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File Number: Date received:



Case Report Ethics Review Form

A case report for Research Ethics purposes is a retrospective analysis of one or two clinical cases. If more than two cases are involved in the analytical activity, the activity will normally constitute *research* and be subject to standard policy and guidelines on research ethics review. A different REB process will need to be followed for *research* projects, including a different ethics form, the Accessing Existing Health Data Application. Journals may require proof of REB review, if publication is a possibility for case studies of less than three then this form should be used along with the consent form templates for case studies (Physician and Medical Learner versions are available). Please note that consent from patients for any case studies (1 or more cases) is required by SHA Privacy and the Privacy approved consent form templates must be used. Please also note that the SHA REB does not under any circumstances review nor acknowledge activities that have already been conducted. Requests for such review to satisfy, for example, publication requirements, will not be entertained. Please consult our website for the Research Procedural Handbook guidelines and for REB forms, including case study consent form templates: <https://www.saskhealthauthority.ca/our-organization/our-direction/research>

The following documents must be

 included as part of your application:

* Master list
* Supervising Physician Name
* Privacy approved Patient Consent Form Template

Case Report Ethics Review Form

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| PART 1: Identification |
| 1.1 | Project Title      Protocol Number (if applicable):       |
| 1.2 | Principal Investigator (Supervising Physician) 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 undergraduates/graduates/postgraduates/residents)  |
| Full Name:      Project Position/Role:      University/Institutional Affiliation:       | Full Name:      Project Position/Role:      University/Institutional Affiliation:       |
| Email:        | Email:        | Email:        | Phone:       |
| Full Name:      Project Position/Role:      University/Institutional Affiliation:       | Full Name:      Project Position/Role:      University/Institutional Affiliation:       |
| Email:        | Email:        | Email:        | Phone:       |
| 1.5 | Research Site(s) where project will be carried out:       |
| 1.6 | Proposed Project Period: From (MM/DD/YY)       To (MM/DD/YY)       |

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| PART 2: BRIEF OVERVIEW OF PROJECT (one page maximum) |
| 2.1 | Case description Describe what is unique about the case(s) being evaluated in 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):[GN 4.1](#G4_1)[ ]  Physician Office Records[ ]  Heath Authority – please specify city, Site & Dept. (if applicable):      [ ]  SK Ministry of Health (Please note that SHA cannot provide approval to access Ministry of Health or eHealth data.)[ ]  SK Cancer Agency[ ]  Other (please specify):       |
| 3.2 | In what format is the data you intend to access?[ ]  Medical Charts[ ]  Electronic Database[ ]  Other (please specify):       |
| 3.3 | Total number of case (s) required for your project:       |
| 3.4 | How will the confidentiality of participant data be protected?      Please note that the master list must be submitted for all applications.  |

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| PART 4: DATA SECURITY AND STORAGE |
| 4.1 | **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 | [ ]  Alternate identifiers  |

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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 the SHA where this project will be conducted, as well as with all applicable federal and provincial laws regarding the protection of human participants in research.

If the person submitting the form is not the Principal Investigator, please complete the following:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_**is authorized to prepare and submit the REB application on the Principal Investigator and their research team.  Full name  |

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| PART 6: ATTACHMENTS  |
| Provide a full and accurate listing of all documents submitted with this application. |
| Document | Included? | Comments |
| Consent Form Template (Submit a signed copy to privacy at Roxane.Priddell@saskhealthauthority.ca)  | [ ]  Yes [ ]  N/A |       |
| Master List:       | [ ]  Yes [ ]  N/A |       |
| Other- please specify:       | [ ]  Yes [ ]  N/A |       |