**INSTRUCTIONS**

* **All sections** of this application **MUST** be completed before it will be considered for REB review.
* A separate detailed protocol must be included with this application.
* All research must be compliant with the most current applicable laws and regulations which include, but not limited to, the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2); the International Conference on Harmonization Good Clinical Practice (ICH/GCP); Part C, Division 5 of the Food and Drug Regulations of Health Canada and the Ontario Personal Health Information Protection Act.

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| **SECTION 1: GENERAL INFORMATION** |
| 1 | Submission Date:       | Anticipated Start Date:       | Anticipated End Date:       |
| **Full Study Title**:      |
| **Short Title/Acronym**:      | **Protocol Number** (if applicable):      |
| 2 | **Is any of the research team a member of the REB?** [ ]  Yes [ ]  No *If yes, please specify who*:       |
| 3 | **Is any member of the research team a student?** [ ]  Yes [ ]  No *If yes, is the student participating as* **part of an academic training program at LH**? [ ]  Yes [ ]  No  |
| 4 | **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**  | **Tel Number** | **Email** |
| Internal PI |       |       |       |       |
| External PI  |       |       |       |       |
| Contact Person |       |       |       |       |
| Research Nurse |       |       |       |       |
| Student |       |       |       |       |
| 5 | **Please specify what kind of research (and substudies) is being submitted, check all that apply:** |
| [ ]  | Chart Review (specify): [ ]  Retrospective [ ]  Prospective |
| [ ]  | Clinical Trial (specify): [ ]  Investigational product (drug, biologic, natural health or approved product for new indication)[ ]  Investigational device [ ]  Health-related intervention, specify:       |
| [ ]  | Qualitative (please check all that apply) [ ]  Observational [ ]  Questionnaire/surveys [ ]  Focus group [ ]  Interviews [ ]  Other, specify:        |
| [ ]  | Human Tissue and Biological Specimens[ ]  Banking [ ]  Biomarker [ ]  Genetic [ ]  Other, specify:       |
| [ ]  | Sub-Study, indicate the REB No. of main/related study:       |
| [ ]  | Case Study |
| [ ]  | Program Evaluation/ Quality Improvement |
| [ ]  | Other:       |
| 6 | **Please answer the below questions and specify what documents will be submitted.** |
| *[ ]  Yes [ ]  No* | Is there a version and date on each document submitted? If no, please update to reflect this. |
| *[ ]  Yes [ ]  No* | Do all the ICFs have the LH logo in the header on the first page and signature page? |
| *[ ]  Yes [ ]  No* | Are you using any eConsents or any patient facing websites? If so, please list link below. |
| **Check all that apply**  | **List Name of Document** | **Version & Date** |
| [ ]  LHREB application (mandatory) |  |  |
| [ ]  Protocol/proposal (mandatory) |  |       |
| [ ]  Informed Consent Form(s) (if applicable) |       |       |
| [ ]  Data Collection Form/CRF (if applicable) |       |       |
| [ ]  Patient Facing Material (if applicable) |       |       |
| [ ]  IB/Product Monograph (if applicable) |       |       |
| [ ]  Other (specify): |       |       |
| 7 | **Does this study involve submission to Health Canada under the Food and Drug Act?**[ ]  Yes [ ]  No *If yes, please attach NOL with this application or check the box if in progress* [ ]   |
| 8 | **Is this study FDA-regulated?** [ ]  Yes [ ]  No *If yes, please provide FDA IND/IDE/PMA number*:        |
| 9 | **Is this study registered on a public website? (i.e., clinicaltrials.gov, isrctn.org, etc.)**[ ]  Yes [ ]  No *If yes, please provide*: Name of site the trial is/will be registered:       Registration number:       |
| 10 | Conflicts of Interest do not imply wrongdoing. It is the responsibility of the PI to determine if any of the conflicts listed below apply to any persons involved in the research study or any member of their immediate family. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflict of interest may also arise with regard to the disclosure of personal health information. NOTE: This disclosure does not replace institutional guidelines and requirements for declaration and management of conflicts of interest. |
| **Do any member(s) of the research team have an actual, potential or perceived conflict of interest with respect to this research application?**  [ ]  Yes [ ]  No *If yes, please fill out the chart below:* |
| a) | **Name** | **Financial** | **Status** | **Undue Influence** | **Competing Interest** | **Other****(Describe)** |
|       |  |  |  |  |       |
|  |  |  |  |  |  |
| b) | **Describe and detail any conflicts of interest**.       |
| c) | **How will conflicts of interest be managed?**       |
| 11 | **Has the research undergone review at another Research Ethics Board?** [ ]  Yes [ ]  No *If yes, please attached a copy with this application.*   |

