

Guidance Note for completing the Interior Health REB Application for Ethical Review Form

The IH REB Application for Ethical Review Form is for use with research studies that exclusively involve Interior Health.

If this study qualifies for harmonized ethical review, please use the UBC RISe platform to submit your application.

For more information on harmonized ethical review in British Columbia, see <u>www.researchethics.bc.ca</u>.

Applications that should be harmonized will be rejected if they are submitted on this form.

1. Title of Research Project

Provide complete title as it appears on the research protocol and all other documents related to this project. Title must match on all documents: protocol, application form, recruitment materials, consent form(s) etc.

RESEARCH TEAM

2. Principal Investigator

The Principal Investigator (PI) bears the overall responsibility for the conduct of the project, including the activities of co-investigators who are assumed to be acting under the delegated authority of the PI. The PI is required to adhere to TCPS2, IH REB policies and all other relevant policies and legislation.

Please use an institutional email address. Do not use Gmail, Hotmail, or other thirdparty service provider for confidential correspondence to the IH REB.

Primary Institutional Affiliation – list the affiliation <u>for the purpose of this research</u> <u>project</u>. For example, if the research is being done to meet academic requirements and the student and is also an IH employee or medical staff, the primary affiliation for research purposes is the academic institution.

The institution must be a Health Authority, academic institution, or other recognized institution, often the applicant's place of employment or school. Do <u>not</u> list an informal group such as a committee, working group or interest group.

If you are affiliated with UBC and you opt to use the IH Application form, UBC will not review it. Per UBC policy, UBC affiliates may not connect the research to UBC in any way (such as citing a UBC affiliation in a publication, presentation, or in study materials; using UBC resources to support the research) unless a UBC REB has reviewed it.

Secondary Institutional Affiliation – if the PI has another institutional affiliation, list it here. If the PI is a graduate student and an IH employee, list their IH role as their secondary affiliation.



3. Primary Contact (if different from PI)

Please use an institutional email address (e.g., @interiorhealth.ca, @ubc.ca). Do not use Gmail, Hotmail, or other third-party email providers for confidential correspondence to the IH REB. This address will be used for all REB correspondence related to the project.

4. Co-Investigators

Anyone who interacts with research project participants or their data should be listed on this application. Use Box 44 if additional space is needed to list co-investigators or other project team members such as research assistants, transcriptionists, or statisticians.

5. Student Research

If the student's academic institution requires the thesis or residency supervisor to be listed as the PI, indicate this in the space where the supervisor's name is given.

6. Researcher Qualifications

Describe who will be conducting the project and his/her qualifications to conduct this kind of research, e.g., relevant training, coursework, or experience. If the research is above minimal risk, include the CV of the PI.

7. TCPS2 Tutorial Completion

Completion of the tutorial is required for the PI for all research that is above minimal risk, and for all studies funded by CIHR, NSERC or SSHRC. It is recommended that all research personnel complete the TCPS2 Tutorial.

The tutorial is available free of charge at <u>https://tcps2core.ca/welcome</u>.

8. Conflict of Interest and potential benefits to investigators

Anyone conducting research in Interior Health must abide by IH Administrative Policy AU0100 <u>Standards of Conduct for Interior Health Employees</u> IH REB Policy RA0800 Conflict of Interest IH Research Department policy RD0100 Research Integrity



Conflict of Interest is defined in TCPS2 as "the incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another situation where financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research. Conflicts of interest may be potential, actual, or apparent".

Members of the research team must disclose to the REB and to research participants any real or potential conflicts of interest related to:

- their professional or employment roles
- the payment of honoraria or fees for recruitment, advice on project design, presentation of results or conference expenses
- direct financial involvement with a sponsor on behalf of the investigator and his/her family members

Finder's Fees: Where the sole activity of a physician or clinician is to submit the names of potential research participants, no fee should be paid for that service. Submission of patient information without their consent would be a breach of privacy. Clinicians who meet with patients, discuss the project, and obtain informed consent for submission of patient information may be remunerated for this activity (Canadian Medical Association © 2007).

PROJECT DETAILS

9. Estimated Project Time period

From month/year to month/year. The start date should not pre-date this application. The end date can be an estimate of when you expect to have completed data collection both directly from research participants and from pre-existing records. The end date can be updated as needed via Annual Renewal requests.

For chart reviews, the dates should correspond with the dates the project will be conducted. Provide the date range of charts to be reviewed in Question 20, Inclusion Criteria.

10. Funding and sponsorship

List all sources of funding that will be used to support this project. Research sponsored by industry such as pharmaceutical or medical device companies are charged a fee for REB review. The fee schedule is on the IH REB website. Please contact the REB Leader if there are questions about fees for ethical review.

The budget from the Clinical Trial Agreement or a copy of the Grant-in-Aid offer must be included with this application.



For industry-sponsored projects, REB fees apply unless the study is funded by an unrestricted grant-in-aid. Please see <u>REB website</u> for details. The REB will bill the applicant; the applicant is responsible for recovering fees from the sponsor.

If IH is contributing to the project through an in-kind donation e.g., use of meeting rooms, facilities, data, staff time, etc., list them as a funder.

If the sponsor is different from the funder, provide the name of each party.

11. Level of Risk

TCPS2 defines minimal risk as:

Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

The IH REB uses a proportionate approach to ethical review of research involving humans. In accordance with the TCPS2, full review by a fully convened REB is the default requirement, unless the REB has determined that the research is of minimal risk and that delegated review by one or more REB members is appropriate. A Risk Matrix is found on the last page of this Guidance Note.

The IH REB meeting schedule for full board review is posted on the IH REB website, along with application deadlines, guidance notes and other resources. There is no deadline for submission of minimal risk research.

The IH REB reserves the right to forward any study submitted as minimal risk for full board review if, in the opinion of the reviewer, the definition of minimal risk is not met.

12. Peer Review

Independent, external peer review is mandatory for all projects that are above minimal risk. Submit the names of committees or individuals involved in the review and all supporting documentation from the peer reviewer(s). Peer reviewers must not be otherwise associated with the project as an investigator, study team member, consultant, etc., and should be from a different institution than the study team.

13. Additional REB Review

If IH is a secondary site and the research has been approved by another Canadian institution's REB, forward a copy of their approval certificate.



14. Regulatory Approvals

If the study is a clinical trial of a drug, device, or natural health product, before submitting the application, confirm with the sponsor:

- Whether or not Health Canada approval is required.
- Whether or not the study is required to comply with United States federal regulations for research ethics.

If Health Canada approval is required, the No Objection Letter must accompany the initial application.

If the trial is US FDA regulated, documentation verifying the IND/IDE number, or an explanation of the exempt status, must accompany the initial application.

15. Location of Research

List all IH locations where the research will be conducted. Be specific e.g., facility or division within a facility such as a ward if applicable.

If you are conducting research remotely, e.g., online or via telephone, and the locations of the participants are not necessarily known, respond "online only" or "remote contact only".

If you are targeting a specific program e.g., "Outpatient Diabetes Clinics" and do not yet know which IH sites who offer that program will choose to participate, list all sites that offer the program.

If you do not have an IH employee or medical staff member on the study team, connect with the appropriate IH sites or teams *before* submitting your application to determine the appropriate response.

16. Purpose Statement

Provide a brief (one or two sentence) statement of the purpose of this research study. Do not exceed 100 words.

17. Summary of Methodology and Procedures

Use this section to fully describe how the standard research protocol will be carried out in IH. Which specific IH resources will be used? Which locations? Will any IH staff be involved? If so, how? Will any IH records be accessed? If applicable, describe what normal clinical care looks like in Interior Health and how the research will differ from usual care.



18. Will existing records be used for research purposes?

Access to information in the custody of IH: Under the British Columbia <u>Freedom of</u> <u>Information and Protection of Privacy Act</u> a public body is forbidden from disclosing personal information in its custody or under its control for a research purpose, without prior consent of the person to whom the information pertains. IH medical staff, employees, students, or contractors with access to patient, resident or employee information are not permitted to disclose the names of potential research participants to anyone outside of the institution without prior permission from the potential participants.

IH employees, medical staff, students, volunteers, and contractors must abide by IH Administrative Policy <u>AR0100 Acceptable Use of Information Systems</u> which stipulates that the IH Information System is provided exclusively for the purpose of conducting IH business. This means that:

- 1. Only the data steward of a given set of records can allow those records to be used for approved research purposes.
- 2. No one is allowed to approve his/her own use of IH records for research purposes.

Access to patient charts or electronic medical records can be obtained one of two ways:

- 1. Patient has provided written consent to have the researcher review his/her medical records for purposes of the research. Researcher provides the signed consent form to the Health Records department after ethical and operational approval have been granted.
- 2. If patient consent cannot be obtained, the researcher may apply for a Waiver of Consent from the IH REB. Justification must be provided (see question 32), and it must meet all of the criteria outlined in the <u>TCPS2</u> Article 5.5.A.
- 3. The researcher must also apply for Operational Approval from the Health Records department responsible for the desired records.

Access to employee distribution lists

Email distribution lists may not be used directly by the researcher to solicit participation in research. A third party who has access to the employee list and who is not in a position of authority over the employees may send out an information email about the project; the email may direct interested parties to contact the researcher.

To obtain Operational Approval for use of IH information for research purposes, submit a Study Intake form found on the Operational Approval page of the IH Research Department website.

19. Creation of a Data Bank or Tissue Bank

Answer "Yes" if the purpose of this study is to create a repository of data or tissue that is intended to be accessed by the researcher or others for future use, and where the researcher intends to be the steward of the information.

Answer "No" if the only database that will be created is for the sole purpose of routine data analysis for the current project; if the sponsor will be the data steward; or if this study only involves secondary use of existing data.



Definitions: a **Registry** is a collection of information about humans specifically for use in subsequent research. It may or may not include personally identifying information, clinical files, clinical test results, diagnostic imaging reports, or information related to age, race, place of origin etc. It may be collected retrospectively or prospectively.

A **Biorepository** is the collection of human biospecimens for use in subsequent research, and may include solid tissues, blood samples, and other fluids. It may or may not also include associated information about individuals from whom the biospecimens were collected.

PARTICIPANT INFORMATION

20. Inclusion Criteria

Do not simply refer to a page of the protocol. If list of criteria is lengthy, summarize it. If this is a retrospective chart review project, include a detailed description of the charts that will be reviewed, including the criteria used to select the charts and the date range of the charts that will be reviewed.

For retrospective reviews, the date range of the charts must precede the date of this application.

21. 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.

Ensure that all Exclusion Criteria are listed and that they match the Exclusion Criteria described in the protocol.

Do not simply refer to a page of the protocol. If list of criteria is lengthy, summarize it.

22. Research with Aboriginal, Metis or First Nations Peoples of Canada

TCPS2 <u>Chapter 9</u> stipulates that the researcher shall seek engagement with the relevant community at the earliest opportunity in the research. Researchers must comply with TCPS2 Chapter 9 and obtain both levels of consent (community engagement and individual participant consent).

A "community" may be territorial, organizational, or a community of interest. For example, the appropriate community for urban-dwelling Indigenous people may be a Friendship Centre or Metis Centre.

Provide evidence of this engagement with the application for ethical review, including a copy of the Research Agreement or other documented evidence of Community Consent.



23(a) How many participants will be enrolled at IH sites?

Provide the recruitment goal for IH sites. If this is for a retrospective chart review, the charts are the *de facto* participants, therefore describe the number of charts that will be reviewed.

If the study exclusively involves the use and/or linking of large pre-existing data sets and the number of cells cannot be determined exactly, please state this.

23 (b) Multi-site studies only: how many participants will be enrolled across all participating sites?

Give recruitment goal for total enrollment, worldwide.

24. How much time will a participant be asked to dedicate to the project?

Include the total time over the life of the project for all research activities that the participant is expected to take part in, e.g., "2.5 hours over a span of three months for consent procedures, participation in an interview, completing a demographics form, and post-interview member-checking".

25. Recruitment procedures

- Provide a detailed description of recruitment procedures, including the source of contact information and how the researcher gained access to it.
- Describe who will contact prospective participants and by what means they will do this.
- Describe how researchers will mitigate potential for undue influence or coercion.
- Describe any existing relationship between project team members and participants (e.g., treating physician, teacher, colleague). Healthcare providers should not directly recruit patients in their care for the purpose of research.
- Include all recruitment materials with the application package e.g., email and phone scripts, social media advertisements, flyers, and posters.

26. Incentives for participation and/or reimbursement of expenses

Provide full details of the amounts, payment schedules, and value of gifts-in-kind. If there is no reimbursement available for expenses participants can reasonably be expected to incur as a direct result of participation, e.g., travel or parking costs, state it clearly in the Consent Form.

If IH employees are recruited as participants, describe in the consent form if they will be permitted to participate on IH-paid work time; Operational Approval must be obtained separately if this is the case.



Employees cannot both be compensated by the research team for their participation and participate on Health Authority-paid (work) time; this would violate IH policy AU0100 Standards of Conduct.

27. Are any participants considered members of a vulnerable group in the context of this research project?

Per TCPS2, vulnerability is defined as a diminished ability to fully safeguard one's own interests in the context of a specific research project. See also the TCPS2 definition of Autonomy.

28. Does this project have the potential for identifying distressed individuals?

The higher the probability of duress precipitated by the research participation, the more comprehensive and immediate the assistance should be. If members of the research team are responsible for providing appropriate care to a research participant who is distressed, describe the research team members' qualifications to do so.

29. Describe any potential risks to participants.

Describe how the risks will be mitigated or what safeguards will be put in place.

Almost all research involving humans has, at a minimum, a potential risk to participant privacy. For studies where there is no direct contact with participants (such as retrospective chart reviews), describe how participant data will be maintained securely throughout the research process.

30. Describe any potential direct benefits to participants.

If there is a possibility that the participants themselves will receive no benefit, state this clearly in application and in the consent form.

PARTICIPANT INFORMATION AND CONSENT

31. Who will consent?

Review all IH policies governing consent, including:

- AL0100 Consent Adults
- AL0200 Consent Persons Under 19 Years of Age
- RR0700 Obtaining Consent for Research
- RS0300 Populations for Special Consideration in Research



The age of majority in British Columbia is 19.

<u>If the participant is under the age of 19</u>: provide an age-appropriate Assent Form for the child or adolescent at an appropriate reading level, and a Consent Form for the parent or guardian. Assent form templates are available on the BC Children's Hospital REB website. If the researcher is proposing that minors (those under the age of 19) will consent on their own behalf, provide the justification for this. For example, "the researchers routinely provide care to youth aged 16-18 and are able to assess them on that basis"; or "asking for parent or guardian consent could pose risk to the potential participants". In the latter example, describe the risks which justify not asking for parent or guardian consent.

If a potential participant may have diminished capacity to consent:

- Describe how capacity to consent will be determined.
- Provide an assent form at an appropriate reading level.
- Describe who will consent on their behalf if assent is provided.

32. Waiver of Consent

A Waiver of Consent may be granted if the request is justified per <u>all six</u> criteria of TCPS2 <u>Article 5.5</u>A. Provide a detailed description of how each of the criteria are met.

Article 5.5A, part e, stipulates that it is impossible or impracticable to obtain consent. 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, essentially impossible to do. If obtaining consent is merely impractical or inconvenient, your study will not qualify for a waiver of consent.

Chart reviews are <u>not</u> automatically granted a waiver of consent. It must be impossible or impracticable to obtain consent from the people to whom the information used for research purposes relates.

33. Describe the process that will be used to obtain informed consent.

- Will participants be given all the necessary information to provide informed consent in writing?
- Is the consent form written in lay language?
- What provisions made for people who may not be fluent in written English or have visual or cognitive deficits or other potential impediments to consenting on their own behalf?
- Will the consent forms and information materials be presented in person? By mail? By email?
- Who will obtain the consent? It cannot be anyone with a power-over relationship with the participant, including manager/employee, doctor/patient, or teacher/student.



34. If any participants are not capable to give informed consent, who will consent on their behalf?

In some cases, it is appropriate to obtain consent from parents or guardians. Whenever possible, an Assent Form should be given to the child or person not capable of consenting on his/her own behalf, e.g., children over the age of seven, adults with mild to moderate dementia, or persons who may have suffered temporary or permanent cognitive deficit secondary to stroke, brain trauma, etc.

35. How long will participants have to decide whether they choose to participate?

Specify "x days" or "x weeks".

If the time allotted for participants to provide consent is brief e.g., less than 72 hours, provide justification for why this is the case.

36. Describe procedures for participants who choose to withdraw at any point during the project.

- Will the participant's data be removed if he/she withdraws from the project?
- If it is impossible to remove the data once it is collected, inform the participant of this in writing prior to enrollment (e.g. via the consent form).
- Will the participant be contacted again for any reason related to his/her participation in the project?
- If the study involves a Focus Group or other group activity, explain the limitations of withdrawing data from Focus Group transcripts (or other grouped data) and how the participant's privacy will be respected if their data cannot be withdrawn.

