

REB#: Click or tap here to enter text.

**RESEARCH ETHICS BOARD APPLICATION FORM**

**CHART REVIEW, DATABASE REVIEW, SECONDARY ANALYSIS OF CLINICAL DATA OR SAMPLES**

***\*Once your application is completed, please send application and all appendices to the REB office for preliminary review:***

***\*Please note that ONLY electronic copies of your ethics submission will be accepted.***

***\*Please submit the Study Information Sheet with this submission.***

Use this form to submit a request for ethical approval to conduct a chart review, database review, or secondary analysis of clinical data or samples where there is no intent of contacting individual participants.

**Application Instructions:**

* Complete all sections of the form as required. Do not reference pages in attached documents (e.g. “see protocol”).
* Do not remove, alter or delete questions included in this application form.
* Please submit an electronic copy of this application and the supporting documents to the REB office for preliminary administrative review to ensure completeness and accuracy.
* The application will be assigned for delegated (expedited) REB review. THE REB office aims to issue an approval letter within two weeks from the date of submission.

**Please include the following with your submission:**

1. Electronic copy of this application form (please do not include this instruction page)
2. Electronic copy of the one page (approximately) description of the proposed research. This should include the

rationale and hypothesis, anticipated benefit, anticipated harms and how these will be addressed if applicable.

1. Electronic copy of the data abstraction form or the list of data fields that will be collected
2. Electronic copy of the investigator’s TCPS2 training certificate
3. Electronic copy of the investigator’s CV

**Note:**

* It is good practice to assign a unique study number to each participant. This ID number may be linked to the MRN in a separate password protected file. Study data should only include the unique identifier therefore ensuring data is completely de-identified. This decreases the risk of personal identifiers being accessible should information be lost or stolen.
* In the event of a privacy breach, the investigator must notify the REB immediately.
* It is the responsibility of the study investigator to ensure this application is complete and accurate. Incomplete applications will be returned to the investigator and will not be reviewed by the REB until they have been completed satisfactorily.



**REB File #:**

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**CHART REVIEW, DATABASE REVIEW, SECONDARY ANALYSIS OF CLINICAL DATA OR SAMPLES**

