Interior Health
Every person matters

Research Ethics Office, Community Health and Services Centre
3rd Floor, 505 Doyle Avenue
Kelowna, BC V1Y 0C5
Tel: (250) 870-4602
Email: researchethics@interiorhealth.ca

Guidance Note for Completing the IH Application for Ethical Review of Research Involving Human Participants

Save the Application Form before filling any of it in.

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 study team members who are assumed to be acting under the delegated authority of the PI, and is required to adhere with the requirements of TCPS2 and other relevant guidelines.

Primary Institutional Affiliation – list the affiliation **for the purpose of this research project**. For example, if the researcher is a graduate student and is also an IH employee or physician, the primary affiliation for research purposes is the university.

If you list your primary affiliation as UBC, do not use the IH Application form; complete your REB submission via RISe.

Secondary Institutional Affiliation – if the PI has another institutional affiliation that is **relevant** for **this** research project, list it here. If the PI is a graduate student and an IH employee, list their IH role as their Secondary affiliation. If the PI is a physician with a private affiliation for the research, and the PI also has IH privileges, list IH as the secondary affiliation.

3. Primary Contact (if different from PI)

This name and email address will be the primary one used by the REB for all correspondence related to the project.

4. Study Team Members

Anyone who interacts with research project participants or their data should be listed on this application. Use Box 43 if additional space is needed to list study team members or other project team members such as research assistants, transcriptionists, or statisticians.

5. Student Research

If the student's academic institution requires the thesis 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 actually conduct the project and what are his / her qualifications to conduct this kind of research?

Describe relevant training, experience, degrees and / or courses. You may include a research CV (mandatory for clinical trials).

7. TCPS2 Tutorial Completion

It is recommended that all research personnel complete the TCPS2 Tutorial.

Completion of the tutorial is a **requirement** for the PI for all research that is above minimal risk, and for all studies funded by CIHR, NSERC or SSHRC.

The tutorial is available free of charge at http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/.

8. Conflict of Interest and potential benefits to investigators

Anyone conducting research in Interior Health must abide by IH REB Policy RA0800 Conflict of Interest.

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.*

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 role
- 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

Access to information in the custody of IH: Under the British Columbia Freedom of Information and Protection of Privacy Act a public body may not disclose personal information in its custody or under its control for a research purpose. IH physicians, employees, students or contractors with access to patient, resident or employee information are not permitted to submit the names of potential research participants to anyone without prior permission from the potential participants; nor are they permitted to access that information for research purposes without prior ethical and operational approval.

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. 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 correspond to the beginning of the period during which you anticipate starting recruitment of participants and 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.

For chart reviews, the dates should correspond with the dates the project will be conducted. The date range of charts to be reviewed should also be indicated in Question 21, Inclusion Criteria.

10. Funding Type and Sources

List all sources of funding that will be used to support this project. Research sponsored by industry such as pharmaceutical or medical device companies will be charged a fee for REB review. The fee schedule is on the IH REB website. Please contact the REB Office 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, provide a sponsor contact for billing, including name / title, complete mailing address, email address and telephone number.

The complete Clinical Trial Agreement must be submitted to research@interiorhealth.ca for review and / or negotiation on behalf of Interior Health.

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 sponsor.

If the project is funded by the DHHS, include the actual grant application with the application package. The DHHS requires that the REB review the actual grant application to compare it to the protocol being approved and ensure that they are the same.

11. Category of Research

Choose only **one** category. If more than one category applies, choose the one that is the best fit.

12. Level of Risk

The TCPS2 definition of minimal risk is:

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 below.

Research Risk			
	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

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

13. Peer Review

If this research proposal received any independent scientific and / or methodological peer review, include the names of committees or individuals involved in the review. Please provide supporting documentation from the peer reviewer(s).

Peer review is mandatory for all projects that are above minimal risk.

14. Harmonized Ethical Review

Research qualifies for harmonized ethical review if two or more of the following BC institutional REBs are participating in the ethical review: BC Cancer, Children's & Women's Hospital, Fraser Health Authority, Interior Health Authority, Island Health Authority, Northern Health Authority, Providence Health Care, Simon Fraser University, University of BC, University of Northern BC, University of Victoria. This includes research where participants are recruited from two or more of these institutions or the primary affiliation of research team members include two or more of these institutions.

The institutional REB receiving the Cover Sheet for Harmonized research ethics review will coordinate the harmonized review and will be the primary contact point for the PI with respect to the ethical review.

UBC Family Practice Residents, Pharmacy Residents, Dietetic Interns and Summer Medical Student Research Project award recipients need apply only to the IH REB if their research project takes place wholly within Interior Health. The IH REB approval will be recognized by the UBC Clinical Research Ethics Board (CREB).

For projects submitted to fulfill requirements of the UBC Faculty of Medicine FLEX program, contact the IH Research Ethics Office.

15. Additional REB Review

If approval from another REB is pending, forward a copy of the other REB's Certificate of Approval as soon as it is available.

16. Location of Research

If you are conducting research remotely, e.g. online or via telephone, and the locations of the participants are not necessarily known, respond "multiple locations – online survey" or "multiple locations – telephone interviews".

If you are targeting a specific program and do not yet know which IH sites who offer that program will choose to participate, describe the target population as specifically as possible, e.g. "Patients attending Outpatient Diabetes clinics at any IH site."

17. Purpose Statement

Provide a brief statement of the Purpose of this research study. Please do not exceed 50 words.

18. Summary of Methodology and Procedures

Describe any procedures that will be carried out for research purposes making a clear distinction between what is normal clinical care and what is being done for research, including: laboratory testing, diagnostic imaging, questionnaires, surveys, focus groups, interviews, or other quantitative or qualitative research methods.

If the project involves an experimental approach to treatment, **specify** how the procedures differ from usual clinical care. Please be brief; a maximum of 300 words.

19. Will existing records be accessed for research purposes? Maximum 250 words

IH employees, physicians, students, volunteers, and contractors must abide by IH Administrative Policy AR0100 Acceptable Use of Information Systems 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 or custodian of a given set of records can allow those records to be used for 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 33), and it must meet all of the criteria outlined in the TCPS2 Articles 3.7 and/or 5.5, whichever is applicable.

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.

All data requests for IH information must be identified on the Operational Approval to Conduct Research within Interior Health form.

20. 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

21. Inclusion Criteria

The selection of participants must take TCPS2 Article 4.1 into consideration. It states that "Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants". The TCPS2 cautions against recruiting participants into research studies solely because they are easy to access or manipulate and highlights researchers' special obligations toward individuals or groups whose circumstances may lead to or increase their vulnerability in the context of a specific research project.

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

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.

22. Exclusion Criteria

The TCPS2 Chapter 4 part B cautions against inappropriate exclusion of potential participants because of their age, gender, capacity to consent, reproductive capacity, or vulnerability.

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

23. Does this research involve the recruitment of Aboriginal, First Nations or Metis participants?

The TCPS2 Chapter 9 stipulates that the researcher shall seek engagement with the relevant community at the earliest opportunity in the research. The researcher shall provide evidence of this engagement with any application for ethical review including a copy of the Research Agreement or other evidence of Community Consent.

24. (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. Provide the number of charts that will be reviewed.

(b) Multi-jurisdictional projects only: how many participants will be enrolled across all participating sites?

Give recruitment goal for total enrollment.

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

Include all hours / minutes 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".

26. Provide a detailed description of 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** this will be done.
- Describe how potential for undue influence or coercion will be mitigated.
- 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, internet or hard copy advertisements

27. Describe any 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, this must be stated clearly in the Consent Form.

28. Are any participants considered to be in a vulnerable situation for participation in this research?

If yes, describe measures to reduce risk of vulnerability during recruitment, enrolment, and interventions.

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

If yes, describe the assistance that will be made to anyone who experiences distress as a result of participation.

30. Describe any potential risks to participants arising from their participation in this project and how risks will be mitigated.

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

31. Describe any potential DIRECT benefits to participants arising from their participation in this project.

Describe potential **direct** benefits to **participants** only.

32. Who will consent?

The legal age of majority in British Columbia is 19. People aged 18 and under require an assent form. Assent form templates for children aged 7-13 and adolescent children aged 14-18 are available at PHSA Ethics Approval Policies and Resources page. Further information on policies governing consent for research can be found in IH REB Policy RR0700 Obtaining Consent for Research and IH REB Policy RS0300 Populations for Special Consideration in Research.

If participants under the age of 19 are being recruited, please include a Consent Form for Parents / Guardians. In cases where a participant's ability to provide informed consent may be compromised or difficult to assess, provide an assent form for the participant if possible, in addition to the consent form for his / her legally authorized representative.

