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| **Biomedical Application**  **Prospective** | **For Internal Use Only** |
| **UnivRS Internal ID:**  **Date Received:** Click here to enter a date. |

**Questions marked with an** \* **are mandatory.**

**Part 1: Key Information**

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| Protocol Number:  Project Title: \*  Level of Risk: \* Choose an item.  Expected Start Date: \* Click here to enter a date.  Expected End Date: \* Click here to enter a date.  Explain why this application is time sensitive or specify not applicable (N/A): |

**Applicants**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Principal Investigator**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |   **Sub-Investigator(s)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |   **Student(s)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |   **Primary Contact**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |   **Secondary Contact**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  | |

**Sponsor** *A sponsor takes responsibility for the initiation and management of research and compliance with applicable regulations. The sponsor may or may not be the main funding organisation****.***

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| |  | | --- | | **Sponsor:** | |  | |

**Agency(ies)** *An agency(ies) provides funding to support research projects. The sponsor may or may not be the main funding organisation****.***

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| |  |  | | --- | --- | | This project is funded: \* | Yes  No | | If yes, the funding supporting this project will be administrated at the University of Saskatchewan: | Yes, complete Part A  No, complete Part B |   **Part A: For Grants and Contracts administered by the U of S:**   |  |  | | --- | --- | | **Agency:** | **Pending / Awarded** | |  |  |   Project Application(s) Directly Associated with the Fund(s) Supporting this Project.  Please list the UnivRS internal ID# (for pending grants or contracts):  Project(s) Directly Associated with the Fund(s) Supporting this Project  Please list the UnivRS internal ID# (for awarded grants or contracts):  **Part B: For Grants or Contracts not administered by the U of S:**   |  |  | | --- | --- | | **Agency:** | **Pending / Awarded** | |  |  |   **Pre- and Post-Award Records Directly Linked to this Application**  Project application(s) UnivRS internal ID#:  Project(s) UnivRS internal ID #: |

**Compliance Records Directly Linked to this Application**

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| Compliance Application(s) UnivRS internal ID#:  Describe the relationship between this compliance application and the linked record(s): |

**Location(s) Where Research Activities Are Conducted**

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| Enter location(s) where this research will be carried out: \*  Specify country(ies) where the research will be conducted under this Research Ethics Approval: \* |

**Other Ethics Approval**

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| |  |  | | --- | --- | | Has this project applied for/received approval from any other Research Ethics Board(s) \* | Yes  No |   If 'yes', identify the other Research Ethics Board(s).  For multi-site clinical trials, identify the Canadian sites only or specify ‘unknown’: |

**Conflict of Interest**

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| Confirm whether any member of the research team or their immediate family members will:   |  |  | | --- | --- | | Receive personal benefits over and above the direct costs of conducting the project, such as remuneration or employment: \* | Yes  No | | Receive significant payments from the Sponsor such as compensation in the form of equipment, supplies or retainers for ongoing consultation and honorarium: \* | Yes  No | | Have a non-financial relationship with the 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  No |   If yes was answered to any question(s), explain the personal benefit(s) and how the conflict will be managed: |

**Part 2: Project Overview**

**Brief Overview of Research Project**

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| State the hypothesis or research question(s): \*  Summarize in lay terms: a) the background and study rationale; b) the research design; c) methodology; and d) statistical analysis: \*  Summarize the anticipated public and scientific benefits of the project: |

**Optional Sub-Studies**

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| Are there any optional sub-studies specified in the protocol?  Yes  No  If yes, describe the purpose and details of each sub-study: |

**No Objection Letter and/or an Investigational Testing Authorization**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identify whether a No Objection Letter and/or an Investigational Testing Authorization has been received for this project.**   |  |  | | --- | --- | | Biologics and Genetics Therapies Directorate (BGTD): | Yes  Pending  Not Applicable | | Investigational Testing Authorization (ITA): | Yes  Pending  Not Applicable | | Natural Health Products Directorate (NHPD): | Yes  Pending  Not Applicable | | Therapeutic Products Directorate (TPD): | Yes  Pending  Not Applicable | |

**Other Regulatory Requirements**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Is there a requirement for this project to comply with the United States Office for Human Research Protections regulations (OHRP): | Yes  No | | Is there a requirement for this project to comply with the United States Food and Drug Administration regulations (FDA): | Yes  No | | Is this project being conducted under an Investigational New Drug (IND) application or Investigational Device Exemption (IDE): | Yes  No | | Does this project meet the definition of a clinical trial requiring registration? \* | Yes  No | | If yes, provide the registration number: |  | | If this project has a Data Safety Monitoring Board, other monitoring systems and/or planned interim analysis, describe, including reporting schedules: | | |

**Procedures and Risks**

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| Identify research-specific procedures that are different from the current standard of care:  Identify any risks associated with research-specific procedures:  Specify any mitigation strategies to minimize and/or manage risk(s):  If applicable, justify the use of a placebo and/or washout:  For double blind projects, identify provisions made to break the code in an emergency situation and indicate who holds the code: |

**Peer Review**

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| --- | --- | --- |
| The extent of peer review that is required will vary depending on the type of research being carried out. Typically minimal risk research will not require peer review.   |  |  | | --- | --- | | This project has received peer review: | Yes  No |   If no, provide details:  If yes, submit the peer review along with the application. |

**Part 3: Community Engagement**

**Community Engagement**

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| Is this research likely to affect the welfare of an Indigenous community, or communities, to which prospective participants belong?  Yes  No  If yes, researchers shall seek engagement with the relevant community as follows:  Outline the process to be followed for consulting with the appropriate community:  Describe how the community representatives will have the opportunity to participate in the interpretation of the data and the review of research findings before the completion of any reports or publications:  Describe how the final project results will be shared with the participating community(ies): |

**Part 4: Recruitment**

**Participant Recruitment**

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| Provide a detailed description of the method of recruitment. How/who will identify and contact prospective participants: \*  Identify the anticipated number of participants to be enrolled at global site(s): \*  Identify the anticipated number of participants to be enrolled at local site(s): \*  List the criteria for including participants: \*  List the criteria for excluding potential participants: \* |

**Part 5: Consent**

**Consent Process**

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| Specify who will explain the consent form and consent participants:  Explain where and under what circumstances consent will be obtained from participants:  If a participant is unable to consent, explain the reason(s), describe the process by which their capacity will be assessed, identify who will consent on his/her behalf and describe the assent process:  Describe any situation where the renewal of consent might be appropriate and how this would take place:  How long will a participant have to decide whether or not to participate? If less than twenty-four hours, provide an explanation:  Provide details on how participants can access, amend or withdraw their data and/or biological materials:  Provide the details of any compensation or reimbursements offered to the participants:  Specify how and when participants will be able to obtain project results and whether the results will be individual and / or aggregate: \* |

**Part 6: Alteration and Exception to Consent**

**Waiver of Consent**

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| |  |  | | --- | --- | | A waiver of participant consent is being requested: | Yes  No |   **If 'yes', justify the waiver by responding to the criteria below:**  Access to identifiable information is essential to the research:  The use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates:  The project team will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information:  The project team will comply with any known preferences previously expressed by individuals about any use of their information:  It is impossible or impracticable to seek consent from individuals to whom the information relates:  The researchers have obtained any other necessary permission for secondary use of information for research purposes: |

**Exception to Consent**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | An exception to the requirement to seek participant consent is being requested: | Yes  No |   **If 'yes', justify the exception by responding to the criteria below:**   |  |  | | --- | --- | | A serious threat to the prospective participant requires immediate intervention: | Yes  No | | Either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care: | Yes  No | | Either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant: | Yes  No | | The prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project: | Yes  No | | Third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so: | Yes  No | | No relevant prior directive by the participant is known to exist: | Yes  No | |

**Part 7: Banking of Biological Materials**

**Banking of Biological Materials**

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| --- | --- | --- |
| |  |  | | --- | --- | | This project involves future undefined use of biological materials: | Yes  No |   **If 'yes', complete the following:**  Describe the type, quantity of biological materials:  Describe how the biological materials will be collected, including the safety and invasiveness:  Describe the intended uses of the biological materials, including any commercial uses, and disclaimers:  Describe the measures employed to protect the privacy of and minimize risks to participants:  Specify the length of time the biological materials will be kept, how they will be preserved, location of storage (e.g. in Canada, outside Canada), and process for disposal:  Describe any anticipated linkage of biological materials with information about the participant:  Describe any plans for handling results and findings, including clinically relevant information and incidental findings:  If biological materials are culturally sensitive, describe what if any permissions are necessary:  If applicable, describe how the banked biological materials will be released to individuals external to the project:  If applicable, specify who has the custodianship of the biobank: |

**Part 8: Data Access, Security and Storage**

**Sources of Personal Health Information**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Participant data collected prospectively: | Yes  No | | Saskatchewan Health Authority: | Yes  No | | Physician or other private health care professional office records: | Yes  No |   Specify the Saskatchewan Health Authority facility(ies) and location(s):  Specify other source(s) of personal health information: |

**Data Access**

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| List the research personnel responsible for abstracting project data and where the data abstraction will occur:  List the research personnel with access to identifiable project data:  List the research personnel responsible for safeguarding the link to the source data: |

**Security and Storage**

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| --- | --- | --- |
| Describe the data storage arrangements, while the project is ongoing: \*  Specify how long data will be retained: Choose an item.  If other, specify duration and provide justification:   |  |  | | --- | --- | | The Principal Investigator will be responsible for the storage of data and/or biological materials: | Yes  No |   If no, specify the reason and indicate who will be responsible: |

**Biological Materials and Data Transfer**

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| --- | --- | --- |
| |  |  | | --- | --- | | Will data or biological materials be transferred outside the institution where they were collected: \* | Yes  No |   **If 'yes', complete the following:**  Organizations where data or biological materials will be transferred:  Indicate how data or biological materials will be transferred: Choose an item.  If 'Other' was selected, specify the method of transfer: |

**Mitigation Safeguards to Privacy Risks**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | | Identify the safeguards/solutions to mitigate the risk to privacy. | | Possible Safeguards/Solutions (check all that apply) | | 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  Data collection tool and Master list stored in separate locations | | Aggregation levels  Alternate identifiers | | Use of non-linkable elements or identifiers | | Confidentiality and security agreements for out-of-province recipients or storage providers |   If applicable, describe any other mitigating strategies: |

**Part 9: Declaration of Principal Investigator:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| By submitting this application form, the Principal Investigator (PI) attests to the following:   * the PI accepts 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. * the PI will comply with all policies and guidelines of the University and 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. * the PI will ensure that project personnel are qualified, appropriately trained and will adhere to the provisions of the Research Ethics Board-approved application. * 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. * any 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 implementation. * 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, the PI assures 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 Research Ethics Board-approved application, except as required by law. * if a contract or grant related to this project is being reviewed by the University or Health Region, the PI understands a copy of the application, may be forwarded to the person responsible for the review of the contract or grant.  |  |  | | --- | --- | | Date the form was completed: Click here to enter a date. | | | Name of Person who completed the form: |  |   If form submitted on behalf of the PI:   |  |  | | --- | --- | | is authorized to prepare and submit this form on behalf of the Principal Investigator | | | Authorized person contact information: | | | Email: | Phone: | |

**Document(s)**

Provide a list of Documents that are being submitted along with this application: