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

**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 Tri-Council Policy Statement, available at http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS\_2\_FINAL\_Web.pdf.
* The Ontario Personal Health Information Protection Act (2004), available at http://www.e-laws.gov.on.ca/html/statutes/english/elaws\_statutes\_04p03\_e.htm.
* Any other relevant regulations or guidelines.

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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 | **List ALL DOCUMENTS submitted for review below:**   * *Informed Consent Form must have LH logo in header and version and date in footer* * *Mandatory documents for submission are LHREB application form and study protocol* | | | | | | | | | | | | | | | | | | | |
| **Use the LHREB Application Form Extra Sheet located on the website if you require more space.** | | | | | | | | | | | | | | | | | | | |
| Document | | | | | | | | | | | | Version | | | | | | | Date |
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| 3 | **Please fill in the research team information below.** *Indicate N/A, if there is a study role not being used.* | | | | | | | | | | | | | | | | | | | |
| **Study Role** | | | | **Name / Credentials** | | | **Institution / Department / Address** | | | | **Tel Number** | | | | | | | **Email** | |
| Internal PI | | | |  | | |  | | | |  | | | | | | |  | |
| External PI | | | |  | | |  | | | |  | | | | | | |  | |
| Contact Person | | | |  | | |  | | | |  | | | | | | |  | |
| Research Nurse | | | |  | | |  | | | |  | | | | | | |  | |
| 4 | **Is any of the research team a member of the REB?**  Yes  No If yes, please specify who: | | | | | | | | | | | | | | | | | | | |
| 5 | **Is any member of the research team a student?**  Yes  No  *If yes, choose the appropriate response below:*  One or more of the researchers is a student participating as **part of an academic training program at LH**. The Student Practicum Liaison (ext. 35003) or Medical Trainee Liaison (ext. 34203) has been notified.  One or more of the researchers is a student but is **NOT** participating as part of an academic training program facilitated by LH. | | | | | | | | | | | | | | | | | | | |
| 6 | **Has your Program Director been given the departmental impact analysis approval form (DIA)?**  Yes  No  In Progress  Not Applicable part of the Research Department (oncology and non-oncology groups) | | | | | | | | | | | | | | | | | | | |
| 7 | **Check off if you included a completed Team Form with all research team members listed:**  Team Form  Not Applicable part of Research Department (oncology and non-oncology groups) | | | | | | | | | | | | | | | | | | | |
| 8 | **Name of Institution/Company/Group Sponsoring the Study and who will be invoiced?**  PI is Sponsor. | | | | | | | | | | | | | | | | | | | |
| Address | | | | | | City | | | | | | | | | | | Province | | Postal Code |
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| Email | | | | | | | | | Phone | | | | | | | | | | |
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| 9 | **Is there funding?**  No – Explain why there is no funding:  Yes - What is the status of the funding?  Obtained  Applied for  *If yes, please answer the questions below:* | | | | | | | | | | | | | | | | | | | |
| Yes  No | | | Is a budget been submitted to LH Research Department? | | | | | | | | | | | | | | | | |
| Yes  No | | | Is funding sufficient to cover all costs? *If no, how will shortfall be addressed:* | | | | | | | | | | | | | | | | |
| Yes  No | | | Will PI receive any direct personal payments? I*f yes, explain:* | | | | | | | | | | | | | | | | |
| Yes  No | | | Is there a funding source(s)? *If yes, list:* | | | | | | | | | | | | | | | | |
| 10 | **Please specify the nature of the study (and substudies), check all that apply:** | | | | | | | | | | | | | | | | | | | |
|  | Chart Review (specify):  Retrospective  Prospective | | | | | | | | | | | | | | | | | | |
|  | Clinical Trial | | | | | | | | | | | | | | | | | | |
|  |  | Investigational Product or Device study | | | | | | | | | | | | | | | | | |
|  | Phase 1  Phase 2  Phase 3  Phase 4  unknown | | | | | | | | | | | | | | | | | |
| Investigational drug(s) – specify drug name: | | | | | | | | | | | | | | | | | |
| Investigational biologic(s) | | | | | | | | | | | | | | | | | |
| Investigational natural health product(s) | | | | | | | | | | | | | | | | | |
| Investigational device(s) | | | | | | | | | | | | | | | | | |
| Approved product for new indication (i.e., new patient population), dosage, or formulation | | | | | | | | | | | | | | | | | |
|  | Health-related intervention(s), specify: | | | | | | | | | | | | | | | | | |
|  | Qualitative (please check all that apply) | | | | | | | | | | | | | | | | | | |
|  |  | Focus group | | | | | | | | | | | | | | | | | |
|  | Interviews | | | | | | | | | | | | | | | | | |
|  | Observational (i.e., naturalistic, field, etc.) | | | | | | | | | | | | | | | | | |
|  | Questionnaire/surveys | | | | | | | | | | | | | | | | | |
|  | Other, specify: | | | | | | | | | | | | | | | | | |
|  | Human Tissue and Biological Specimens | | | | | | | | | | | | | | | | | | |
|  |  | Banking | | | | | | | | | | | | | | | | | |
|  | Biomarker | | | | | | | | | | | | | | | | | |
|  | Genetic | | | | | | | | | | | | | | | | | |
|  | Other (i.e., pharmacokinetic/pharmacodynamics, etc.), specify: | | | | | | | | | | | | | | | | | |
|  | Sub-Study, indicate the RID# of main/related study: | | | | | | | | | | | | | | | | | | |
|  | Case Study | | | | | | | | | | | | | | | | | | |
|  | Educational | | | | | | | | | | | | | | | | | | |
|  | Epidemiological | | | | | | | | | | | | | | | | | | |
|  | Health Services/ Evaluation Research (i.e., program evaluation, quality improvement, observation etc.) | | | | | | | | | | | | | | | | | | |
|  | Other: | | | | | | | | | | | | | | | | | | |
| 11 | **Does this study involve submission to Health Canada under the Food and Drug Act?**  Yes, see attached NOL/ITA dated:  Yes, in progress – will provide once received from Health Canada  No | | | | | | | | | | | | | | | | | | | |
| 12 | **Is this study FDA-regulated?**  Yes, if yes please provide FDA IND/IDE/PMA number:  No | | | | | | | | | | | | | | | | | | | |
| 13 | **Will this study be registered on a public website? (i.e., clinicaltrials.gov, isrctn.org, etc.)**  Yes  No  The International Committee of Medical Journal Editors (ICMJE) has indicated that clinical trials will not be published without the registration of that trial prior to participant enrolment. In June 2007, the ICMJE adopted the World Health Organization's definition of clinical trial: "Any research study that prospectively assigns human participants of groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.” This definition includes drugs, surgical procedures, devices, behavioural treatments, process-of-care changes and the like. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration." Health related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.  *Please provide*: Name of site where the trial is/will be registered:  Registration number: | | | | | | | | | | | | | | | | | | | |
| 14 | Conflicts of Interest do not imply wrong-doing. 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)** | |
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| b) | **Describe and detail any conflicts of interest**. | | | | | | | | | | | | | | | | | | |
| c) | **How will conflicts of interest be managed?** | | | | | | | | | | | | | | | | | | |
| 15 | **Has the research undergone review at another Research Ethics Board?**  Yes, name of REB:       *If yes, please attach.*   No | | | | | | | | | | | | | | | | | | | |
| 16 | All studies require a contract/ agreement unless the study is an internal study only. This may include a clinical trial agreement, data transfer agreement, or collaboration agreement. Agreements outline roles and responsibilities, insurance, indemnification, publication rights, privacy, conflicts of interest, budget etc. Generally, a contract agreement is required if resources or funds will be received by sources external to Lakeridge Health. A data sharing agreement is required if any information (i.e. data including video and audio, personal health information) or biological materials will be sent outside of Lakeridge Health: "Before a health information custodian discloses personal health information to a researcher, the researcher shall enter into an agreement with the custodian in which the researcher agrees to comply with the conditions and restrictions, if any, that the custodian imposes relating to the use, security, disclosure, return or disposal of the information". *Personal Health Information Protection Act, 2004*, c. 3, Schedule A, s. 44 (5). Research contracts, including the budget, must be reviewed, negotiated and signed by the Lakeridge Health Research Department before a study can proceed. If a contract/agreement is required, one will be drafted and forwarded by the Research Office upon request.  **Are there any agreements or contracts related to this study?**  Yes  No  Internal Study Only  *If yes, has the agreement/contract been submitted to:* | | | | | | | | | | | | | | | | | | | |
|  | 1. The LH Research Department for review (have funding)? | | | | | | | | | | | | Yes  No  In progress or | | | | | | |
| 1. The LH Research Liaison for review (have no funding)? | | | | | | | | | | | | Yes  No  In progress | | | | | | |

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| **SECTION 2: 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 |  | |
| 31 | **Indicate the rationale for control groups?**  Not Applicable | |
| 32 | **Indicate how many participants will be enrolled.**  Total number of participants in this study:      . Total number at Lakeridge Health:      . | |
| 33 | **Time period for enrolment**. | |
| 34 | **Is the sample size justified in the protocol?**  Yes  No  *If no, provide sample size justification:* | |
| 35 | **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).** |
| 36 | **Briefly explain what methods will be used to analyze study data?** | |

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| **SECTION 3: 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/date in the footer. | | | | | |
| 37 | **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): | | | |
| 38 | **Who will identify potential study participants?** | | | | |
|  | Investigator/Study Personnel | | | |
|  | Other Healthcare Professional (i.e., non-study personnel) | | | |
|  | Self-Referral (i.e., response to advertisement) | | | |
| 39 | **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 | | | | |
| 40 | **Are you seeking permission for an alteration to consent requirements?**  Yes  No  *If yes, answer questions below::* | | | | |
| 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. | | | |
| e) | 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. | | | |
| 41 | **Describe the consent process (e.g. will consent be written, oral, telephone). Include script with this submission.** | | | | |
| 42 | **Who will obtain consent?** | | | | |
| 43 | **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.* | | | | |
| 44 | **How much time will be given to participants to review the information before being asked to give consent?** | | | | |
| 45 | **Does your research involve any of the following:** | | | | |
| a) | ***Special Considerations (check all that apply).*** | | | |
|  |  | Age Inclusion/Exclusion |  | Staff |
|  | Gender Inclusion/Exclusion |  | Students |
|  | Ethnicity Inclusion/Exclusion |  | Healthy Volunteers |
|  | Race Inclusion/Exclusion |  | Prisoners |
|  | Language Inclusion/Exclusion |  | Genetic Research |
|  | Participants Unable to Communicate |  | Tissue Samples |
|  | Women of Child Bearing Potential |  | Fetal Tissue or Placenta |
|  | Pregnant Women |  | None of the Above |
|  | Other (specify): | | |
| **Please provide a justification for any special considerations you checked off in part a):**    **Did you include the LH REB genetic wording below in the ICFs?**  Yes, it is on page       in the ICF  No, explain:  “*When you donate your blood or tissue for research, you are sharing genetic information, not only about yourself, but also about biological (blood) relatives who share your genes or DNA. There is a risk that information gained from genetic research could eventually be linked to you. This potential re-identification of the information could lead to loss of privacy for you or your biological relatives.”* | | | |
| b) | ***Capacity/Competency (check all that apply).*** | | | |
|  |  | 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.** | | | |
| **If participants are incapable of providing consent, how will substitute decision-makers 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) | ***Communication Difficulties (check all that apply):*** | | | |
|  |  | Individuals Who May Require Translation | | |
|  | Individuals Who Are Illiterate | | |
|  | Participants Who Have Trouble Understanding and/or Producing Speech (and require special support including the use of assistive devices) | | |
|  | None of the Above | | |
| **Provide an explanation of what procedures will be used to address any communication difficulties (e.g., the use of translated forms, translator and impartial witness).** | | | |
| 46 | **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 4: RISKS, BENEFITS AND SAFETY** | | |
| 47 | **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 |
| 48 | **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: | |
| 49 | **Does participation in this study affect alternatives for future care?**  Yes  No  *If yes, explain:* | |
| 50 | **List anticipated benefits to the participant, if any.**  Not Applicable | |
