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| **Biomedical Application**  **Secondary Use of Biological Materials** | **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 (if applicable):  Title: \*  Expected Start Date: \* Click here to enter a date.  Expected End Date: \* Click here to enter a date.  If applicable, explain why this application is time sensitive: |

**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.*

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| |  |  | | --- | --- | | This project is funded: \* | Yes  No | | 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 Project**  Project application(s) UnivRS internal ID#:  Project(s) UnivRS internal ID #: |

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

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| Enter location(s) where this research will be carried out: \* |

**Other Ethics Approval**

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| |  |  | | --- | --- | | Has this project applied for/received approval from any another Research Ethics Board(s) \* | Yes  No |   If 'yes', identify the other Research Ethics Board(s) or specify ‘unknown’: |

**Conflict of Interest**

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| Describe any potential conflict of interest (e.g. research team, study sponsors) and how the conflict will be managed or specify Not Applicable (N/A):\* |

**Part 2: Project Overview**

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| State the hypothesis or research question(s): \*  Summarize in lay terms: a) the research design; b) methodology; and c) statistical analysis: \*  Summarize the anticipated public and scientific benefits of the project: \*  Specify the approximate number of samples required to answer the research question(s):  Describe the inclusion criteria for the samples being requested: |

**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: Consent/ Request for Waiver of Consent**

**Consent**

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| |  |  | | --- | --- | | Will participant consent be obtained prior to accessing the biological material(s)? | Yes  No |   If 'yes', complete the following:  Who will explain the consent form and consent participants?  Where and under what circumstances will consent be obtained?  If a participant is unable to consent, explain the reason(s), describe the process by which his/her capacity will be assessed, identify who will consent on his/her behalf and describe the assent process: |

**Request to Conduct Research without Consent**

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| **The REB may approve research without requiring consent from individuals to whom the information relates only if the research complies with TCPS2 article 5.5A:**   1. Access to/use of identifiable information is essential to the research; 2. The use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates; 3. The project team will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information; 4. The project team will comply with any known preferences previously expressed by individuals about any use of their information; 5. It is impossible or impracticable to seek consent from individuals to whom the information relates.   Explain why:   * Waiver of consent is unlikely to adversely affect the welfare of individuals to whom the biological material(s) relate: \* * Obtaining consent from individuals to whom the biological materials(s) relate is impractical, impossible and/or would adversely affect the research: \* |

**Part 5: Source(s) OF EXISTING Biological Materials /DATA LINKAGE**

**Biological Materials**

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| Describe and justify the type and number of biological materials:  Indicate the source(s) of biological materials:  Indicate how the biological materials will be obtained:  If authorizations are necessary to obtain the biological materials, describe:  Indicate how the biological materials will be protected to maintain confidentiality: Choose an item. |

**Biological Materials Linking**

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| |  |  | | --- | --- | | Do you plan to link health data to the biological materials? | Yes  No |   If Yes:  Specify the data source(s):  List the variables:  Describe how the data will be linked to biological materials:  Describe how will shared information be safeguarded: |

**Part 6: Security and Storage**

**Biological Materials and Health Data Retention**

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| How long will the biological materials be retained: \*  How long will the linked data be retained: Choose an item.  If 'other' was selected, specify the duration:  Identify the location of storage of the biological materials: \*  If applicable, indicate the planned method for the final disposition of the biological materials:  Confirm that the Lead Principal Investigator will be responsible for the storage of data and biological materials. If not, specify why not, and indicate who will be responsible for data / biological materials storage: \* |

**Biological Materials and Data Transfer**

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| |  |  | | --- | --- | | Will biological materials and individual level data be transferred outside the institution where they were collected? \* | Yes  No |   If yes, specify where the data and biological materials will be transferred:  Indicate how the data and biological materials will be transferred: |

**Mitigation Safeguards to Privacy Risks**

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| Identify the safeguards/solutions to mitigate the risk to privacy.   |  | | --- | | 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 7: 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.  |  |  | | --- | --- | | 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)**

Please provide a list of Documents that are being submitted along with this application, as applicable: