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| **Biomedical Application**  **Creation of Biobank and Data Registry** | **For Internal Use Only** |
| **UnivRS Internal ID:**  **Date Received:** Click here to enter a date. |

**Part 1: Key Information**

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| Protocol Number:  Project Title: \*  Indicate the nature of the project: \*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, 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** | |  |  | |

**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 Boards \* | Yes  No |   If 'yes', identify the other Research Ethics Board(s) 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: Description of Biobank/Registry**

**Description of Biobank/Registry**

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| Explain the scope and purpose of the biobank/registry: \*  Outline the anticipated public and scientific benefits of the biobank/registry: \*  Over what period of time will data or biological materials be collected: \*  Specify the custodian of the biobank/registry: \*  Specify the institution and address of the biobank/registry: \*  Provide a full description of the standard operating procedures for the biobank/registry: \* |

**Other Regulatory Requirements**

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| --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | There is a requirement for this project to comply with the United States Office for Human Research Protections regulations (OHRP): | Yes  No | | There is a requirement for this project to comply with the United States Food and Drug Administration regulations (FDA): | Yes  No | |

**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 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 local site(s): \*  Identify the anticipated number of participants to be enrolled at global 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**

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| |  |  | | --- | --- | | 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: Data / Biological Materials Access, Security and Storage**

**Sources of Personal Health Information**

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| --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | 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:  Specify any other source(s) of personal health information: |

**Source of Biological Materials**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Collected expressly for a specific research purpose: | Yes  No | | Collected incidentally to medical or diagnostic procedures: | Yes  No | | Collected for research or diagnostic purposes uses with some  expectation that they may, or will, also be used for future undefined research: | Yes  No |   Indicate what personal information will be linked to biological materials and include a justification for its inclusion in the biobank: |

**Physical / Non-physical Risks**

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| Specify any physical risks associated with the collection of biological materials: \*  Specify any non-physical risks associated with the disclosure of genetic information: \*  Specify any mitigation strategies to minimize and/or manage the identified risk(s): |

**Biological Materials and Data Linking**

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| |  |  | | --- | --- | | Do you plan to link the locally collected data or biological materials with any other data source(s): \* | Yes  No |   If yes, specify the data source(s) and variables:  If applicable, identify what personal information will be used to link the data sources and how the confidentiality of this shared information will be protected: |

**Biological Materials and Data Retention**

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| How long will banked biological materials be stored:  If applicable, indicate the planned method for the final disposition of the biological materials:  Describe the storage arrangements of the data, including retention period and final disposition:\*  Describe any commercial uses for which the data or biological materials may be used, including any disclaimers concerning participant remuneration for such use: |

**Mitigation Safeguards to Privacy Risks**

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| --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | | 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 5: Declaration of Principal Investigator:**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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: