**INSTRUCTIONS**

All research must comply with the latest applicable laws and regulations, including but not limited to the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2), International Conference on Harmonization Good Clinical Practice (ICH/GCP), Part C, Division 5 of the Food and Drug Regulations (Health Canada), and the Ontario Personal Health Information Protection Act.

This application is for the initial REB review of studies analyzing **existing data** to investigate past events, trends, or behaviors. It applies to data previously collected for purposes other than the current research. Do not use this form if the study involves direct contact with or observation of human participants.

This application is for:

* Chart Reviews
* Secondary Data Analysis (research data or admin/health data)

**All sections** of this application **MUST** be completed for REB review. All documents require a version and date in the footer, excluding the application form. Send the completed application and study documents to Lori-Ann Larmand, Research Liaison/REB Coordinator, via email at REB@lh.ca.

**A complete application includes the application form, a separate protocol, and the data collection form.**

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| **REB No.**: *(REB Office Use Only)* |  |

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| **SECTION 1: GENERAL INFORMATION** | | | | | | | | | | | | |
| 1 | **Full Study Title & Protocol Number** | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Submission Date  (dd-mmm-yyyy) | | |  | | ~ Start Date  (dd-mmm-yyyy) | | |  | ~ End Date  (dd-mmm-yyyy) | |  |
| 2 | **Is this a multi-centre study?**  Yes  No | | | | | | | | | | | |
| 3 | **Please specify what kind of research is being submitted** (*select all that apply*): | | | | | | | | | | | |
| Secondary data  Retrospective chart review  Prospective chart review | | | | | | Registry  Case report study that answers a question or analysis  Other (specify): | | | | | |
| 4 | **Indicate what type of review you are requesting?** *(Note: REB will decide which review pathway to follow)* | | | | | | | | | | | |
| Full Board review  Delegated review | | | | | | | | | | | |
| 5 | **Is this a student initiated study?**  Yes, answer questions below  No | | | | | | | | | | | |
| a) | Student name: | | |  | | | | | | | |
| b) | Student academic Institution: | | |  | | | | | | | |
| c) | Student academic email: | | |  | | | | | | | |
| d) | Student faculty advisor: | | |  | | | | | | | |
| e) | Student LH staff supervisor: | | |  | | | | | | | |
| 6 | **Please fill in the research team information below.** *Indicate N/A, if there is a study role not being used.* | | | | | | | | | | | |
| **Study Role** | | **Name** | | | | | **Institution / Dept** | | | **Email & Tel No.** | |
| PI | |  | | | | |  | | |  | |
| Co-PI/Sub-I | |  | | | | |  | | |  | |
| Contact | |  | | | | |  | | |  | |
| Nurse/CRC | |  | | | | |  | | |  | |
| 7 | **Has the research undergone review at another Research Ethics Board?** | | | | | | | | | | | |
| Yes, please attached a copy No | | | | | | | | | | | |
| 8 | How is this study being funded? Please list the agency/sponsor below**?**  Internal  External  None | | | | | | | | | | | |
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| 9 | **Please outline the study's dissemination plan, including how findings will be shared with stakeholders** *(e.g., participants, academics, policymakers)***, as well as the methods, timeline, and platforms** *(e.g., publications, presentations, reports)* **for communicating the results.** | | | | | | | | | | | |
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| 10 | **Summary of study suitable for lay audience**: | | | | | | | | | | | |
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| 11 | **What is the rationale, primary outcome measures/goals of the study?** | | | | | | | | | | | |
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| 12 | **What are the study hypotheses or research questions?** | | | | | | | | | | | |
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| 13 | **Describe the design and methodology of the study.** | | | | | | | | | | | |
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| 14 | **What is the overall anticipated public and/or scientific benefits of this study?** | | | | | | | | | | | |
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| 15 | **Please describe any foreseeable risks and/or harms that may arise from the collection, use and storage of personal information for this study and how will they be managed?** | | | | | | | | | | | |
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| 16 | **Is the sample size adequately justified in the protocol, and can you provide justification for the chosen sample size?**  Yes  No | | | | | | | | | | | |
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| 17 | **Briefly explain what methods will be used to analyze the study data?** | | | | | | | | | | | |
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| **SECTION 2: COLLECTION, STORAGE AND USE OF PERSONAL INFORMATION** | | | | | | | | | | | | | | | | | |
| 18 | **Indicate the location(s) where the collection/abstraction of personal information will occur:** | | | | | | | | | | | | | | | | |
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| 19 | **What is the source of the personal information you are accessing?** | | | | | | | | | | | | | | | | |
| Health records or decision support | | | | | | | | | | | | | | | | |
| Electronic medical records (specify): | | | | | | | | | | |  | | | | | |
| Clinic office records (specify): | | | | | | | | |  | | | | | | | |
| From other Institution (specify): | | | | | | | | |  | | | | | | | |
| Existing database (specify): | | | | | | | | |  | | | | | | | |
| Other (specify): | | | | | |  | | | | | | | | | | |
| 20 | **Identify if you require any resources from the following:** | | | | | | | | | | | | | | | | |
| N/A | | | | | | | | | | | | | | | | |
| Health records (specify): | | | | | | | |  | | | | | | | | |
| Decision support (specify): | | | | | | | |  | | | | | | | | |
| Other (specify): | | | | | |  | | | | | | | | | | |
| 21 | **Will you be using aggregated data?** *(e.g., no personal information from individual medical records)*  Yes, answer question below  No, go to next question | | | | | | | | | | | | | | | | |
| Specify search criteria: | | | | | | |  | | | | | | | | | |
| 22. | **Will you be using identifiable data?** *(e.g., access to individual medical records)*  Yes, answer question below  **Explain how your request for a waiver of consent will comply with TCPS2 Articles 3.7 to 3.11 and PHIPA 44, 3c and d.**  The REB may approve research that involves an alteration to the requirements for consent when *all five* of the requirements listed in article 3.7A of the TCPS2 are met.   1. The research involves no more than minimal risk to participants. 2. Altering the consent requirements is unlikely to adversely affect the welfare of participants. 3. It is impossible or impracticable (referring to undue hardship or onerousness that jeopardizes the conduct of the research, not mere inconvenience) to carry out the research and address the research question properly, given the research design, if prior consent from participants is required. 4. In the case of a proposed alteration, the precise nature and extent of the alteration must be defined; 5. A plan must be in place to provide a debriefing (if applicable) that offers participants the possibility of refusing consent and/or withdrawing their data and/or biological materials. | | | | | | | | | | | | | | | | |
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| 23 | **Please list all data that will be collected, used, and disclosed throughout the study. Attach the data collection form with this submission.**  Researchers should aim to collect personal information at the lowest level of identifiability necessary to achieve the study's objectives. For instance, age (in years) should be collected instead of the full date of birth (dd/mm/yyyy), when possible. Even datasets without direct identifiers can still pose a risk of indirectly identifying subjects if they contain enough detailed information.  *Examples of data points include: name, initials, address, postal code, telephone number, fax number, email, sex and/or gender, date of birth, age or year of birth, medical record number, health card number, healthcare provider name, admission date, discharge date, participant study ID, health information (e.g., medications), and images.* | | | | | | | | | | | | | | | | |
| **DATA POINTS**  *(list all that will be used)* | | | | | | | | | | **Justify why these are required** | | | | | **Remain Onsite** (LH) | **Transfer Externally** |
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| 24 | **What is the minimum number of records you require to achieve this study?** | | | | | | | | | | | | | | | | |
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| 25 | **How did you determine this minimum number?** | | | | | | | | | | | | | | | | |
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| 26 | **What is the time period for abstraction?** | | | | | | | | | | | | | | | | |
| From: | | | | |  | | | | | | | To: | |  | | |
| 27 | **Do you plan to link the collected data with any other datasets** *(e.g., health registries, Statistics Canada)***?**  Yes, answer questions below  No | | | | | | | | | | | | | | | | |
| a. | Why is the data being linked? | | | | | | | | |  | | | | | | |
| b. | Identify the linked dataset(s): | | | | | | | | |  | | | | | | |
| c. | Identify how the linage will occur: | | | | | | | | |  | | | | | | |
| d. | List data items contained in it: | | | | | | | | |  | | | | | | |
| 28 | **Describe how the collected data will be transferred and any security measures to be used** *(e.g., de-identified data, secure network upload or download)***.** | | | | | | | | | | | | | | | | |
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| 29 | **Explain why the study cannot reasonably be accomplished without using personal information and how long will it be identifiable.** | | | | | | | | | | | | | | | | |
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| 30 | **Describe the steps that will be done if personal information is inappropriately released?** | | | | | | | | | | | | | | | | |
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| 31 | **Describe how and when the personal information will be disposed of or returned to the health information custodian.** | | | | | | | | | | | | | | | | |
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| 32 | **Indicate how study participants will be identified on data collection forms.** | | | | | | | | | | | | | | | | |
| Study participant ID number | | | | | | | | | | | | | | | | |