37. What is the reading comprehension level of all participant facing documents?

For documents used with members of the public, the English reading level should be no higher than grade 8. This includes all documents used with potential participants such as recruitment documents and consent forms. For assent forms used with children, the reading level must be age appropriate.

Unless you are recruiting participants from a population that is required to have a minimum language proficiency higher than middle school level (e.g., recruiting physicians as participants), check all documents for readability prior to submitting them to the REB. There are numerous ways to check this:

- Flesch-Kincaid readability score in MS Word®
- Online readability tools such as webfx.com/tools/read-able/
- Interior Health Plain Language Writing Guide on InsideNet
- BC Support Unit Plain Language Guide on the Michael Smith Health Research website



If the language level cannot be brought down to the required level due to technical or medical terms that are required information, indicate this in the application, e.g. "certain terms brought the grade level up; all of these terms have been defined the first time they are used and replaced with plain language where possible".

DATA SECURITY

38. Who will have access to the data?

Describe who will have access to the new data generated by this research. Only members of the research team listed on this application should have access to the data, and then <u>only if</u> their role on the research team requires such access.

39. If a participant withdraws partway through the project, what will happen to his/her data?

If it is logistically impossible to remove individual participant data, make this clear to participants before they provide consent. If it will be used in the analyses if the participant agrees, make sure this is clearly described in the Consent Form.

40. Provide a detailed description of all procedures for maintaining confidentiality of data and identifiable information at all times, throughout the course of the project.

<u>TCPS2 Article 5.3</u> states: "*Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of the information: Its collection, use, dissemination, retention and/or disposal.*" Researchers are expected to adhere to all principles related to Confidentiality and Data Security as described in <u>TCPS2 Chapter 5</u>.

Research-related documents (except the master randomization schedule, consent forms, or screening logs) shall not include information that would allow the participant to be identified. Fields for participant's name, the first or last three letters of a participant's name, actual initials, reversed initials, birth date, hospital medical record number, provincial personal health number, social insurance number, address or phone number or full postal code are <u>not permitted</u> on project-related documents.

Information is considered de-identified if the following conditions are met:

- The unique project code is not derived from or related to information about the participant.
- The unique project code could not be translated to identify the participant.



- The investigator or his/her institution could not use OR disclose the unique project code for other purposes OR disclose the mechanism for re-identification.
- All documents that may correlate participant names with project code numbers, such as enrolment logs or databases, must be kept securely and separately from the rest of the project documents. It is the responsibility of the PI to secure all project data.

Include descriptions of the following processes, as applicable:

- How data will be transported or transmitted in a secure manner.
- How long the data will be kept, where it will be kept, how it will be kept secure, and how it will eventually be disposed of or deleted.
- How data linkage will occur and how confidentiality will be preserved throughout this process.
- What type of information will be transferred to or from another institution, and in what form it will be during the transfer.

It is the PI's responsibility to store project materials securely upon completion of the project and shred or delete them at the end of the specified storage period. For clinical trials regulated by Health Canada, data must be securely stored for fifteen years; for all other research projects, the data must be stored for five years per IH Policy <u>AL0700</u> <u>Records Retention</u>.

Important resources:

- TCPS2 Glossary, for accepted definition of de-identified, anonymized, anonymous.
- TCPS2 Chapter 5 Privacy & Confidentiality
- BC Freedom of Information & Protection of Privacy Act
- IH policy AR0400 Privacy and Management of Confidential Information

41. Describe any plans for future use of data.

Will the data gathered during this research project be used in any future research projects? Note that ethical approval must be obtained prior to using existing data for a research project.

42. Describe how results will be shared with participants.

Researchers are expected to share research results with participants. If contact information is required in order that results can be shared, make this clear in the consent form and ensure that providing contact information for this purpose is optional for the participant.

43. Describe plans for publication and presentation.

Will the results be shared directly with Interior Health? Will the results be published in a journal? Will the results be published in a thesis? Will the data be presented to others not involved in the research?



Explain any restriction on publication imposed by sponsors or others. If it is possible that results will not be published, provide the justification for conducting the research.

44. Additional Information

Use this space to provide information which may be helpful to the Research Ethics Board **OR** to continue any item for which sufficient space was not available.

SUBMISSION CHECKLIST

Submission Requirements:

- Include both a version number and a date in a footer of each document.
- Submit each document separately as individual attachments.
- Submit only clean versions of documents for an initial application.
- Ensure that digital file names are descriptive enough that it is easy to identify the document by its name.
- Insert the Interior Health logo on materials that are provided to participants or shared publicly.
- Do not submit scanned copies of documents. The only exception is the Application form, which may have been printed in order to obtain signatures of the PI and the PI's Department Head.
- Submit the completed application package to <u>researchethics@interiorhealth.ca</u>.
- If there are too many documents to submit in a single email, bundle them by category. For example:
 - $\circ~$ Bundle 1: Application for Ethical Review Form, protocol, consent forms, recruitment documents
 - Bundle 2: Health Canada No Objection Letter, peer review, budget or full Clinical Trial Agreement, CV of PI, approval certificate from primary REB (if applicable)
 - Bundle 3: standardized tests such as the SF36 or EQ5D5L; standard administrative participant documents such as Instructions on how to store a drug, use a device, etc.

Required Documents:

- Protocol or Research proposal. <u>The research protocol is the reference document;</u> <u>information on the application form and in other documents in the application</u> <u>package must be internally consistent with the protocol</u>.
- Application for Ethical Review Form should be submitted as a Word file signed electronically by both the PI and his/her Department Head. If a copy must be printed and scanned in order to obtain the required signatures, include <u>both</u> the Word version and the scanned pdf.
- Operational Approval to Conduct Research is facilitated by the IH Research Department via their online study intake form. See their website or contact research@interiorhealth.ca.



Additional documents required for above minimal risk research:

- CV of PI these are kept in each study file; please submit even if the PI has another active, above-minimal risk study with the IH REB.
- Written evidence of independent peer review. The IH REB can provide a peerreviewer form template if required.
- TCPS2 completion certificate of PI need not be submitted, but should be available upon request.

Clinical trials require all of the above, plus:

- Budget pages of the Clinical Trial Agreement. This is often an attachment or 'Schedule A' – please ensure the document is named such that it is clear what it is.
- Health Canada No Objection Letter (drug trials) or Investigational Device Exemption (device trials)
- The project must be registered with an online clinical trial registry such as <u>clinicaltrials.gov</u>

Submit as Applicable:

- Research Agreement with relevant Aboriginal, First Nations or Metis peoples. For studies involving urban Indigenous participants who may belong to many and varied Nations, the endorsement of the Friendship Society or other representative group should be included.
- If this study has been reviewed and approved by another Canadian REB and this application is for a secondary site, submit a copy of the Certificate of Ethical Approval from the primary institution.

Incomplete application packages will be returned to the Primary Contact or PI and will not be reviewed by the IH REB.

SIGNATURES

The signature of the Principal Investigator and his/her Department Head, Academic Supervisor, or Administrator indicates that both parties take responsibility for:

- reviewing the contents of the application package
- ensuring the information contained within is complete and accurate
- ensuring the protocol is methodologically sound and complies with professional research ethics standards
- ensuring the proposed research will not commence until ethical approval has been granted
- abiding by the TCPS2
- abiding by all IH REB Policies and all applicable IH Administrative Policies and Research Polices,
- abiding by all relevant legislation, e.g., FIPPA
- The Department Head or Academic Supervisor confirms by signing that the Principal Investigator has the qualifications, experience, and facilities to carry out this research project.
- The PI confirms by signing that



- the research will not commence prior to receiving a Certificate of Institutional Approval from Interior Health
- s/he will apply for Renewal of ethical approval at least one month prior to the expiration date on the Certificate of Ethical Approval.

TITLE OF RESEARCH PROJECT

Please repeat the research project title here. This is especially important if the signature page of this application is scanned and submitted as a single page -- the full title of the project must be provided on the signature page.



APPENDIX

1. Risk Matrix

	Research Risk			
Group Vulnerability		Low	Medium	High
	High	Full Board	Full Board	Full Board
	Medium	Minimal Risk (Delegated Review)	Full Board	Full Board
	Low	Minimal Risk (Delegated Review)	Minimal Risk (Delegated Review)	Full Board

See the Interior Health <u>Research Ethics Board</u> and <u>Research</u> webpages for additional resources