Application for Behavioural Research Ethics Review

*Evaluating Applications*

The matters of utmost concern to the Research Ethics Board (REB) are the issues of informed consent of participants, voluntary participation, protection of individual privacy (confidentiality and anonymity), and safeguarding participants from harm due to participation or non-participation in the proposed investigation or research project. Our evaluation of an application is based on the degree to which each of these concerns is satisfied. When filling out the application, researchers are urged to consider these points and to explain to the REB the steps they will take to address the concerns. Researchers are also urged to consult the [Tri-Council Policy Statement 2 (TCPS 2)](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html) for more information and guidance.

The REB acknowledges the variety of paradigms and methodologies currently available to researchers and that each of these paradigms entails particular ethical issues. Thus, there may be more than one way to address an ethical issue. Researchers should feel free to suggest alternative approaches or to explain why a particular requirement is not appropriate in the context of a given project.

\*\*All text boxes will expand once <Enter> is selected, or the cursor moves to the next section. \*\*

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| PART 1: Identification | | | | | | |
| 1.1 | Project Title  Protocol Number (if applicable): | | | | | |
| 1.2 | Principal Investigator  Full Name:  Mailing Address: | | | | | |
| Email: | | Phone: | | NSID number (U of S faculty only): | |
| University/Institutional Affiliation of Principal Investigator  Position:  Department:  Division:  Curriculum Vitae (CV) required. Included in this application:  **Yes  No** | | | | | |
| 1.3 | Project Personnel (including graduates/post graduates/residents) | | | | | |
| Full Name:  Project Position/Role:  University/Institutional Affiliation: | | | Full Name:  Project Position/Role:  University/Institutional Affiliation: | | |
| Email: | Phone: | | Email: | | Phone: |
| Full Name:  Project Position/Role:  University/Institutional Affiliation: | | | Full Name:  Project Position/Role:  University/Institutional Affiliation: | | |
| Email: | Phone: | | Email: | | Phone: |
| If this is a student/graduate/resident project, please provide the following information: | | | | | |
| a) Name and status: | | | b) Supervisor Name: | | |
| 1.4 | Primary Contact Person for Correspondence (if different than Section 1.2)  Full Name:  Mailing Address: | | | | | |
| Email: | | | Phone: | | |
| 1.5 | Research site(s) where the project will be carried out:  1.5.1 Country(ies): List all countries where you will be conducting your research under this Research Ethics Approval:  1.5.2 If this project will be conducted within schools or other organizations, specify how you will obtain permission to access the site. Submit a copy of the certificate or letter of approval when obtained**. Applicable:  Yes  No**  1.5.3 If this project is conducted across different Saskatchewan Health Authority sites, submit a letter of acknowledgement from the Directors of the respective areas. Applicable:  Yes  No  If you do not plan to seek site approval, provide a justification: | | | | | |
| 1.6 | Proposed Project Period:From (MM/DD/YY)       To (MM/DD/YY)  Specify any time considerations the REB should be aware of (e.g., short enrolment period; for student projects, please include proposed project timelines): | | | | | |
| 1.7 | Has an application for ethical approval been made for, or received from, any other REBs for this project?  Yes  No If yes, specify where: | | | | | |
| 1.8 | Provide the name of the funding source: | | | | | |
| Source of funds:   |  |  | | --- | --- | | Internally funded (list department)  Grant-in-aid  Not-for-profit foundation | Tri-Council Grant  Industry  National Institute of Health (NIH)  Cooperative Group (NCIC, COG, RTOG) | | | | | | |
| Status of Funds:  Awarded  Pending | | | | | |
| 1.9 | Name of Sponsor if different from above funding source: | | | | | |

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| PART 2: CONFLICT OF INTEREST | |
| 2.1 | Is there any real, potential or perceived conflict of interest (personal or financial) in the conduct or outcome of this project)? |
| 2.2 | Will any of the researcher(s), members of the research team and/or their immediate family members:   |  |  |  | | --- | --- | --- | | Yes | No | Receive personal benefits in connection with this project over and above the direct costs of conducting the project, such as remuneration or employment? | | Yes | No | Receive significant payments of other sorts from the sponsor, such as grants or compensation in the form of equipment, supplies, or retainers for ongoing consultation and honoraria? | | Yes | No | Have a non-financial relationship with a sponsor (such as an unpaid consultant, board membership, advisor or other non-financial interest?) | | Yes | No | Have any direct involvement with the sponsor, such as stock ownership, stock options or board membership? | | Yes | No | Hold patents, trademarks, copyrights, licensing agreements or intellectual property rights linked to this project or the sponsor? | | Yes | No | Have any other financial or non-financial relationship that, if not disclosed, could be construed as a conflict of interest? | | If yes was answered to any of the above mentioned items, please provide a brief explanation of how this conflict will be managed. | | | |

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| PART 3: BRIEF OVERVIEW OF RESEARCH PROJECT | |
| 3.1 | Briefly describe the project, its objectives and potential significance (250-500 words) (include references): |
| 3.2 | Provide a description of the research design and methods to be used: |
| 3.3 | Provide details regarding the duration and location of data collection event(s):   |  |  | | --- | --- | | Questionnaire (s)  Individual Interview (s)  Group Interview (s)  Video/audio recording (s)  Home Visit (s)  Other: | Participant Observation (s)  Focus Group (s)  Non-invasive physical measurement (s)  Ethnography  Secondary use of data or analysis of existing data | |

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| PART 4: PROJECT DETAILS | |
| 4.1 | **4.1.1 Will you have any internet-based interaction with participants, including emails?**  Yes  No  *If yes was answered, please complete the following:*  4.1.1.1 If you use a third-party research tool, website survey software, transaction log tools, screen capturing software, or masked survey sites, how will you ensure the security of data gathered at that site?  4.1.1.2 Describe how permission to use any third-party owned site(s) will be obtained, if applicable:  4.1.1.3 How will you protect the privacy and confidentiality of participants who may be identified by email addresses, IP addresses, and other identifying information that the system may capture during your interactions with these participants?  4.1.1.4 If you do not plan to identify yourself and your position as a researcher to the participants, from the onset of the research study, explain why you are not doing so and at what point you will disclose that you are a researcher. Provide details of debriefing procedures, if any, and if participants will be given **a way to opt out, if applicable.** |
| 4.2 | **4.2.1 Will your research involve Indigenous Peoples, including First Nations, Inuit or Métis peoples:**  The primary focus is on Indigenous peoples.  **Yes  No**  Indigenous persons comprise a sizeable proportion of the larger community that is the subject of the research.  **Yes  No**  Indigenous-specific conclusions will be made from this project.  **Yes  No**  *If yes was answered to any of the above mentioned items, please complete the following:*  4.2.1.1 Please outline the plans to obtain community engagement for this project. Describe the nature and extent of the community engagement as determined jointly by the researcher and the relevant community. If no community consent is being sought, please justify.  4.2.1.2 Describe any relevant customs and codes of research practice that apply to the particular community or communities affected by the research:  4.2.1.3 Will a research agreement between the research and community be prepared?  4.2.1.4 How will your research plan consider the mutual benefit to the participating community, support capacity building through enhancement of the skill of community personnel and the recognition of the role of elders and other knowledge holders?  4.2.1.5 Will community representatives have the opportunity to participate in the interpretation of the data and the review of research finding before the completion of any reports or publications?  4.2.1.6 How will the project's final results be shared with the participating community? |
| 4.3 | 4.3.1 Will the project involve community-based participatory research?  Yes  No  *If yes was answered, please complete the following:*  4.3.1.1 Please outline the plans to obtain community engagement for this project. Describe the nature and extent of the community engagement as determined jointly by the researcher and the relevant community. If no community consent is being sought, please justify.  4.3.1.2 Describe the organizational structure and community processes required to obtain approval within specific communities.  4.3.1.3 Will a research agreement between the researcher and community be prepared? The agreement should outline the project's goals, partnership principles, decision-making processes, partners' roles and responsibilities, and guidelines for how the partnership will handle and disseminate data.  4.3.1.4 Will community representatives have the opportunity to participate in the interpretation of the data and the review of research finding before the completion of any reports or publications? How will the project's final results be shared with the participating community? |
| 4.4 | Will deception of any kind be necessary for this project?  Yes  No  *If yes was answered, please explain and describe the protocol for debriefing and re-consenting of participants upon completion.* |
| 4.5 | **Indicate how the participants will be debriefed following their participation (if applicable), and describe how the information on the results of the research will be made available to participants once the study has ended. Debriefing is particularly important if deception has been used.** |
| 4.6 | **Will participants be compensated?  Yes  No**  ***If yes was answered, please include details:*** |
| 4.7 | **4.7.1 Will participants be anonymous in the data gathering phase of the study? (Anonymous means that no link can be established between the participant and the research - no one, including the researcher, knows who has participated in the research):  Yes  No**  **4.7.2 Will the confidentiality of participants and their data be protected? (Confidentiality means that no link can be established between the collected information and the participant's identity)**  Yes  No  **4.7.2.1. If yes, are there any limits to confidentiality:**  Limits due to the nature of group activities (e.g., focus groups): The researcher cannot guarantee confidentiality.  Limits due to context: Individual participants could be identified because of the nature or size of the sample or because of their relationship with the researcher.  Limits due to selection: Procedures for recruiting or selecting participants may compromise the confidentiality of participants (e.g. participants are referred to the study by a person outside the research team).  Other: |

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| PART 5: ESTIMATION OF RISK AND BENEFITS | |
| 5.1 | 5.1.1 Do you consider this project to be:  Minimal Risk  Above Minimal Risk  5.1.2 Indicate if the participants might experience any of the following and provide a brief description:  Risk of psychological or emotional harm or discomfort (e.g., trauma, anxiety, stress)  Legal repercussions for participating in the study (e.g., the possibility of being sued, charged with criminal activity, disclosure of past or future criminal activities, etc.)  Social repercussions (e.g., ostracized, being negatively judged by peers or employer, fired from your job)  Risk of physical harm or discomfort (e.g., falling, muscle pain, tiredness, weakness, nausea)  5.1.3 Describe how the risk will be managed (including explaining why an alternative approach could not be used). If appropriate, identify any resources, e.g., physician or counsellor, to which participants can be referred.  5.1.4 If above minimal risk, what are the likely benefits of the research to the researcher, participant, and the research community and society that would justify asking participants to participate? |

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| PART 6: PARTICIPANT RECRUITMENT | |
| 6.1 | 6.1.1 Indicate the number of expected participants and a brief rationale for the intended number of participants:  6.1.2 Describe the participant study population:  6.1.3 Describe participant inclusion criteria:  6.1.4 Describe participant exclusion criteria: |
| 6.2 | 6.2.1 Provide a detailed description of the method of recruitment.  6.2.2 How will prospective participants be identified?  6.2.3 Who will contact prospective participants?  6.2.4 Describe the source of the contact information, how they will be contacted and, as applicable, who originally collected the contact information.  *\*Ensure any initial contact letters or other recruitment materials are attached, e.g., advertisements, flyers, telephone scripts, etc.* |
| 6.3 | In cases where the research involves special or vulnerable populations, distinct cultural groups, or in cases where the research is above minimal risk, the researcher should describe their experience or training in working with the population. If none of these criteria apply, please indicate “not applicable”. |
| 6.4 | Where relevant, please explain any relationship (pre-existing, current or expected to have) between the researcher(s) and the researched (e.g., instructor-student, manager-employee, co-workers, family members/intimate relationships, etc.). Please pay special attention to relationships in which there may be a power differential. Describe any safeguards and procedures to prevent possible undue influence, coercion or inducement. |

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| PART 7: CONSENT PROCESS | |
| 7.1 | Describe the process that will be used to obtain informed consent. Please note that it is the content of the consent, not the format, that is important. If the research involves collecting personally identifiable information from a research participant or extracting personally identifiable information from an existing database, please describe how consent from the individuals or authorization from the data custodian will be obtained. If there will be no written consent, please provide a rationale for oral or implied consent (e.g., cultural appropriateness, online questionnaire, etc.) and explain how consent will be recorded.  7.1.1 Describe the consent process.  7.1.2 Who will ask for consent?  7.1.3 Where and under what circumstances will consent be obtained?  7.1.4 Describe any situation in which the renewal of consent for this research might be appropriate and how this would occur (e.g., longitudinal studies, multiple data collection events, etc.). |
| 7.2 | If any or all of the participants are children and/or are not competent to consent, describe the process by which capacity/competency will be assessed, and the proposed alternate source of consent - including any permission/information letter to be provided to the person(s) providing the alternate consent - as well as the assent process for participants. |
| 7.3 | Describe your plans for providing project results to the participant. |
| 7.4 | How and when are participants informed of the right to withdraw? What procedures will be followed for participants who wish to withdraw at any point during the study? |

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| PART 8: DATA SECURITY AND STORAGE | |
| 8.1 | **Indicate from which sources personal and health information data will be collected:**  Participant data collected prospectively for the purpose of this project (e.g., case report form)  Family physician or other private medical clinic office records  Saskatchewan Heath Authority, please specify Service Area, Site and Department if applicable:  SK Ministry of Health **(Please note that the Saskatchewan Heath Authority cannot provide approval to access Ministry of Health or eHealth data)**  SK Cancer Agency Registry  Other – please specify:  Not applicable (No personal or health information to be collected). Proceed to Section 8.3 |
| 8.2 | What is the total number of records/cases/charts required for your project? |
| 8.3 | Identify all research personnel responsible for data collection. |
| 8.4 | Who will have access to the original/raw data of the study? |
| 8.5 | **8.5.1 How will the confidentiality of the original data be maintained, and the preservation and destruction of data after the research is completed?**  **8.5.2 For all data (e.g. paper records, audio or visual recordings, electronic recordings), indicate:**  8.5.2.1 Whether the Principle Investigator will be responsible for data storage:  **Yes  No If not, specify the reasons and the person responsible for data storage:**  8.5.2.2 Data security during transportation from collection site:  8.5.2.3 Means and location of storage (e.g., a locked filing cabinet, password-protected computer files, encryptions):  8.5.2.4 Time duration of storage (Must be > 5 Years):  8.5.2.5 Final disposition of research materials (e.g., archive, shredding, electronic file deletion):  8.5.2.6 Dissemination of collected data (e.g., published, presented, reported):  8.5.2.7 Will data be transferred to a third-party:  Yes  No  If yes, the organization and how the data will be transferred (e.g., Canada Post-tracked, encrypted electronic data transfer, password-protected and encrypted portable drive, if other-please specify): |
| 8.6 | If patient health information will be accessed, please outline and specify how data will be de-identified.  *\*Please submit data collection tool and master list with unique study codes.* |

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| PART 9: Declaration by Principal Investigator  *(or Supervisor for student projects)* |
| Project Title |
| * I confirm that the information provided in this application is complete and correct. * I accept responsibility for the ethical conduct of this project and for protecting the rights and welfare of the human participants who are directly or indirectly involved in this project. * I will comply with all policies and guidelines of the University and Saskatchewan Health Authority/affiliated institutions where this project will be conducted, as well as with all applicable federal and provincial laws regarding the protection of human participants in research. * I will ensure that project personnel are qualified and appropriately trained and will adhere to the provisions of the REB-approved application. * I certify that any significant changes to the project, including the proposed method, consent process or recruitment procedures, will be reported to the Research Ethics Board for consideration in advance of its implementation. * I certify that a status report will be submitted to the Research Ethics Board for consideration within one month of the current expiry date each year the project remains open and upon project completion. * If personal health information is requested, I assure that it is the minimum necessary to meet the research objective and will not be reused or disclosed to any parties other than those described in the REB-approved application, except as required by law. * I confirm that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place *before* implementing the research project and that the research will *stop* if adequate resources become unavailable. * I understand that if the University or Saskatchewan Health Authority is reviewing the contract or grant related to this research project, a copy of the ethics application, inclusive of the consent document(s), may be forwarded to the person responsible for the review of the contract or grant. * I understand that if the project involves Saskatchewan Health Authority resources or facilities, a copy of the ethics application may be forwarded to the Saskatchewan Health Authority research coordinator to facilitate operational approval.   \_     \_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Principal Investigator Printed Name of Principal Investigator Date (MM/DD/YY)  **Department Head:** The signature/approval of the Department/Administrative Unit acknowledges that he/she is aware of and supports the research activity described in the proposal.  \_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Department Head Printed Name of Department Head Date (MM/DD/YY) |

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| PART 10: APPENDICES  Please note that all applications for projects accessing or using Saskatchewan Health Authority resources, (personnel, facilities, equipment for tests/ procedures/tasks, or specific tests or procedures and includes outpatient and inpatient participants) will require a completed Operational Approval form and letter of authorization. The form is available online at: <https://www.saskhealthauthority.ca/our-organization/our-direction/research/getting-started/operational-approval>. Please note that an REB file number will be necessary to fill out the Operational Approval form even for studies exempt from research ethics review. Once you submit to the REB and a file number is issued, submit an application form for operational approval. | | |
| Document | Included? | Document name if applicable/Comments |
| Recruit Material(s) | Yes  N/A |  |
| Letter(s) of Initial Contact | Yes  N/A |  |
| Consent Form(s) | Yes  N/A |  |
| Assent Form(s) | Yes  N/A |  |
| Research Tool(s) (e.g., Master list, questionnaires, focus group guides, interview scripts, etc.) | Yes  N/A |  |
| Transcript Release Form(s) | Yes  N/A |  |
| Training documents | Yes  N/A | TCPS2 tutorial (list names)  Other (list names) |
| Curriculum vitae of principle investigator: | Yes  N/A |  |
| Other (please specify): | Yes  N/A |  |