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| **Section 1 – General Information** | |
| **Full Study Title:**  Click here to enter text. | |
| 1. **Principal Investigator** (This individual has overall responsibility for the project at all sites) | |
| **Last Name:**  Click here to enter text. | **First Name:**  Click here to enter text. |
| **Title/Position:**  Click here to enter text. | **Phone:**  Click here to enter text. |
| **Department/Unit:**  Click here to enter text. | **Email:**  Click here to enter text. |
| **Is the Principal investigator a student?  Yes\*  No** | |
| **\*If yes, provide supervisor’s name:**  Click here to enter text. | |
| 1. **Co-Investigator** (List only one Co-Investigator on the application who is responsible for the study in absence of the site investigator) (On the **Co-Investigator form**, please list all Co-Investigators affiliated with the Royal) | |
| **Last Name:**  Click here to enter text. | **First Name:**  Click here to enter text. |
| **Title/Position:**  Click here to enter text. | **Phone:**  Click here to enter text. |
| **Department/Unit:**  Click here to enter text. | **Email:**  Click here to enter text. |
| **Section 2 – Study Information** | |
| **Indicate which of the following best describes the type of study proposed:**  Retrospective Chart Review  Retrospective Database Review  Prospective secondary use of clinical data  Secondary use of biological specimens | |
| 1. **List members of the research team who will have access to project data/information (other than the PI/Co-I)** | |
| **Name of Team Member** | **Role of Team member** |
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| 1. **Provide an approximation of the number of charts/records/samples that you expect to review.** | |
| **Expected number:** Click here to enter text. | |
| 1. **Indicate how the charts/records will be obtained/accessed. (max. ¼ page)** | |
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| **Section 3 – Consent Process and Documentation** | |
| **Will consent be obtained from potential participants prior to reviewing the charts/databases/samples?**  **Yes  No\***  **\*If “no” please explain why participant approval to review this information is impractical, impossible and/or would adversely affect the research. (max. ¼ page)** | |
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| **Section 4 – Data Collection** | |
| 1. **Data that will be reviewed for this study is:**   De-Identified or anonymized data (e.g.) larger data sets with scrambled IDs or other anonymized IDs)  Identifiable data (e.g. medical records with names included) | |
| 1. **Provide a copy of the data capture sheet or list the fields that detail precisely the specific information that you will be collecting.**   Data capture/extraction sheet attached (mandatory for chart review studies)  List of data fields attached (this is acceptable for large database studies) | |
| *Investigators should plan to collect personal data at the lowest level of identifiability necessary to achieve the study objectives. Even a dataset without direct identifiers may present a risk of indirectly identifying data subjects if the database contains extensive information about the individuals concerned. For guidance, consult the CIHR Best Practice Guidelines for Protecting Privacy and Confidentiality.* | |
| 1. **If personal/identifiable level data is to be used, please indicate which of the following personal identifiers will be collected:** | |
| **Direct Identifiers\*** | **Indirect Identifiers** |
| Full Name | Initials |
| Address | Date of Birth (month and year only) |
| Telephone Number | Age at time of data collection or year of birth |
| Medical Record Number | Postal Code (recommend first 3 digits only) |
| Email Address | Health Care Provider (recommend type of provider, e.g. MD, RN) |
| Full Face Photograph | Scrambled PHINs or other anonymized identifiers |
| Other (specify):Click here to enter text. | Other (specify):Click here to enter text. |
| 1. **\*If you are collecting any of the direct identifiers noted above, justify why each item is required.  Not Applicable** | |
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| **Section 5 – Funding Source/Budget** | |
| 1. **Classify the type of funding in place for this project.**   Grant  For-Profit Sponsor (Industry)  Internal Funds  Other (specify): Click here to enter text. | |
| 1. **Name of funding source (sponsor/funding agency/industry partner):**   Click here to enter text. | |
| **Note:** *Industry sponsors will be invoiced a fee of $3000.00 Canadian for the review (not approval) of any research study that they partially or fully fund. This fee applies whether the study undergoes full Board review or expedited review. Fees also apply to major amendments.* | |
| 1. **Is a budget included with this submission?** Yes  No\* | |
| **\*If “no”, please briefly explain why.** | |
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| **Section 6 – Participant Population** | |
| 1. **Specify the population being studied, including the ages and conditions of the participant(s),etc. (max. ¼ page)** | |
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| 1. **Will the research hypothesis be concerned with whether a participant is Aboriginal (Inuit, Metis and members of First Nations)?**  Yes  No – \*proceed to Section 7 | |
| 1. **Will the analysis of the research results use Aboriginal community membership as a variable?**   Yes  No | |
| 1. **Will the interpretation of the research results refer to Aboriginal people, language, history or culture?**   Yes  No | |
| 1. **If yes to any of the above, please outline any process to be followed respecting the consultation with the appropriate community in the design and conduct of the study. (max ¼ page) OR  Not Applicable** | |
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| **Section 7 – Project Description** | |
| 1. **Provide a clear statement of the purpose, objectives and the question(s) to be examined in the review. (max. ¼ page)** | |
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| 1. **Describe in general terms how the information to be collected relates to the study’s purpose, hypotheses, and study questions. If the information does not relate directly to these, provide explanation why the information is required. (max. ¼ page)** | |
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| 1. **Specify the approximate time period during which information from the charts/records will be extracted (e.g. January 2019 to March 2019)**   **From:** Click here to enter text.  **To:** Click here to enter text. | |
| **Section 8 – Data Presentation/Publication of Results** | |
| 1. **Outline your intentions with respect to how the data will be used in reports, presentations and/or publications:**   Only aggregate data will be presented  Individual de-identified/anonymized data will be presented  Other (specify): Click here to enter text. | |
| **Section 9 – Privacy & Confidentiality** | |
| 1. **Provide a detailed description of the methods that you will use to protect the privacy and confidentiality of individuals whose information is being reviewed.** | |
| **Note:** *Data capture should be done only on paper or electronic forms that are coded and do not contain personal identifying information. All direct identifiers should be stripped from clinical data; a unique study identifier should be assigned to each patient/participant record; the Master List linking the ID with identifiable material should be stored separately on a secure network that is password protected.* | |
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| 1. **Will data be sent outside of the institution where it was collected or will you be receiving data from other sites (e.g. multicentre study where you are the coordinating center**)?  Yes\*  No   **\*If “yes,” explain why it is necessary to send/receive data outside of the institution where it was collected and how this data will be transmitted.** | |
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| 1. **Specify how long the study data will be retained (record storage years).** Click here to enter text. | |
| 1. **Will an electronic database be created in the process of review**?  Yes  No | |
| **Section 10 – Potential Conflict of Interest** | |
| 1. **Do any of the study personnel have an affiliation with, or financial involvement in any organization or entity with a direct or indirect interest in the participant matter or materials of this research?**  Yes\*  No   **\*If yes, please describe:** | |
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| **Section 11 – Attestation & Signatures** | |
| **Signature of Principal Investigator attesting that:**   1. All investigators/co-investigators have reviewed the research as outlined in this application and are in agreement with the application submitted; 2. All investigator/co-investigators have read the Tri-Council Policy Statement (TCPS2) and agree to abide by the guidelines therein; 3. I, and all study personnel, will adhere to the application as approved by the Royal’s Research Ethics Board (REB); 4. I, and all study personnel, have signed a pledge of confidentiality with the institution(s) from which we are collecting data; 5. Information will not be used for any purpose other than for the project for which it is provided; 6. Information will be kept in a location that is physically secure and to which access is given only to the appropriately approved individuals; 7. As the Principal Investigator, I will be responsible for notifying the REB of any changes made to the approved study proposal; 8. The study will not commence until approval has been received from the REB; 9. I will submit a request for annual approval to the REB prior to the expiry data indicated on the approval letter; 10. I will submit a final study status report to the REB when all study activity is completed at the local site; 11. I understand that the $3,000 fee associated with REB review of protocols from for-profit funders is not dependent on approval and must be paid in a timely manner. The review fee applies even if the submission is withdrawn or not approved by the REB. I have made the sponsor aware of this policy.   **Principal Investigator Name:** Click here to enter text.  **Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| **Required Signature for Student Projects or  Not Applicable**  **Supervisor Name:** Click here to enter text.  **Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| **Required Signature of Department Head/Clinical Director attesting that:**  I have reviewed this research protocol and confirm that there is sufficient scientific merit to warrant this submission.  **Department Head/Clinical Director:** Click here to enter text.  **Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |

**Please retain a copy of this completed form for your records**