Application for Biomedical Research Ethics Review

|  |  |  |
| --- | --- | --- |
| PART 1: Identification | | |
| 1.1 | Project Title | |
| 1.2 | Principal Investigator  Full Name:  Email: | |
| 1.3 | Affiliation of Principal Investigator  Full Name:  Position:  University/Institutional Affiliation: | |
| If this is a student/graduate/resident project, please provide the following information: | |
| a) Student Name: | b) Supervisor Name: |
| 1.4 | Research Site(s) where project will be carried out: | |
| 1.5 | Proposed Project Period:From Click or tap to enter a date. To Click or tap to enter a date. | |
| 1.6 | Do you consider this project to involve:  Minimal Risk  More than Minimal Risk | |
| 1.7 | Name of funding source: | |

|  |  |
| --- | --- |
| PART 2: REGULATORY REQUIREMENTS | |
| 2.1 | The project involves intervention study (Clinical trials):  YES  NO  If the answer is YES, proceed to 2.2; otherwise go to part 3 |
| 2.2 | Clinical trials are required to be registered with <https://www.who.int/clinical-trials-registry-platform> (or with official platform where the research is conducted). Please submit confirmation of registration when available. |

|  |  |
| --- | --- |
| PART 3: BRIEF OVERVIEW OF RESEARCH PROJECT (two page maximum) | |
| 3.1 | Research Question/Hypothesis  Specify the research question(s) being evaluated in the project. |
| 3.2 | Research Design/Methods  Provide a description of research design (e.g. parallel group or cross-over design) and methods to be used. Include a justification for the use of a placebo, if applicable. Please note that if the analysis or the interpretation of the research results refers to Aboriginal people, language, culture or history as a primary focus of the project, consultation with the appropriate community is required. Please outline the process to be followed. |
| 3.3 | Potential Significance/Justification  What are the anticipated public and scientific benefits of the project?. |

|  |  |
| --- | --- |
| PART 4: PARTICIPANT RECRUITMENT | |
| 4.1 | How many participants will be enrolled in the project:Globally?       Locally? |
| 4.2 | Describe the target population and the criteria for their inclusion. |
| 4.3 | Describe who will be excluded from participation. |
| 4.4 | Provide a detailed description of the method of recruitment.   1. How will prospective participants be identified? 2. Who will contact prospective participants? 3. How will this be done? (Ensure that any letters of initial contact or other recruitment materials are attached to this submission (e.g. advertisements, flyers, verbal or telephone script, etc.). |

|  |  |
| --- | --- |
| PART 5: CONSENT PROCESS | |
| 5.1 | Describe the consent process.   1. Who will ask for consent? 2. Where, and under what circumstances? |
| 5.2 | How long will the participant have to decide whether or not to participate? If less than twenty-four hours, provide an explanation. |
| 5.3 | Will all participants be able to consent on their own behalf?  YES  NO  If No, explain why:   1. If a participant is unable to consent, who will consent on his/her behalf? 2. Will the participant be able to assent to participate?   YES  NO  If yes, explain how assent will be sought: |
| 5.4 | **If monetary compensation or reimbursements for expenses will be offered to the participants please provide the details.** |
| 5.5 | **Describe your plans for providing project results to the participant?** |

|  |  |
| --- | --- |
| PART 6: PROCEDURES AND RISKS | |
| 6.1 | Identify those procedures that are different from the current standard of care (i.e. unique to the research project). |
| 6.2 | What are the known risks associated with the project procedures? |
| 6.3 | What strategies will be put in place to minimize and/or manage the potential risk(s) to participants and other affected individuals? |

|  |  |
| --- | --- |
| PART 7: DATA SECURITY AND STORAGE | |
| The *Saskatchewan Health Information Protection Act (HIPA)* requires an assessment of the risks to privacy and how the risks will be minimized. Accessing existing patient information, such as Health Records, requires consent of the individual which must be addressed in the consent form. | |
| 7.1 | **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)  Ministry of Health  Other – please specify:  Not applicable (No personal or health information to be collected). Proceed to Section 8. |
| 7.2 | **How will the confidentiality of participants and their health information be protected?** |
| 7.3 | **Describe the storage arrangements and final disposition of the project data collected.** |
| 7.4 | **List the project personnel who have access to any identifiable personal health information and who will have access to any list that links participant names to their project ID number, consent form, enrolment log, etc.** |

|  |  |
| --- | --- |
| PART 8: CONFLICT OF INTEREST | |
| 8.0 | Is there any real or perceived conflict of interest (any personal or financial interest in the conduct or outcome of this project)? Will any of the researcher(s), members of the research team and/or their immediate family members:  YES  NO  If yes, please describe the personal benefits or relationship. |

|  |
| --- |
| 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 the protection of the rights and welfare of the human participants who are directly or indirectly involved in this project. * I will ensure that project personnel are qualified, appropriately trained and will adhere to the provisions of the REB-approved application. * I will ensure that any significant changes to the project, including the proposed method, consent process or recruitment procedures, will be reported to the College of Science Research Ethics Committee for consideration in advance of its implementation. * 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.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Principal Investigator Printed Name of Principal Investigator Date Click or tap to enter a date.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Student Investigator Printed Name of Student Investigator Date Click or tap to enter a date. |