Application to Access Existing Health Data for Research

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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) | | | |

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| 1.8 | **Specify any time considerations the REB should be aware of (e.g. short enrolment period):** | | |
| **Has this project applied for/received ethical approval from any other Saskatchewan REB?**  Yes No  If yes, specify where: | | |
| 1.9 | **Provide name of funding source:** | | |
| **Source of Funds:** | Industry  Not-for-Profit Foundation Tri-Council Grant  Grant-in-aid | National Institute of Health (NIH) Cooperative Group (NCIC, COG, RTOG) Internally funded |
| **Status of Funds:** | Awarded Pending |  |
| 1.10 | **Name of Sponsor if different from above funding source:** | | |

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| **PART 2: BRIEF OVERVIEW OF RESEARCH PROJECT (one page maximum)** | |
| 2.1 | **Research Question/Hypothesis**  Specify the precise research question or questions being evaluated in the project. |
| 2.2 | **Research Design**  Include the planned sample size (with justification), primary and secondary end-points/outcomes and planned statistical analyses. |
| 2.3 | **Potential Significance/Justification**  Explain 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 3: DATA ACCESS** | |
| 3.1 | **Indicate from which sources personal and health information data will be collected (check all that apply):**  Physician Office Records  Saskatchewan Heath Authority – please specify Site & Dept. (if applicable): SK Ministry of Health  SK Cancer Agency  Other (please specify): |
| 3.2 | **In what format is the data you intend to access?**  Medical Charts Electronic Database |

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|  | Other (please specify): |
| 3.3 | **What is the total number of records/cases/charts required for your project?** |
| 3.4 | **Describe the inclusion criteria for the records being requested:** |
| 3.5 | 1. Section 29 of the Saskatchewan Health Information Act (SK HIPA) *legislates* that access to existing personal health information for research purposes requires consent of the individual. If consent is not being considered for this project, please provide a justification for waiving the requirement, otherwise, please append a consent form. For waiver of consent please address each of the following items to ensure that all pertinent points from HIPA and TCPS 2 Article 5.5A are met:    1. 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 researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;    4. the researchers 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; and    6. the researchers have obtained any other necessary permission for secondary use of information for research purposes. |
| 3.6 | **How will the confidentiality of participant data be protected?**  Please note that the master list and data abstraction form (i.e. list of data fields to be collected and from what source) must be submitted for all applications. |

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| **PART 4: DATA SECURITY AND STORAGE** | |
| 4.1 | **Project personnel with access to personal health information**   1. List project personnel that have access to identifiable health data to be collected. 2. Specify who will be responsible for abstracting the data and where the data abstraction will occur. 3. Who will have access to any list that links participant names to their project ID number? |
| 4.2 | **Describe the storage arrangements and final disposition of the research data collected:** |
| 4.3 | **Do you plan to link the locally collected data with any other data set(s)?**  Yes No  If yes, identify the data set: |
| 4.4 | **Will data be sent outside of the institution where it was collected?**  Yes – If yes, specify where it will be stored at that site, who will then be the custodian (i.e. the person responsible for the data storage and integrity), who will have access to it, and security measures:  No – Proceed to Question 4.6 |
| 4.5 | **If you are sending your data to a collecting/coordinating site what method will be used?**  Web-based data collection portal |

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|  | Email  Private courier – must be able to trace delivery  Canada Xpress Post or Priority Courier – regular mail may not be used Other (please specify): | |
| 4.6 | **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 5: 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 Saskatchewan Health Authority/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 certify 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 certify 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 Saskatchewan Health Authority, 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 Saskatchewan Health Authority resources or facilities, a copy of the ethics application may be forwarded to the Saskatchewan Health Authority research coordinator to facilitate operational approval.     Signature of Principal Investigator Printed Name of Principal Investigator Date (MM/DD/YY)  **Department Head:** The signature/approval of the Department/Administrative Unit acknowledges that he/she is aware of and supports the research activity described in the proposal.    Signature of Department Head Printed Name of Department Head Date (MM/DD/YY) |