| 51 | **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): |
| 52 | **Is there a safety monitoring plan for the study?**  Yes  No  *If yes, please provide details:* | |
| 53 | **Is an interim analysis planned?**  Yes  No  *If yes, describe briefly:* | |
| 54 | **Is there a steering committee?**  Yes  No | |
| 55 | **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:* | |
| 56 | **Is the DSMB independent of the sponsor?**  Yes  No | |
| 57 | **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.** | |

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| **SECTION 5: 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 Health Information (PHI):** In this Application, PHI has the meaning ascribed to it in the *Personal Health Information Protection Act, 2004* (PHIPA). With limited exceptions, PHI 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, 1994* 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. | | | | | | | |
| 58 | **Has your research team been given training in privacy and confidentiality issues for this study?**  Yes  No  *If yes, what type of training has been provided:*  *If no, when and what type of training will be provided:* | | | | | | |
| 59 | **Will ANY Lakeridge Health data be transferred to other parties (identifying or de-identified)?**  Yes  No  Not Using LH data  *If yes, list the party where the data will be transferred (Note: if an agreement is required, please contact the LH Research Liaison)* | | | | | | |
| **Party** | | | | **De-identified Data** | | **Identifying Data** |
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| 60 | **Please list all the identifiers that will be collected, used and disclosed from the records during the course of the study and include the data collection form in this submission.** | | | ***Please check the applicable boxes below to indicate whether the information will remain at Lakeridge Health or be transferred to an external party.*** | | | |
| Part of LH Research Study Records & Remain on Site | | De-Identified Data Transferred to External Party | |
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| 61 | **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 | | | | | | |
| 62 | **Indicate how long the personal health information will remain identifiable and explain why.**  Not Applicable | | | | | | |
| 63 | **Explain why the research cannot reasonably be accomplished without using personal health information.**  Not Applicable | | | | | | |
| 64 | **Describe what will be done if personal health information is inappropriately released?** | | | | | | |
| 65 | **Describe how and when the personal health information will be disposed of or returned to the health information custodian.** | | | | | | |
| 66 | **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): | | | | | |
| 67 | **If personal health information is to be linked to other databases (e.g., health registries, Statistics Canada information) provide the details:**  Not Applicable | | | | | | |
| 68 | **Describe the data to which the personal health information will be linked.** | | | | | | |
| 69 | **Explain how the linkages will be made.** | | | | | | |
| 70 | **Explain why these linkages are required.** | | | | | | |
| 71 | **Indicate how study participants will be identified on data collection forms (e.g. study number, initials).**  Participant Identification #  Other (specify): | | | | | | |
| 72 | **Indicate how data will be stored.** | | | | | | |
|  | Computerized files: | | | | | |
|  |  | Server –  Internal  Contracted service 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): | | | | | |
| 73 | **Where will data be stored?**  On-Site  Off-Site, describe location (Institution name, city, country): | | | | | | |
| 74 | **Indicate which of the following measures will 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): | | | | | |
| 75 | **Indicate what, if any, additional security measures will be taken at the end of the study?** | | | | | | |
| 76 | **Indicate who might have access to data in the future.** | | | | | | |
| 77 | **Indicate how long study data will be retained, how it will be destroyed and by whom?** | | | | | | |

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| **SECTION 6: 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 *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 project  Declaration: 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. | | | | | | |
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|  | Name of Principal Investigator |  | Signature of Principal Investigator |  | Date |  |
|  | | | | | | |