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| **Biomedical Application**  **Secondary Use of Health Data** | **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 other 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 records required to answer the research question(s):  Describe the inclusion criteria for the records 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 reviewing the record(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 information relates: \* * Obtaining consent from individuals to whom the information relates is impractical, impossible and/or would adversely affect the research: \* |

**Part 5: Source(s) OF EXISTING HEALTH Data**

**Source(s)/Type of Personal Health Information**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Saskatchewan Health Authority: | Yes  No | | Physician or other private health care professional office records: | Yes  No | | Saskatchewan Cancer Registry: | Yes  No | | Saskatchewan Cancer Agency: | Yes  No | | eHealth Saskatchewan: | Yes  No | | Ministry of Health: | Yes  No | | Health Quality Council: | Yes  No |   Specify any other data source(s) that will be accessed:  Specify the facility(ies) and location including country:  **The organization, custodian or trustee of the data must be aware of this access and use and, in some cases, must provide operational approval for the access/use.**   |  |  | | --- | --- | | Has access/use for research purposes been granted? \* | Yes  No Pending REB Approval | |  |  | |

**Part 6: Data collection, use and disclosure**

**Data Security and Storage**

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| Identify the research personnel responsible for abstracting data and where the data abstraction will occur: \*  Describe how the data will be stored (i.e. computerized files, hard copy, personal digital device, other): \*  How long will data be retained? \* Choose an item.  If 'other' was selected, specify the duration:  Describe the safeguards in place to protect the confidentiality and security of the data. If a coding procedure is being used, describe in detail: \*  Identify the research personnel responsible for safeguarding the link to the source data (I.e. master list): \*  Describe the storage arrangements, including the data retention period and final disposition of the data:\*  Confirm that the Lead Principal Investigator will be responsible for the storage of data. If not, specify why not, and indicate who will be responsible for data storage: \* |

**Data Linkage**

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| |  |  | | --- | --- | | Do you plan to link the locally collected data with any other data source(s): | Yes  No |   If yes, explain:  What data will be linked:  How data will be linked:  Why the data linkage is required:  How will the shared information be safeguarded? |

**Data Transfer**

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| |  |  | | --- | --- | | Will individual level data be transferred outside the institution where the data was collected: \* | Yes  No |   If yes, specify where it will be transferred:  Indicate how the data will be transferred: Choose an item.  If 'Other' was selected, specify the other method of transfer: |

**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. * 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: