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File Number: Date received:

 

Application for Biomedical Research Ethics Review

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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):       |
| 1.3 | University/Institutional Affiliation of Principal Investigator Position:      Department:      Division:       |
| 1.4 | 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) Student Name:       | b) Supervisor Name:       |
| 1.5 | Primary Contact Person for Correspondence (if different than Section 1.2)Full Name:      Mailing Address:      Email:      Phone:       |
| 1.6 | Research Site(s) where project will be carried out:      |
| 1.7 | 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):       |
| 1.8 | Has this project applied for/received ethical approval from any other Saskatchewan REB? [ ]  Yes [ ]  NoIf yes, specify where:       |
| Has this project applied for/received ethical approval from another Research Ethics Board outside of Saskatchewan? [ ]  Yes [ ]  NoIf yes, specify where (if known):       |
| 1.9 | Do you consider this project to involve: [ ]  Minimal Risk [ ]  More than Minimal Risk |
| 1.10 | Provide name of funding source:       |
| Source of Funds: [ ]  Industry [ ]  National Institute of Health (NIH)  [ ]  Not-for-Profit Foundation [ ]  Cooperative Group (NCIC, COG, RTOG)  [ ]  Tri-Council Grant [ ]  Internally funded [ ]  Grant-in-aid |
| Status of Funds: [ ]  Awarded [ ]  Pending |
| 1.11 | Name of Sponsor if different from above funding source:       |

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| PART 2: REGULATORY REQUIREMENTS |
| 2.1 | If the project involves an investigational drug, natural product, medical device or marketed drug/device being used outside of the approved indication, check whether or not the No Objection Letter (NOL) or the Investigational Testing Authorization (for devices) has been obtained from the appropriate Health Canada regulatory agency. [GN 2.1](#G2_1)[ ]  N/A – Proceed to Question 2.2

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|  | Yes | Pending | N/A |
| Therapeutic Products Directorate (TPD) | [ ]  | **[ ]**  | **[ ]**  |
| Natural Health Products Directorate (NHPD) | **[ ]**  | **[ ]**  | **[ ]**  |
| Biologics and Genetics Therapies Directorate (BGTD) | **[ ]**  | **[ ]**  | **[ ]**  |
| Investigational Testing Authorization (ITA) | **[ ]**  | **[ ]**  | **[ ]**  |

Date of approval (MM/DD/YY):      Please forward the NOL and/or ITA to the Research Ethics Office when available. |
| 2.2 | Is there a requirement for this research to comply with United States (OHRP/FDA) regulations for research ethics? [ ]  Yes [ ]  No |
| 2.3 | Clinical trials are required to be registered with clinicaltrials.gov. Please submit confirmation of registration when available.  |
| 2.4 | Peer Review For research with *more than minimal risk*, the REB must be satisfied about both the value and the scientific validity of the project. Under some circumstances and depending on the level of risk, the REB may request that a peer review be conducted as a condition of approval. Research that poses minimal risk will not usually require peer review. Has this research proposal received any independent scientific review? [ ]  Yes (please attach) [ ]  No [ ]  Not applicable |
| 2.5 | According to Good Clinical Practices Section 3.1.2, the Principal Investigator should submit a current curriculum vitae (CV) providing evidence of qualifications to conduct the project. If a CV has not been submitted within last 5 years, please attach. Is the PI’s CV attached? [ ]  Yes [ ]  Not applicable |

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| PART 3: BRIEF OVERVIEW OF RESEARCH PROJECT (two page maximum) |
| 3.1 | Research Question/HypothesisSpecify the research question(s) being evaluated in the project.      |
| 3.2 | Academic Validity Provide evidence (scientific literature, pilot projects, etc.) that the scientific reasoning and design of the project are sufficiently sound to meet the objectives of this project.      |
| 3.3 | Research Design/MethodsProvide 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.      |
| 3.4 | Statistical AnalysisInclude a summary of the primary and secondary end-points/outcomes, the planned sample size (with justification) and planned statistical and interim analyses.      |
| 3.5 | Potential Significance/JustificationExplain the significance of the project in order to support the ethical tenet that the proposed research has value (i.e., what are the anticipated public and scientific benefits of the project?).      |

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| PART 4: PARTICIPANT RECRUITMENT |
| 4.1 | How many participants will be enrolled in the project:Globally?       Locally?       |
| 4.2 | Describe who will be selected (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.).
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| PART 5: CONSENT PROCESS |
| 5.1 | Describe the consent process. 1. Who will ask for consent?
2. Where, and under what circumstances?
3. Describe any situation in which the renewal of consent for this research might be appropriate and how this would take place (e.g. Participant turns 18 or emergency situation).
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| 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 [ ]  NoIf 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 [ ]  NoIf 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?**       |

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| 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 procedures outlined in Section 6.1? Also include any risks associated with the placebo or wash out periods, if applicable.       |
| 6.3 | What strategies will be put in place to minimize and/or manage the potential risk(s) to participants and other affected individuals?       |
| 6.4 | For double blind projects, describe the provisions made to break the code in an emergency situation [24 hour availability], and indicate who has the code. If it is clearly articulated in the clinical protocol, it is acceptable to append the information or provide the protocol page reference.       [ ]  N/A, not a double blind project |

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| 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)[ ]  Family physician record[ ]  Heath Region – please specify Region, Site & Dept. if applicable:       [ ]  SK Ministry of Health[ ]  SK Cancer Agency[ ]  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.**       |
| 7.5 | **Check all applicable boxes below to provide an assessment of the potential privacy risks and the safeguards/solutions that you will put in place to mitigate the risks**. |
|  | **Potential Privacy Risks** | **Possible Safeguards/Solutions** (check all that you will use) |
|  | [ ]  Unauthorized external or internal access to identifying information through active use or transmission  | [ ]  Project personnel screening/agreements [ ]  Access authorization procedures [ ]  Designated systems administrator [ ]  Passwords/screen timeouts [ ]  System access audits/disclosure logs [ ]  Secure mail/transport [ ]  Firewall/virus protect [ ]  Encrypted transmission |
|  | [ ]  Identification through publication or release | [ ]  Aggregation levels [ ]  Alternate identifiers  |
|  | [ ]  Identification through data-matching | [ ]  Use of non-linkable elements or identifiers |
|  | [ ]  Loss of data control outside jurisdiction | [ ]  Confidentiality and security agreements for out-of- province recipients or storage providers |

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| 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:* 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, compensation in the form of equipment or supplies or retainers for ongoing consultation and honoraria?

[ ]  Yes [ ]  No* Have a non-financial relationship with a sponsor (such as 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 in any way to this project or the sponsor?

[ ]  Yes [ ]  No* Have any other relationship, financial or non-financial, that if not disclosed, could be construed as a conflict of interest?

[ ]  Yes [ ]  NoIf yes, please describe the personal benefits or relationship.        |

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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 the protection of 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 Health Region/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, 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 Research Ethics Board for consideration in advance of its implementation.
* I will ensure 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 contract or grant related to this research project is being reviewed by the University or Health Region, 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 Health Region resources or facilities, a copy of the ethics application may be forwarded to the Health Region research coordinator to facilitate operational approval.

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