No citing your UBC affiliation in publications
- No citing your UBC affiliation in presentations
- No citing the project during annual review for faculty
- No adding the study to a CV that includes your UBC affiliation

Q6. 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.***

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Please note that, per TCPS2 Interpretations, "*Publishing or otherwise disseminating the results of an activity is **not** a factor that determines whether the activity is research or not*."

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., create ***generalizable*** results and disseminate them broadly (globally) in a widely-distributed format such as a journal? This is more likely to be research.

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 policy AL1600 Project Ethics

Should you wish to obtain an Exemption Letter from the IH REB, please submit the request to the REB and include the ARRECI Assessment Tool results and the project charter or proposal.

Q7. 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 except as approved by the REB; the REB is only permitted to approve research that meets all applicable policies and legislation.

Under certain specific criteria listed in the TCPS2 Article 5.5.A, REBs may grant access to personal information for research purposes on behalf of the people who own the information. Your project must meet all six criteria, including 5.5.A(e), ***it is impossible or impracticable to seek consent from individuals to whom the information relates***.

Please note impracticable is a much higher standard than impractical. Impracticable means there is such a great degree of onerousness or hardship involved with obtaining consent that it is, essentially, impossible to do. **If obtaining consent is merely impractical or inconvenient, your study will not qualify for a waiver of consent**.

Q8. 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.

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Q9. 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 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 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.

Q10. 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 for the REB to respond.

For studies requiring **full board review**, please allow at least one week following the REB meeting to receive Provisos from the REB. The meeting dates and deadlines are posted on the REB website.

Total time to the awarding of approval status depends upon the completeness of the submitted application, outcome of the review, completeness of responses and the response time of the PI.

Q11. 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 RR0300 Initial Review of Research.

Q12. Who signs my IH REB Application Form under the "Department Head Signature" line?

If you are an IH employee or medical staff and you are submitting via the IH REB paper Application form, please have your IH department head sign the application. For medical staff, this may be the Chief of Staff at the site where you have privileges, an Executive Medical Director, or a Department Head (e.g. Department of Medicine, Department of Surgery).

If you are not formally affiliated with IH as an employee or medical 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.

If you are submitting via RISe, the application will automatically go to your Department Head for approval prior to being forwarded to the REB(s) for review.

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Q13. Do I need to put the IH logo on my consent form, recruiting materials, etc.?

The current IH logo is required on all participant-facing documents associated with the study. The IH Research Department can provide you with the logo if you do not have an IH study team member.

Q14. When can I close the study with the IH REB?

For Social Sciences research projects, please submit a Study Completion Report any time after all contact with participants, including any use of their personal information or source data derived from them, is completed. 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.

For research that is subject to Health Canada and/or FDA regulation, the study may not be closed until the formal close out visit has been completed by the study monitor.

For studies submitted via the IH REB paper application process, a Completion Report may be obtained by contacting researchethics@interiorhealth.ca. For studies housed on the RISe electronic platform, Completion Reports must be submitted via a RISe post-approval activity.

Q15. The Consent Form template used for this international study comes from the United States. Do I have to change the language?

Canadian terminology must be used for all documents used with participants at Canadian research sites. Common vocabulary differences are listed below; this is not an exhaustive list.

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)
Study procedures	Study treatment

Q16. 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, located at https://www.interiorhealth.ca/about-ih/policies.
- 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* (2018). Completion of the TCPS2 tutorial is recommended for all researchers and is required for those leading above minimal risk research.

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Q17. Why do REB Applications ask for both inclusion and exclusion criteria?

Exclusion criteria refer to characteristics that serve to render individuals who meet the inclusion criteria ineligible to participate. They are not merely the inverse of the inclusion criteria.

Q18. If I recruit IH patients, should a copy of the research study consent form go on his/her chart?

What goes on a patient chart is the decision of Health Information Management. If you wish to add something to a patient's chart that is not part of the standard documentation at the IH facility in question, contact the site's Director of Health Information Management.

Q19. What do I do next if my study receives "Provisional Approval"?

Provisional approval means that the research will be ready to approve once all of the REB's provisos are addressed. After your study is reviewed, the REB will issue provisos via RISe (or via an email attachment if submitting to IH REB only). In either case, the PI must address the provisos before an approval certificate is issued. This includes updating the REB Application Form, protocol, and other study documents as indicated in the provisos letter. The IH REB cannot accept email explanations of changes made. The application form and all documentation must be edited as indicated.

Q20. Do I need to submit a renewal application if I have completed participant recruitment but not my study analysis and publication?

If there is doubt then it is best to renew the ethical approval, in order that the investigator retains the right to check source data or contact participants if need be (in more formal terms, until the data is locked). Some investigators will choose to maintain REB approval through the analysis period for this reason. See also IH policy RR0500 Renewals.

Q.21. I need to submit a Post-Approval Activity (Amendment, Protocol Deviation, Serious Adverse Event) which only affects the Interior Health site. The study is harmonized. How do I submit the PAA so that only the IH REB reviews it?

If a study file exists in RISe, all REB-related activity must be reported via RISe. If the PAA applies only to the IH site of a multi-site study, the Board of Record may review and acknowledge it on behalf of the IH REB, or may assign it to the IH REB for review, depending upon the nature of the PAA.

Q.22. I am waiting for some documents from the sponsor and the application deadline for the next full board meeting is coming up. Should I submit an incomplete package?

No. The Research Ethics Board will not undertake the review of an Application for Ethical Review or schedule it for a full board meeting until the application package is complete. There is no advantage to submitting an incomplete application package.

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Q. 23. What are the best practices for data collection, storage and transfer?

Best practices and institutional capability (e.g. available software) can vary and can evolve over time. The REB advises reviewing current IH policies relating to Information Privacy & Security (IH policy manual section AR) and Records Retention (policy AL0700) to ensure you are following current best practices.

The REB will review your application to ensure that all reasonable standards are met. For example:

- Study data is only accessed by study team members who need that access.
- Study data is housed on a secure institutional server such as the IH F: drive. It is never housed on a personal device, a portable device, or on the desktop or local drive of a device.
- Institutional devices are used to collect, store, and transfer data; never personal devices.
- If data needs to be transferred between institutions, it is done via a secure channel (e.g. SFTP).
- Study data is never emailed between institutions.

Research teams are encouraged to consult IMIT and/or IH Information Privacy as needed.

Q. 24. Does the REB have any requirements when it comes to labelling documents?

The REB does not have a policy defining document naming conventions. Please name documents in such a way that they are easy to identify and easily differentiated from other study documents. Tips:

a. Use the shortest possible name to describe a document
b. Avoid putting the study name or nickname at the beginning of every document label.
c. Assign a version number to each document.
d. Change the date and version number of the document each time it is updated
e. Make sure dates are identifiable as dates, rather than as a string of numbers, e.g. 01April2020 rather than 01042020.
   Example:
   i. Easy to identify: “Consent Form (Main) DDCT v1_April 1, 2020”.
   ii. Hard to identify: “DCCT-NIH PROTOCOL 00928 v 5.0 (ENGLISH-CAN) ICF v1.1_01042020

Q. 25. My study data is only identified by a participant code, and the crosswalk file linking the code to the data is kept separately. Why did I receive a proviso indicating the data is not anonymized?

Per the primary reference used by Canadian REBs (TCPS2 Glossary of Terms), data can be:

a. Anonymized: the information is irrevocably stripped of identifiers; a code is not kept to allow future re-linkage.
b. Anonymous: the information never had identifiers associated with it.
c. Coded or de-identified: direct identifiers are removed and replaced with a code. If there is a list that connects the code to personal identifiers, it is possible to re-identify participants therefore the data is neither anonymous nor anonymized.

Best practice is to destroy the crosswalk file at the first opportunity, usually once the data has been analyzed and re-identification for verification or auditing is no longer needed.

Q.26. How can I check if my consent form has a suitable reading level for the intended participants?

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REBs will check to ensure that documents used with members of the general public have a suitable reading level. This varies and can be as low as grade 7 for some REBs; the IH REB generally accepts up to a grade 9 reading level.