33. If requesting a Waiver of Consent, provide justification per Article 3.7 or Article 5.5 as applicable of the TCPS2.

An alteration of the consent process may be accepted if the request is justified per **all** of the criteria of TCPS2 Article 3.7.

A Waiver of Consent may be granted if the request is justified per **all** of the criteria of TCPS2 Article 5.5.

Provide detailed description of which Article is applicable and how all the criteria are met.

34. 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?
- Are provisions made for people who may not be fluent in written English?
- Will the consent forms and information materials be presented in person? By mail? Email?
- Who will actually obtain the consent? Note that it cannot be anyone with a power-over relationship with the participant, including manager / employee, doctor / patient, or teacher / student.

35. 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. For Assent Form templates, please contact the Research Ethics Office.

36. How long after being provided with detailed information about the project will participants have to decide whether or not 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.

37. 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, will the participant be informed of this prior to enrolling in the project?

Will the participant be contacted again for any reason related to his / her participation in the project?

Data Security

38. Who will have access to the data?

Only members of the research team listed on this application should have access to the data, and then only if their role on the research team requires access to the data.

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, this must be made clear to participants before they provide consent. If it will be used in the analyses if the participant agrees, describe how agreement will be obtained (e.g. will it be in writing?) and by whom.

40. Describe all procedures for maintaining confidentiality and security of the data and personal information both during the project and after it is completed.

The TCPS2 Article 5.3 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 TCPS2 Chapter 5.

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. To this end, 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 not permitted 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.

The following processes should be described:

- If data will be transported or transmitted, describe how it will be kept secure during this process.
- 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.
- If data is to be linked to any other data source, describe how the linkage will occur and how confidentiality will be preserved throughout this process.
- If data is to be transferred to or received from another institution, describe what type of information will be transferred, and in what form it will be during the transfer.

It is the responsibility of the PI 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, data must be securely stored for twenty-five years; for all other research projects, the data must be stored for seven years per IH Policy AL0700 Records Retention.

41. Describe how results will be shared with participants.

If results will not be shared with participants directly, provide justification for this.

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.

42. Describe plans for publication and presentation. Explain any restriction on publication imposed by sponsors or others.

Will the data be published in a journal?
Will the data 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, explain why this is justifiable.

43. Additional Information

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

Submission Checklist

Include both a version number and a date in a footer of each document.

Submit each document separately as individual attachments.

Ensure that digital file names accurately reflect the name and version of the document.

Insert the Interior Health logo on materials that are provided to the project participant or shared publicly if either (a) the project is sponsored in whole or in part by Interior Health or (b) the primary affiliation of the PI or Co-investigator is Interior Health

Submit the completed application package to researchethics@interiorhealth.ca.

Required Documents	
☐ Protocol or Research proposal	The research protocol is the reference document; information on the application form and in other documents in the application package must be internally consistent with the protocol.
☐ Signed Application for Ethical Review Form	
☐ Operational Approval to Conduct Research form	Submitted to research@interiorhealth.ca
Additional Requirements for Clinical Trials	
☐ Budget pages of the Clinical Trial Agreement	submitted to the REB with this application package
☐ Health Canada No Objection Letter or IDE	submitted to the REB with this application package
☐ CV of PI	submitted to the REB with this application package
☐ Clinical Trial Agreement	submitted to research@interiorheatlh.ca for negotiation on behalf of Interior Health
☐ The project is registered at clinicaltrials.gov	
Submit as Applicable	
☐ Research Agreement	with relevant Aboriginal, First Nations or Metis peoples (if applicable)
☐ Recruitment materials (posters, flyers, email or telephone scripts, Letters of Introduction, social media posts, etc)	
☐ Consent and / or Assent Forms	
☐ Standardized tests, Focus Group or Interview questions, or other materials administered to participants	
☐ Certificate of Ethical Approval from primary institution	If primary institution is not a BCEHI partner.
☐ Other documents related to this application (e.g. DHHS Grant Application or Biobank registration completed with OBER)	

Incomplete application packages will be returned to the Primary Contact or PI with a request for the missing documents.

Incomplete application packages 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 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

The Department Head or Academic Supervisor also 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 (a) the research will not commence prior to receiving a Certificate of Ethical Approval from the IH REB (b) 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.