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| **SECTION 2: INSTITUTIONAL APPROVAL REQUIREMENTS** |
| 12 | **Has a Departmental Impact Assessment (DIA) Form been completed & submitted with this application?**[ ]  Yes [ ]  No [ ]  Not Applicable part of the Research Department (oncology and non-oncology groups) *Note: Research department will review DIA prior to PI obtaining signatures.*  |
| 13 | **Has a Team Form been completed & submitted with this application?**[ ]  Yes [ ]  No [ ]  Not Applicable part of Research Department (oncology and non-oncology groups) |
| 14 | **Who will be funding the study?**      *(Please check all that apply)* |
| [ ]  Industry (Pharmaceutical) | [ ]  Granting Agency | [ ]  Internal Funding |
| [ ]  Government | [ ]  US Federal Funds | [ ]  Other:       |
| [ ]  Tri-Council (e.g., CIHR, NSERC, NCE) | [ ]  Charitable Foundation | [ ]  No Funding |
| 15 | **Provide the Institution, Company, or Sponsor who will be invoiced for the REB Fees?**      |
| 16 | ***In accordance with the Personal Health Information Protection Act, 2004, c. 3, Schedule A, s. 44 (5), agreements are required for all research studies, unless the study is an internal study only*.** Agreements outline roles and responsibilities, insurance, indemnification, publication rights, privacy, conflicts of interest, budget etc. Some agreements used at Lakeridge Health are: a). A clinical trial agreement which is required if resources/funds will be received by external sources; b). A data transfer agreement which is required if any information or biological material are sent outside Lakeridge Health; and c). A collaboration agreement which is required when parties want to work collaboratively on a study together and information is transferred between the parties.All agreements, *including the budget*, must be reviewed and negotiated by the Lakeridge Health Research Department before a study can proceed. **Has an unsigned agreement been submitted with this application?** [ ]  Yes – *If yes, please check what type*: [ ]  External agreement [ ]  LH agreement [ ]  N/A, internal study only (no data leaving LH) |

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| **SECTION 3: STUDY SUMMARY *(The full protocol must be attached with this application still)*** |
| 17 | **Lay Summary of Study**:      |
| 18 | **What is the rationale for this study?**      |
| 19 | **What are the study hypotheses or research questions?**      |
| 20 | **What is the significance of the study (i.e., the overall anticipated public and/or scientific benefits?**      |
| 21 | **Describe the design and methodology (e.g., pre/post design, pilot, study visits, procedures, and intervention).**      |
| 22 | **Describe the primary outcome measures/goals of the study.**      |
| 23 | **List all criteria for withdrawal of a participant from the study.** [ ]  Not Applicable      |
| 24 | **Is a placebo used in this study?**[ ]  Yes [ ]  No*If yes, provide justification (i.e., no alternative standard treatment available). Include any provisions in place to minimize risks to participants assigned to placebo (i.e., increased monitoring, rescue medication).*       |
| 25 | **Does this study involve deception or intentional lack of disclosure?**[ ]  Yes [ ]  No*If yes, justify and indicate how participants will be debriefed.*       |
| 26 | **Will the participant be withdrawn from or denied usual therapy for any condition in order to participate in the study?** *(This would include medications that are prohibited or restricted in order to be eligible for the study or that may be prohibited or restricted during the study).*[ ]  Yes [ ]  No*If yes, please explain:*       |
| 27 | **Will the participant be subject to other restrictions (i.e., lifestyle, birth control, etc.) during the study?**[ ]  Yes [ ]  No*If yes, please explain:*       |
| 28 | **List the inclusion criteria for this study.**      |
| 29 | **List the exclusion criteria for this study.**      |
| 30 | **Indicate the rationale for control groups?** [ ]  Not Applicable      |
| 31 | **Indicate how many participants will either be enrolled or reviewed if study is a chart review.**Total number of participants in study:      . Total number at Lakeridge Health:      . |
| 32 | **Time period for enrolment and/or length of study**.       |
| 33 | **Is the sample size justified in the protocol?** [ ]  Yes [ ]  No*If no, provide sample size justification:*       |
| 34 | **Does this study involve an intervention?**[ ]  Yes [ ]  No *If yes, please fill out the questions below:*   |
| a) | **What is the usual standard of care for this population?**       |
| b) | **What procedures will be carried out that are not part of standard of care?**       |
| c) | **Indicate additional risks associated with the study as compared to usual standard of care**.       |
| d) | **Indicate the duration of study visits and extra time commitment (length, number and frequency of test sessions).**  |
| 35 | **Briefly explain what methods will be used to analyze study data?**      |

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| **SECTION 4: ETHICAL ISSUES** |
| **Any document** to be viewed by a study participant (e.g., recruitment posters/letters, consent/assent forms, information sheets) **must accompany this submission**. Participant material must display LH logo in header. Please ensure all documents contain a version and date in the footer. |
| 36 | **What tools will be used to identify potential participants for recruitment into the study?** |
| [ ]  | Permanent health record/clinical chart (specify source):       |
| [ ]  | Existing Database (specify):       |
| [ ]  | Advertisement, including web based tools (specify):       |
| [ ]  | Other (specify):       |
| 37 | **Who will identify potential study participants?** |
| [ ]  | Investigator/Study Personnel |
| [ ]  | Other Healthcare Professional (i.e., non-study personnel) |
| [ ]  | Self-Referral (i.e., response to advertisement) |
| 38 | **Who will make initial contact with potential participants, family member or substitute decision maker (SDM)? Is this individual(s) already known to the participant, family member or SDM? How will contact be made (e.g. in person, phone, letter etc.)?** **Include all scripts and/or any written materials with this submission.**[ ]  Not Applicable      |
| 39 | **Are you seeking permission for an alteration to consent requirements?**[ ]  Yes [ ]  No *If yes, answer the below questions.***NOTE: Article 3.7A of TCPS2, states the REB may approve research that involves an alteration to the requirements for consent when *all five* of the requirements listed *are met*:**1. research involves no more than minimal risk to participants;
2. alteration to consent requirements is unlikely to adversely affect the welfare of participants;
3. impossible or impracticable to carry out the research and to address the research question properly, given research design, if the prior consent of participants is required;
4. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined;
5. plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials.

 “Impracticable” refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience. |
| a) | What type of alteration is proposed (waived consent, deferred consent, emergency consent etc.)?       |
| b) | Explain how your request for an altered consent process will comply with TCPS2 Articles 3.7 to 3.11 and PHIPA 44, 3c and d.      |
| c) | How and when will the participant be debriefed/informed of their involvement in the study?      |
| d) | Please provide the name and contact information that will be provided to the participant for any questions or concerns.      |
| 40 | **Describe the consent process (e.g. will consent be written, oral, telephone). Include script with this submission.**      |
| 41 | **Who will obtain consent?**      |
| 42 | **Is there a relationship between the participant and the Investigator or person obtaining consent?**[ ]  Yes [ ]  No*If yes, explain the nature of the relationship(s) and what steps will be taken to avoid the perception of undue influence.*       |
| 43 | **How much time will be given to participants to review the information before being asked to give consent?**       |
| 44 | **Does your research include any special considerations for inclusion/exclusion, additional studies and/or sampling? *(Check all that apply).*** |
| a) | [ ]  | Age Inclusion/Exclusion | [ ]  | Child Bearing Women  | [ ]  | Tissue Samples |
| [ ]  | Gender Inclusion/Exclusion | [ ]  | Pregnant Women | [ ]  | Fetal Tissue/Placenta |
| [ ]  | Ethnicity Inclusion/Exclusion | [ ]  | Staff | [ ]  | None of the Above |
| [ ]  | Race Inclusion/Exclusion | [ ]  | Students | [ ]  Other (specify):       |
| [ ]  | Language Inclusion/Exclusion | [ ]  | Prisoners |
| [ ]  | Unable to Communicate | [ ]  | Genetic Research |
| **Please provide a justification for any considerations you checked off listed above:**        |
| b) | **If participant lacks capacity or temporarily is unable to consent check off the reason why?**  |
|  | [ ]  | Children | [ ]  | Emergency Patients |
| [ ]  | Individuals Who Lack the Capacity to Consent | [ ]  | None of the Above |
| [ ]  | Individuals Temporarily Unable to Consent |
| **Describe by whom and how capacity will be assessed.**      |
| **How will a substitute decision maker be identified?**       |
| **When inability to provide an informed consent is expected to be temporary, describe what procedures will be used to regularly assess capacity and to obtain consent if the participant later becomes capable of providing consent.**      |
| c) | **If participant has communication difficulties (i.e., require translation, illiterate or require special support or assistive devices) please provide an explanation of what procedure will be used to address these difficulties (e.g., the use of translated forms, translator and impartial witness)?**      |
| 45 | **What steps will be taken to determine if the participants are already enrolled in other studies or are likely to be enrolled in other studies during the term of this study? If enrollment in multiple studies is likely to be an issue in this population, indicate how this will be addressed.**      |