There are numerous readily available tools to ensure you submit the best version of your application package the first time. For example:

- Readability checkers as an MS Word function or online.
- Michael Smith Health Research BC Plain Language Guide, available on the BC SUPPORT Unit website.
- Consent Form checklist available from the IH REB website
- Have a colleague, preferably someone unfamiliar with the study, proofread your application documents prior to submission to see if they can obtain a thorough understanding of what participants are being invited to consider, based on the documents that will be provided to participants.
- If possible, have a layperson read participant-facing documents intended for a lay audience.

Q. 27. Why do REBs need to know if a clinical trial is regulated by the Health Canada or the FDA?

Health Canada has regulations regarding how long clinical trial documentation must be retained by the investigator (currently 15 years post completion). The REB retains its records related to Health Canada-regulated research for the same length of time. All other research records are retained by the IH REB for five years. Therefore, it is essential for the study team to inform the REB whether Health Canada regulations are in effect or not for each study they submit.

The US Code of Federal Regulations has specific requirement pertaining to renewal of ethical approval and to amendments for research that is regulated by the FDA. Not all research is Health Canada or FDA regulated. If you are not sure, the study sponsor can inform you of which regulations are in effect.

Q.28. When do I need to use tracked changes on study documents?

- The initial application package documents should always be submitted as clean versions.
- When submitting a PI Response to Provisos, show all changes as tracked changes. For RISe Applications, changes on the electronic application are automatically tracked. If you used an IH REB Application for Ethical Review form, you must show all changes as tracked changes in a Word file.
- It is assumed that research participants will only ever be provided with clean copies of documents; there is no need to submit both tracked and clean versions of revised documents.
- For subsequent revisions, ensure that you accept all tracked changes which have been approved by the REB ***prior*** to inserting new changes. If there is material in tracked changes that the REB has already approved, it will slow down the review process and delay receipt of approval.
- If you receive documents from a sponsor that are changed but not tracked, please edit them so that it is clear to the REB reviewer what edits have been made. If you receive information in pdf format, you may use the 'highlight' and 'insert sticky note' features in Adobe Reader to point out changes.

Q.29. What are the submission requirements for the various types of Safety Reports that are either initiated by our site or are sent to us by the sponsor?

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Please see IH policy RR0900 Safety and Serious Adverse Event Reporting and IH policy RA0900 Reportable Events for specific requirements.

Q.30. Do the IH co-investigators need to be named on the consent form?

No, the IH REB does not require this. Please note it is helpful for the participant to have the name and contact information of the study team member(s) with whom they may be in contact during recruitment and all other phases of the study.

Q. 31. RISe-related tips:

- The RISe electronic platform has an archiving feature built in. If you wish to see a previous version of an existing application, it is available under the 'Application Changes' tab. The attachments from previous iterations of each application are archived with it, so they are available also.
- RISe Approval Certificates and Acknowledgement Letters list the attached documents exactly as you name them when uploading them to the application; please be careful that the version # and version date you enter matches the version # and version date found in the footer of the document itself.
- If you are asked to edit an attachment prior to that attachment receiving approval, please remove the old (not approved) version. Any documents which you attach in Section 9 will auto-populate the Approval Certificate once the initial approval or amendment is approved; therefore, the REBs cannot issue an Approval if unapproved versions are still attached.
- The REB cannot alter your application. Only the PI and people who are designated by the PI to have online access privileges can modify the application and attachments.
- Carefully proofread your application prior to submitting it. The application will truncate automatically based on your response to specific questions. For example, if you respond to question 4.8.A 'Yes, this application is for research which exclusively requires access to clinical charts', the application will truncate and will **only** ask questions about chart reviews. If your protocol describes additional methods of collecting data, your application will be returned to you and you will have to start over.
- RISe Applications can only be 'with' the REB or 'with' the PI at any given time. Once you submit an application or Post-Approval Activity, you cannot make any edits to the application until the REB takes an action that returns the application to you. Similarly, when the application is with you, it cannot be assigned to a Reviewer until you submit it.

Q. 32. Conflict of Interest

- Conflicts of interest may arise with research projects. If you perceive you may have a conflict of interest please ensure the application addresses the nature of the conflict of interest and how all aspects will be managed for the entire time the participant is involved in the study, from recruitment to completion. See also IH policy AU0100 Standards of Conduct for Interior Health Employees.