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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

# Application For Ethical Review Of Research Involving Human Participants

Submit the signed, completed form, research protocol, and all attachments to researchethics@interiorhealth.ca.

| **1. Title of Research Project** |
|---|
| |

## Research Team

| **2. Principal Investigator (PI)** – Last Name | First Name | Phone |
|---|---|---|
| Email Address | | |
| Institutional Affiliation and Department | Primary | Secondary |

| **3. Primary Contact** *(if different from PI)* – Name | Email Address |
|---|---|
| Phone | Role on the Research Team |

| **4. Study Team Members** – Name | Institution | Role |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

| **5. If this research is for a student research project, please provide the following information:** | |
|---|---|
| Name of Student | University and Degree Sought |
| Thesis Supervisor Name | Thesis Supervisor Email |

| **6. Researcher Qualifications** |
|---|
| |

| **7. TCPS2 Tutorial Completion:** Which members of the research team have completed the TCPS2 online tutorial? | PI: ☐ Yes ☐ No<br>Student: ☐ Yes ☐ No ☐ N/A ☐ (no students involved)<br>Others, please list: |
|---|---|

| **8. Describe any conflicts of interest and any potential benefits to investigators** |
|---|
| |

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## Project Details

| 9. **Estimated Project Time Period** – Start Date | End Date |
|---|---|
| | |

**10. Funding Type and Sources**

- ☐ For-profit / industry sponsor
- ☐ Unrestricted grant-in-aid
- ☐ Grant from non-profit
- ☐ Unfunded
- ☐ Government agency grant
- ☐ Interior Health (includes in-kind donations)
- ☐ Other _____

Identify specific funding agency / agencies

For industry-sponsored research, provide a sponsor contact

**11. Category of Research** Choose one category which is the best fit for this research project from the following list:

- ☐ **Health Services**: research with the goal of improving the efficiency and effectiveness of health professionals and the health care system, through changes to practice and policy.
- ☐ **Social, Cultural, Environmental and Population Health**: research with the goal of improving the health of the Canadian population or of defined sub-populations, through a better understanding of the ways social, cultural, environmental, occupational, and economic factors determine health status.
- ☐ **Clinical**: research with the goal of improving the diagnosis and/or treatment of disease and injury; and improving the health of individuals.
- ☐ **Biomedical**: research with the goal of understanding normal and abnormal human functioning at the molecular, cellular, organ system and/or whole body levels.

**12. Level of Risk** – Does this research meet the TCPS2 definition of minimal risk? ☐ Yes ☐ No

**13. Peer Review** – Describe the peer review this project has received. *Mandatory for all above-minimal risk projects.

**14. (a) Harmonized Ethical Review**
Does this project qualify for harmonized ethical review under the terms of the **BC Ethics Harmonization Initiative**? ☐ Yes ☐ No

**(b) Harmonized Ethical Review – student research**
Does this project qualify for harmonized ethical review under the terms of the Guidance Note for Students doing a Family Practice Residency, Pharmacy Residency, Dietetic Internship or Summer Medical Student Research Project? ☐ Yes ☐ No

**15. Additional REB Review** – Has this application been submitted to any other Research Ethics Board? ☐ Yes ☐ No
If yes, submit a copy of the Certificate of Ethical Approval with this application package.

**16. Location of Research** – (1) List all IH locations where the research will be conducted.

(2) List all non IH locations where the research will be conducted.

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**17. Purpose Statement** (max 50 words)

**18. Summary of Methodology:**
Summarize the research protocol: hypothesis, goals and objectives, justification, research design and statistical analysis plan.

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**19. Will existing records be accessed for research purposes?** – Does this project involve the use of existing charts, electronic medical records, clinical lists, employee lists, email distribution lists, or other existing records or databases? ☐ Yes ☐ No

If yes, describe in detail the data elements that will be accessed or requested as well as how permission to access records, collect, and use the information will be obtained.

**20. Does this study involve the creation of a registry (a Data Bank) or the collection or use of any biological specimens?** ☐ Yes ☐ No

If Yes, describe exactly what specimen(s) or data will be collected.

If Yes, is the purpose of this application exclusively to obtain approval for the creation of a research database, registry or tissue bank? ☐ Yes ☐ No

## Participant Information

**21. Inclusion Criteria**

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**22. Exclusion Criteria**

**23. Does this research involve the recruitment of Aboriginal, First Nations or Metis participants?** ☐ Yes ☐ No

If YES, researchers must comply with TCPS2 Chapter 9 and obtain both levels of consent (community consent and individual participant consent).

Has community consent obtained? ☐ Yes ☐ No

Will individual participant consent be obtained in addition to the community consent? ☐ Yes ☐ No

**24. (a) How many participants will be enrolled at IH sites?**

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

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

**26. Provide a detailed description of recruitment procedures**

**27. Describe any incentives for participation and / or reimbursement of expenses**

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**28. Are any participants considered to be in a vulnerable situation for participation in this research?** ☐ **Yes** ☐ **No**
If yes, please describe measures to reduce risk of vulnerability during recruitment, enrolment, and interventions.

**29. Does this project have the potential for identifying distressed individuals?** ☐ Yes ☐ No
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.**

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

**32. Who will consent?**

- ☐ Research Participant
- ☐ Parent / Guardian
- ☐ Legally authorized representative
- ☐ Requesting a Waiver of Consent → see question 33

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

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

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

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

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

## Data Security

**38. Who will have access to the data?**

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

- ☐ It will not be used in the analyses.
- ☐ It is logistically impossible to remove individual participant data.
- ☐ It will be used in the analyses if the participant agrees. If this box is checked, describe how agreement will be obtained.

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

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**41. Describe how results will be shared with participants.**

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

**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.

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## Submission Checklist

See Submission Requirements in the Guidance Note. Submit the completed application package to researchethics@interiorhealth.ca.

**Required**

- ☐ Protocol or Research proposal
- ☐ Signed Application for Ethical Review Form
- ☐ Operational Approval to Conduct Research form (the Operational Approval form is submitted to research@interiorhealth.ca)

**Additional Requirements for Clinical Trials**

- ☐ Budget pages of the Clinical Trial Agreement
- ☐ Health Canada No Objection Letter
- ☐ CV of PI
- ☐ Clinical Trial Agreement submitted to research@interiorheatlh.ca
- ☐ The project is registered at clinicaltrials.gov

**As Applicable:**

- ☐ Recruitment materials
- ☐ Consent and/or Assent Forms
- ☐ Research Agreement with Aboriginal, Metis or First Nation participants (*required if response to Q. 23 is yes)
- ☐ Standardized tests
- ☐ Certificate of Ethical Approval from primary institution
- ☐ DHHS Grant Application
- ☐ Other, please specify (e.g. Biobank registration completed with OBER):

## Signatures

**By signing below, you verify that:**

1. You have reviewed the contents of this application package and ensured it is complete and accurate.
2. This application package is methodologically sound and complies with research ethics standards.
3. The conduct of the proposed research will not commence until ethical approval has been granted.
4. The PI will apply for Renewal of ethical approval at least one month prior to the expiration date on the Certificate of Ethical Approval.
5. Each signing party agrees to abide by the Tri-Council Policy: Ethical Conduct for Research Involving Humans.
6. The Administrative / Department Head or the academic supervisor confirms that the Principal Investigator has the qualifications, experience and facilities to carry out this research project.

| **Title of Research Project** | | |
|---|---|---|
| **Principal Investigator** Signature | | **Date** (dd / mm / yyyy) |
| **Administrator / Department Head / Academic Supervisor** Signature | | **Date** (dd / mm / yyyy) |
| Printed Name | Title | Institution |