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| **SECTION 5: RISKS, BENEFITS AND SAFETY** |
| 46 | **Potential harms (injury, discomfort and inconvenience) to participant (including psychological factors).** [ ]  Not Applicable |
| a) | List the known risks of study intervention(s) including approximate rates of occurrence, severity and rates of reversibility.      |
| b) | List the risks of any tests, procedures, or other protocol-mandated activities that are conducted for research purposes only.      |
| c) | For studies involving placebo or withholding treatment, list any risks related to withdrawal or absence of treatment. [ ]  Not Applicable      |
| 47 | **Include a summary of the data regarding reproductive risks such as teratogenicity or embryotoxicity of the study drug, any risk with breastfeeding, or risk to men regarding conception.**[ ]  Risks Unknown [ ]  Not Applicable Describe:       |
| 48 | **Does participation in this study affect alternatives for future care?**[ ]  Yes [ ]  No*If yes, explain:*       |
| 49 | **List anticipated benefits to the participant, if any.**[ ]  Not Applicable       |
| 50 | **What payment(s) will be provided to participants, family member or substitute decision makers (if applicable)?** |
| [ ]  | Not Applicable |
| [ ]  | Reimbursement for expenses incurred as a result of research. Specify amount and reason:       |
| [ ]  | Gifts for participation. Specify value:       |
| [ ]  | Compensation for time. Specify amount:       |
| [ ]  | Other forms of compensation (specify):       |
| 51 | **Is there a safety-monitoring plan for the study?**[ ]  Yes [ ]  No*If yes, please provide details:*      *If no, justify and explain if alternative arrangements are in place to monitor the safety data and by whom and how the overall risk/benefit information will be communicated to the REB.*       |
| 52 | **Is an interim analysis planned?**[ ]  Yes [ ]  No*If yes, describe briefly:*       |
| 53 | **Is there a steering committee?**[ ]  Yes [ ]  No |
| 54 | **Is there a Data and Safety Monitoring Board (DSMB)?**[ ]  Yes [ ]  No*If yes, provide a brief description of the DSMB, including its purpose, membership and relationship to the sponsor:*      *If no, please provide an explanation as to why there is not a DSMB?*       |
| 55 | **Is the DSMB independent of the sponsor?**[ ]  Yes [ ]  No [ ]  N/A |

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| **SECTION 6: PRIVACY AND CONFIDENTIALITY** |
| Investigators must comply with the duties set out for researchers in the Personal Health Information Protection Act (PHIPA), with the privacy and confidentiality and consent guidelines outlined in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans.**Personal Information (PI):** In this Application, PI has the meaning ascribed to it in the *Personal Health Information Protection Act* (PHIPA). With limited exceptions, PI is defined as identifying information about an individual in oral or recorded form, if the information,* relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,
* relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual,
* is a plan of service within the meaning of the *Long-Term Care Act* for the individual,
* relates to payments or eligibility for health care in respect of the individual,
* relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,
* is the individual's health number, or
* Identifies a provider of health care to the individual or a substitute decision-maker of the individual.
 |
| 56 | **Has your research team been given training in privacy and confidentiality issues for this study?**[ ]  Yes [ ]  No *If yes, please check all that apply:* [ ]  TCPS2 [ ]  ICH/GCP [ ]  Division 5*If no, who, when and what type of training will be provided:*       |
| 57 | **Will ANY data be transferred outside of Lakeridge Health (identifying or de-identified)?** [ ]  Yes [ ]  No [ ]  Not Using LH data *If yes, list the party where the data will be transferred or uploaded through the CRF.* |
| **Party** | **De-identified Data** | **Identifying Data** |
|       | [ ]  | [ ]  |
|       | [ ]  | [ ]  |
|       | [ ]  | [ ]  |
| 58 | **Please list all identifiers that will be collected, used and disclosed during the course of the study & include the data collection form in this submission.** *(Examples: Name, Initials, Address, Tel/Fax, Gender, Age, DOB, Weight, Email/IP Address/URL, Health Card No., Medical Record No., Health Care Provider Name, Health Information (inclusion etc.), Discharge Date, Participant Study No., Images (required to be de-identified)*  | ***Please check boxes below if information will remain at LH or be transferred.*** |
| Part of LH Research Study Records & Remain On Site | De-Identified Data Transferred Externally |
|        | [ ]  | [ ]  |
|        | [ ]  | [ ]  |
|        | [ ]  | [ ]  |
|        | [ ]  | [ ]  |
|        | [ ]  | [ ]  |
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|        | [ ]  | [ ]  |
|        | [ ]  | [ ]  |
|        | [ ]  | [ ]  |
| 59 | **Describe how the information will be transferred and any security measures to be used (e.g. de-identified data, secure network upload or download).**[ ]  Not Applicable      |
| 60 | **Indicate how long the personnel information will remain identifiable and explain why.**[ ]  Not Applicable      |
| 61 | **Explain why the research cannot reasonably be accomplished without using personal information.**[ ]  Not Applicable      |
| 62 | **Describe the steps that will be done if personal information is inappropriately released?**      |
| 63 | **Describe how and when the personal information will be disposed of or returned to the health information custodian.**      |
| 64 | **Identify all potential sources of this information.** |
| [ ]  | Directly from the patient |
| [ ]  | Permanent health record/clinical chart (specify source):       |
| [ ]  | Existing database (specify):       |
| [ ]  | From other Institutions (specify):       |
| [ ]  | Other (specify):       |
| 65 | **If personal information is to be linked to other databases (e.g., health registries, Statistics Canada information) provide the details:**[ ]  Not Applicable      |
| 66 | **Describe the data to which the personal information will be linked.**      |
| 67 | **Explain how the linkages will be made.**      |
| 68 | **Explain why these linkages are required.**      |
| 69 | **Indicate how study participants will be identified on data collection forms (e.g. study number, initials).**[ ]  Participant Identification #[ ]  Other (specify):       |
| 70 | **Indicate how data will be stored.** |
| [ ]  | Computerized files:  |
|  | [ ]  | Server:         |
| [ ]  | 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):       |
| 71 | **Where will data be stored?**[ ]  On-Site [ ]  Off-Site, describe location (Institution name, city, country):       |
| 72 | **Indicate which of the following measures will be employed 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):       |
| 73 | **Indicate what, if any, additional security measures will be taken at the end of the study?**      |
| 74 | **Indicate who might have access to data in the future.**      |
| 75 | **Indicate how long study data will be retained, how it will be destroyed and by whom?**      |

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| **SECTION 7: DECLARATION AND SIGNATURE PAGE** |
| **PRINCIPAL INVESTIGATOR APPROVAL AND DECLARATION FOR THIS SUBMISSION**Principal Investigator Agreement: I assume full responsibility for the scientific and ethical conduct of this study as described in this application and submitted protocol, and agree to conduct this study in compliance with the current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2),* the *Personal Health Information Protection Act (PHIPA),* and any other relevant regulations or guidelines. I also agree that if I receive any personally identifiable information (including but not limited to personal health information and biological samples), I will only use or disclose the information as set out in the Protocol, the conditions of the REB, the research participant's consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information guardian who supplies the information. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this projectDeclaration: I certify that the above declaration is accurate and is/will be in force until the data is destroyed. I acknowledge that I, and all members of my research team, are aware that all charts will be reviewed in the Health Information Management Department, and/or all tissue samples will be reviewed in the Laboratory Services Department, and will not be removed from this area under any circumstances. I agree to adhere to the policies and procedures of LH, and the Research Ethics Board approval, with respect to confidentiality and privacy of all health information to which I may have access. If identifying information is collected, the information will be kept secure and identifiers removed at the completion of collection. I acknowledge that I, and my research team, are prohibited from releasing any identifying patient information received from LH, unless I am specifically authorized to do so by LH or required by law. I accept full responsibility for protection of information that has been accessed and/or collected by members of my research team. Conflict of Interest Statement: I hereby declare that I have read this Declaration, have discussed this Declaration with the members of my research team, and that to the best of my knowledge and belief, my responses are true and complete. Should a conflict of interest arise during the course of the research, it will be declared to the Research Ethics Board. |
|  |       |  |       |  |       |  |
|  | Name of Principal Investigator |  | Signature of Principal Investigator |  | Date |  |
|  |