| Other (specify): | | | | | |  | | | | | | | | | | |
| 33 | **Indicate how data will be stored.** | | | | | | | | | | | | | | | | |
|  | | Computerized files: | | | | | | | | | | | | | | |
|  | |  | | Server 🡪  Internal  Contracted Server Provider  Other (specify): | | | | | | | | | | | | |
|  | | Desktop | | | | | | | | | | | | |
|  | | Laptop | | | | | | | | | | | | |
|  | | Hard copy | | | | | | | | | | | | | | |
|  | | Audio recordings | | | | | | | | | | | | | | |
|  | | Video recordings | | | | | | | | | | | | | | |
|  | | USB key or similar portable storage device | | | | | | | | | | | | | | |
|  | | PDA, e-reader or similar hand-held computer | | | | | | | | | | | | | | |
|  | | Other (specify): | | | | | | | | | | | | | | |
| 34 | **Where will data be stored?**  On-Site  Off-Site | | | | | | | | | | | | | | | | |
| If off-site, describe location (Institution name, city, country): | | | | | | | | | | | | |  | | | |
| 35 | **Which measures will be used to protect the confidentiality and security of the data?** | | | | | | | | | | | | | | | | |
|  | | Data stored on mobile devised will be encrypted | | | | | | | | | | | | | | |
|  | | Data will be password protected | | | | | | | | | | | | | | |
|  | | Data will be stored on an Institutional network drive that has firewalls and security measures in place | | | | | | | | | | | | | | |
|  | | Hard copy records will be stored in a locked cabinet in a secure location | | | | | | | | | | | | | | |
|  | | Access to records and data limited to authorized personnel | | | | | | | | | | | | | | |
|  | | Study data will be de-identified or coded. A key will be kept and stored separately from the data.  Where will the link to the code be stored? | | | | | | | | | | | | | | |
|  | | Study data will be anonymized. All identifiers will be removed once the data has been:  Collected  Verified  Analyzed | | | | | | | | | | | | | | |
|  | | Study data will be anonymous. Identifiers/Identifying information will not be collected | | | | | | | | | | | | | | |
|  | | Audio recordings will be used. | | | | | | | | | | | | | | |
|  | |  | Recordings will be destroyed upon:  Transcription  Review  Verification  Analysis | | | | | | | | | | | | | |
|  | Recordings will be coded | | | | | | | | | | | | | |
|  | Recordings will not capture date and time | | | | | | | | | | | | | |
|  | | Other (specify): | | | | | | | | | | | | | | |
| 36 | **Indicate what, if any, additional security measures will be taken at the end of the study?** | | | | | | | | | | | | | | | | |
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| 37 | **Indicate who might have access to data in the future.** | | | | | | | | | | | | | | | | |
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| 38 | **Indicate how long study data will be retained, how it will be destroyed and by whom?** | | | | | | | | | | | | | | | | |
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| **SECTION 3: DECLARATION AND SIGNATURE PAGE** | | | | | | |
| **PRINCIPAL INVESTIGATOR APPROVAL AND DECLARATION FOR THIS SUBMISSION**  Principal Investigator Agreement: I take full responsibility for the scientific and ethical conduct of this study, as described in the application and protocol, and agree to comply with the Tri-Council Policy Statement (TCPS2), the Personal Health Information Protection Act (PHIPA), and relevant regulations. I will use personally identifiable information (including health information and biological samples) only as outlined in the Protocol, REB conditions, participant consent (unless waived), and restrictions from the information guardian. I confirm that all researchers involved are qualified or will receive necessary training.  Declaration: I certify that the information above is accurate and will remain in effect until the data is destroyed. I acknowledge that the Health Information Management and Laboratory Services Departments will review all charts and tissue samples, and they will not be removed. I agree to follow LH policies, the Research Ethics Board's approval, and confidentiality procedures for all health information accessed. I will secure and remove identifying information after data collection. I understand that my team and I are prohibited from disclosing identifying information unless authorized by LH or required by law. I accept responsibility for protecting this information.  Conflict of Interest Statement: I have read and discussed this Declaration with my research team. To the best of my knowledge, the information is accurate. Any conflicts of interest during the research will be disclosed to the REB. | | | | | | |
|  |  |  |  |  |  |  |
|  | Name of Principal Investigator |  | Signature of Principal Investigator |  | Date |  |
|  | | | | | | |
| **PRINCIPAL INVESTIGATOR’S PROGRAM DIRECTOR APPROVAL FOR THIS SUBMISSION**  I am aware of this proposal and support its submission for research approval at Lakeridge Health. I am fully aware of the impact, if any, that this study may have on resources in the program and have assessed all costs. All negotiated costs will be listed on the Department Impact Analysis Form, if applicable. I attest that the Lakeridge Health Principal Investigator responsible for the conduct of this study is qualified by education, training and experience to perform his/her role in the study. | | | | | | |
|  |  |  |  |  |  |  |
|  | Name of Program Direct |  | Signature of Program Director |  | Date |  |
|  | | | | | | |