**INSTRUCTIONS**

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.

This form is used to apply for **initial** REB review of new research studies that will **ACTIVELY RECRUIT** participants.

**All sections** of this application **MUST** be completed before it will be considered for REB review. All submitted study documents require a version and full date in footer, excluding application form. Please send your completed application and study documents to the Research Liaison/REB Coordinator, via email at REB@lh.ca.

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

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| **SECTION 1: GENERAL INFORMATION** |
| 1. | **Full Study Title & Protocol Number**  |
|  |
| **Short Title** *(if applicable)* |
|  |
| 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 done** (*select all that apply*): |
| a) | Clinical Trial:  | [ ]  Investigational product (drug, biologic, approved product new indication etc.)[ ]  Investigational device [ ]  Health-related intervention, specify:  |
| b) | Qualitative:  | [ ]  Observational [ ]  Questionnaire/surveys [ ]  Focus group [ ]  Interviews [ ]  Other (specify):  |
| c) | Biospecimen: | [ ]  Banking [ ]  Biomarker [ ]  Genetic [ ]  Other (specify):  |
| d) | Other (specify): |  |
| 4. | **Please specify the type of review you are requesting.** *(Note: REB will decide 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. | **Please answer the below questions and specify what documents will be submitted.** |
| [ ]  Yes [ ]  No | Do all the ICFs have the LH logo in the header? |
| [ ]  Yes [ ]  No | Are you using any eConsents or any patient facing websites? *If yes, please list link below.* |
| **Document**  | **Name of Document**  | **Version & Date**(dd-mmm-yyyy) |
| *LHREB application (mandatory)* | *LHREB Initial Application* |  |
| Protocol/proposal (mandatory) |  |  |
| Informed Consent Form(s)  |  |  |
| Data Collection Form/CRF  |  |  |
| Patient Facing Material  |  |  |
| IB/Product Monograph  |  |  |
| Other(s) (specify): |  |  |
| 8. | **Does this study involve submission to Health Canada?**  |
| [ ]  Yes, see attached [ ]  No [ ]  In Progress, still waiting to receive |
| 9. | **Is this study FDA-regulated?**  |
| [ ]  Yes [ ]  No *If yes, please provide FDA IND/IDE/PMA number*:  |  |
| 10. | **Is this study registered on a public website?** *(e.g., clinicaltrials.gov, etc.)*[ ]  Yes, list below [ ]  No  |
| Name of site registered:  |  |
| Registration number: |  |
| 11. | Conflicts of Interest (COI) do not mean wrongdoing. PIs must determine if any of the listed conflicts apply to any persons involved in the research study or their immediate family members. All contracts and potential conflicts of interest related to this project should be disclosed. A conflict of interest may also arise when health information is disclosed. Conflicts of interest guidelines and requirements do not replace this disclosure. |
| **Do any member(s) of the research team have an actual, potential or perceived COI with respect to this research application?**  [ ]  Yes, list below [ ]  No |
| a) | **Name** | **Financial** | **Status** | **Undue Influence** | **Competing Interest** | **Other**(Describe) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| b) | **Describe in detail COI**.  |  |
| c) | **How will COIs be managed?**  |  |
| 12. | **Has the research undergone review at another Research Ethics Board?**  |
| [ ]  Yes, please attached a copy[ ]  No  |
| 13. | **How will this study receive funded?** [ ]  Internal [ ]  External [ ]  None *List funding agency/sponsor name below:* |
|  |
| 14. | **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.** |
|  |
| 15. | **Choose the most effective way you will be delivering the study information.** *(check all that apply)* |
| [ ]  Peer reviewed publication [ ]  Thesis or dissertation [ ]  Study Registry [ ]  Presentation [ ]  Other (explain): |
| **SECTION 2: STUDY SUMMARY** *(A full separate protocol must be attached with this application)* |
| 16. | **Summary of study suitable for lay audience**: |
|  |
| 17. | **What is the rationale, primary outcome measures/goals of the study?** |
|  |
| 18. | **What are the study hypotheses or research questions?** |
|  |
| 19. | **Describe the design and methodology of the study.** |
|  |
| 20. | **What is the overall anticipated public and/or scientific benefits of this study?** |
|  |
| 21. | **List any criteria for premature withdrawal of a participant from the study for safety concerns.** [ ]  N/A |
|  |
| 22. | **Is this study using a placebo? If so, please provide justification and outline the provisions in place to minimize risks for participants assigned to the placebo.** [ ]  Yes [ ]  No  |
|  |
| 23. | **Does this study have control groups, please explain the rationale for using them?** [ ]  Yes [ ]  No  |
|  |
| 24. | **Does this study involve deception or intentional lack of disclosure? If so, please justify and explain how participants will be debriefed?** [ ]  Yes [ ]  No  |
|   |
| 25. | **Will the participant be withdrawn from or denied their usual therapy for any condition to participate in the study?** (*Includes prohibited/restricted medications for study*)[ ]  Yes, please explain below [ ]  No |
|   |
| 26. | **Will the participant be subject to other restrictions during the study?** [ ]  Yes, please explain below [ ]  No |
|  |
| 27. | **List the main inclusion and exclusion criteria for this study.** |
|  |
| 28. | **What is the total study enrollment:**  |
|  |
| 29. | **What is the number of participants to be enrolled at this Institution:**  |
|  |
| 30. | **Indicate the time period for enrollment:**  |
|  |
| 31. | **Is the sample size adequately justified in the protocol, and can you provide justification for the chosen sample size?** [ ]  Yes [ ]  No  |
|   |
| 32. | **Does this study involve an intervention?** [ ]  Yes, answer questions below [ ]  No |
| a) | What is the usual standard of care for this population?  |
|  |
| b) | What procedures will you carry out that are not part of standard care?  |
|  |
| c) | Indicate additional risks associated with the study as compared to usual standard of care.  |
|  |
| d) | Indicate duration of study visits & extra time commitment *(length, number and frequency of test sessions)*.  |
|  |
| 33. | **Briefly explain the methods you will use to analyze the study data.** |
|  |
| **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 and date in the footer. |
| 34. | **What tools will you use to identify potential participants for recruitment in the study?** |
| [ ]  | Permanent health record/clinical chart (specify source):  |
| [ ]  | Existing Database (specify):  |
| [ ]  | Advertisement, including web based tools (specify):  |
| [ ]  | Other (specify):  |
| 35. | **Who will identify potential study participants?** |
| [ ]  | Investigator/Study Personnel |
| [ ]  | Other Healthcare Professional (e.g., non-study personnel) |
| [ ]  | Self-Referral (e.g., response to advertisement) |
| 36. | **Will there be contact with potential participants, family members or substitute decision makers (SDM)?** [ ]  Yes, answer questions below[ ]  No |
| a) | List name of initial contact person: |
|  |
| b) | Does the participant, family member, or substitute decision-maker know this contact? |
|  |
| c) | How will contact be made (e.g. in person, phone, etc.)? Include scripts/written materials with submission. |
|  |
| 37. | **Are you seeking permission for an alteration to the consent requirement?** [ ]  Yes, answer questions below[ ]  No**The REB may approve research involving a change to consent when *all five* requirements outlined *in article 3.7A of the TCPS2 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 (refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience) 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 proposed alteration, the precise nature and extent of any proposed alteration id defined; plan to provide a debriefing (if any) that may also offer participant the possibility of refusing consent and/or withdrawing data and/or human biological materials.
 |
| a) | Specify the type of alteration: |
|  |
| b) | Explain how your request 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 provided to the participant for any questions or concerns. |
|  |
| 38. | **Describe the consent process** *(e.g., consent be written, oral, telephone)***. Include script with submission.** |
|  |
| 39. | **Who will obtain consent?** |
|  |
| 40. | **Is there a relationship between the participant and the Investigator or person obtaining consent?**[ ]  Yes, clarify relationships and outline steps to prevent undue influence[ ]  No  |
|  |
| 41. | **How much time will you provide participants to review the information before asking for their consent?** |
|  |
| 42. | **Does your research involve any special considerations with inclusion or exclusion, additional studies or sampling methods? If so, check all the apply and please justify each selected item.**  |
| **Special Consideration** | **Justification** |
| [ ]  | N/A |  |
| [ ]  | Age |  |
| [ ]  | Ethnicity |  |
| [ ]  | Language |  |
| [ ]  | Gender |  |
| [ ]  | Race |  |
| [ ]  | Child Bearing Women  |  |
| [ ]  | Fetal Tissue/Placenta |  |
| [ ]  | Genetic Research |  |
| [ ]  | Pregnant Women |  |
| [ ]  | Prisoners |  |
| [ ]  | Staff |  |
| [ ]  | Students |  |
| [ ]  | Tissue Samples |  |
| [ ]  | Unable to Communicate |  |
| [ ]  | Other *(specify)*: |  |
| 43. | **Does the participant lack capacity or is temporarily unable to provide consent?***According to* ***TCPS 2****, lack of capacity is the inability to provide* ***free, informed, and ongoing consent*** *due to factors such as* ***cognitive impairment*** *(e.g., dementia, intellectual disabilities, brain injury),* ***developmental stage*** *(e.g., children, some adolescents), or* ***temporary incapacity*** *(e.g., illness, injury, medical treatment).*[ ]  Yes, answer questions below[ ]  No |
| a) | Specify the reason for lack of capacity or temporary inability to consent. |
|  |
| b) | Detail the process for assessing capacity and identify the individual responsible for the assessment. |
|  |
| c) | Will a substitute decision-maker be designated, and if so, what is the process for their identification? |
|  |
| 44. | **If participant has communication difficulties** *(e.g., requires translation, is illiterate or needs special support or assistive devices)* **please explain the procedure that will be used to address these difficulties?** |
|  |
| 45. | **What steps will you take to determine if participants are already enrolled in other studies or are likely to enroll in other studies during this study's duration? If enrollment in multiple studies may be an issue for this population, please explain how you will address it.** |
|  |
| **SECTION 4: RISKS, BENEFITS AND SAFETY** |
| 46. | **Potential harms to participant** *(e.g., injury, discomfort and inconvenience, 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 associated with any tests, procedures, or other activities mandated by the protocol conducted solely for research purposes. |
|  |
| 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 payments will you provide to participants, family members, 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. | **Please confirm the following for the study and provide details where applicable:** |
| a) | Is a safety-monitoring plan in place? [ ]  Yes [ ]  No |
| If yes, provide details: |  |
| If no, describe alternative safety monitoring: |  |
| b) | Is an interim analysis planned? [ ]  Yes [ ]  No |
| If yes, briefly describe: |  |
| If no, explain why: |  |
| c) | Is a Data and Safety Monitoring Board (DSMB) established? [ ]  Yes [ ]  No |
| If yes, briefly describe: |  |
| If no, explain why: |  |
| Is the DSMB independent of the sponsor? [ ]  Yes [ ]  No [ ]  Not Applicable |
| If no, explain why: |  |
| **SECTION 5: PRIVACY AND CONFIDENTIALITY** |
| Researchers must adhere to Personal Health Information Protection Act (PHIPA) duties and Tri-Council guidelines on privacy, confidentiality, and consent in research. Personal Information (PI) in this application, as per PHIPA, refers to identifying information about an individual in oral or recorded form, with few exceptions, if information, * Pertains to physical or mental health, including family health history,
* Involves provision of health care, including identifying health care providers,
* Concerns long-term care plans under the Long-Term Care Act,
* Relates to health care payments or eligibility,
* Involves organ donation or testing/examination of bodily substances,
* Includes the individual’s health number,
* Identifies a provider of health care to the individual or a substitute decision-maker of the individual.
 |
| 52. | **Will you transfer any data outside of Lakeridge Health, whether identifying or de-identified?**[ ]  Yes, list the party below [ ]  No |
| **Party** | **De-identified Data** | **Identifying Data** |
|  | [ ]  | [ ]  |
|  | [ ]  | [ ]  |
| 53. | **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** | **Remains Onsite** (LH) | **Transfer Externally** |
|  |  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  |
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|  |  | [ ]  | [ ]  |
| 54. | **How are you transferring information and what security measures will be implemented?** *(e.g., de-identified data, secure network upload or download)*[ ]  Not Applicable |
|  |
| 55. | **Indicate how long personal information will remain identifiable and explain why.** |
|  |
| 56. | **Explain why you cannot reasonably conduct the research without using personal information.** |
|  |
| 57. | **List the steps you will follow if you inappropriately release personal information.** |
|  |
| 58. | **Describe how and when the personal information will be disposed of or returned to the Institution.** |
|  |
| 59. | **Identify all potential sources of this information.** |
| [ ]  | Directly from the patient |
| [ ]  | Health record/clinical chart (specify source):  |  |
| [ ]  | Existing database (specify):  |  |
| [ ]  | From other Institutions (specify):  |  |
| [ ]  | Other (specify):  |  |
| 60. | **Is personal information linked to other databases?**[ ]  Yes, answer below [ ]  No[ ]  Not Applicable  |
| a) | Provide details *(e.g., health registries, Statistics Canada information)* |
|  |
| b) | Describe the data to which you will link the personal information. |
|  |
| c) | Explain how you will create the linkages. |
|  |
| d) | Explain why these linkages are required. |
|  |
| 61. | **Indicate how you will identify study participants on data collection forms** *(e.g., study ID, initials. etc.)*[ ]  Participant Identification number |
| [ ]  Other (specify):  |  |
| 62. | **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):  |  |
| 63. | **Where will data be stored?** [ ]  On-Site [ ]  Off-Site  |
| If off site, describe location *(Institution name, city, country)*:  |  |
| 64. | **Which of the following measures will be done 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):  |
| 65. | **Indicate what additional security measures you will take at the end of the study, if any.** |
|  |
| 66. | **Indicate who might have access to data in the future.** |
|  |
| 67. | **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 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 |  |
|  |