**LHREB CONTINUING REVIEW FORM**

The Lakeridge Health Research Ethics Board (REB) exists to ensure that all research involving human participants conducted at LH meets the highest ethical and acceptable scientific and safety standards. These guidelines are in compliance with the requirements for continuing ethical review as set out in the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans Version 2 (TCPS),* the *International Conference on Harmonization Good Clinical Practice (ICH/GCP)*, and *Part C, Division 5 of the Food and Drug Regulations of Health Canada.*

The intent of this form is to update the REB on the progress of the study. It is the responsibility of the PI to submit this form to the REB a month prior to the REB expiry date for review and approval before the study can continue at LH. This form notifies the REB of the status of the study to date, and any potential amendments to the protocol. If there are changes, then the *Amendment Form* must be submitted. If the study is closed (i.e., completed as scheduled or prematurely terminated) the *Research Completion Form* must be submitted*.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **REB No.:** | **Contact Person:** | | | **Submission Date:** *(dd-mmm-yyyy)* | |
|  |  | | |  | |
| **Full Study Title:** | | | | | |
|  | | | | | |
| **LH Principal Investigator:** | | | **Email:** | | |
|  | | |  | | |
| **Current Protocol - Version & Date** *(dd-mmm-yyyy)*: | | | **Current Consent Form(s) - Version & Date** *(dd-mmm-yyyy*): | | |
|  | | |  | | |
| **Study Start Date**: *(dd-mmm-yyyy)* | | **Study End Date**: *(dd-mmm-yyyy)* | | | **Is this study closed to accrual?** |
|  | |  | | | Yes  No |
| **Initial REB Approval Date**: *(dd-mmm-yyyy)* | | | **REB Approval Expiry Date**: *(dd-mmm-yyyy)* | | |
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| **Please specify the nature of the study.** *(Check all that apply)* | | | | | | |
|  | Interventional | |  | Case Study |  | Chart Review |
|  | Prospective | |  | Educational |  | Human Tissue and Biological Specimens |
|  | Clinical Trial | |  | Observational |  | Epidemiological |
|  | Qualitative | |  | Retrospective |  | Quality Improvement/ Program Evaluation |
|  | Other *(specify)*: |  | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | **Please provide a lay summary of the study:** | | | | | | | | |
|  | | | | | | | | |
| 2. | **Please provide a brief summary (under 200 words) of the study’s activities, progress, or any interim findings from the past 12 months. This could include details such as data analysis, sponsor changes, or slower-than-expected global recruitment.** | | | | | | | | |
|  | | | | | | | | |
| 3. | **Was there a lapse in REB Approval?**  Yes  No | | | | | | | | |
| a. | If Yes, when was the last date of REB approval? | | | |  | | | |
| b. | Were study-related activities, such as data collection, conducted during the lapsed timeframe?  Yes  No *If Yes, please justify the continuation of data collection or treatment*: | | | | | | | |
|  | | | | | | | |
| c. | Provide the reason for the lapse and identify the steps taken to prevent future lapses: | | | | | | | |
|  | | | | | | | |
| 4. | **Summary of Study Participation at Lakeridge Health to Date** | | | | | | **No. of Participants** | | **Not Applicable** |
| *Number of participants originally planned to enroll in the study* | | | | | |  | |
| 1 | Currently screening or receiving intervention/observation | | | | |  | |  |
| 2 | In post-intervention follow-up | | | | |  | |  |
| 3 | Completed the study | | | | |  | |  |
| 4 | Transferred to another site | | | | |  | |  |
| 5 | Withdrew consent | | | | |  | |  |
| 6 | Expired prior to completing intervention/observation | | | | |  | |  |
| 7 | Screen-failed | | | | |  | |  |
| 8 | Planned chart reviews (retrospective/prospective) | | | | |  | |  |
| 9 | Completed chart reviews (retrospective/prospective) | | | | |  | |  |
| 10 | **Total number of participants enrolled in study:**  *(For recruited participant, lines 1-7 should total 10)*  *(For chart reviews, lines 7-9 should total 10)* | | | | |  | | |
| Additional Notes/Comments: | | |  | | | | | |
| 5. | **Since the last renewal, check if there have been any changes to the following:** | | | | | | | | |
|  | PI / Research Team *(submit research team form with this annual renewal)* | | | | | | | |
|  | Impact on LH Programs *(submit a revised DIA with this annual renewal)* | | | | | | | |
|  | Conflict of Interest/Privacy Breach, explain below: | | | | | | | |
|  | | | | | | | |
| 6. | **Have all reportable Serious Adverse Events (SAEs) and protocol deviations/violations involving Lakeridge Health participants been reported to the REB in the past 12 months?** | | | | | | | | |
|  | Yes, How many SAEs |  | | and/or Protocol Deviations/Violations | | |  | |
|  | No reportable SAEs have occurred | | | | | | | |
|  | No significant deviations/violations | | | | | | | |
|  | No, will submit immediately. *Please provide a reason below for the delay in reporting and identify the steps taken to prevent future delays.* | | | | | | | |
|  | | | | | | | |
| 7. | **In the PI's opinion, are there any safety concerns (local or global) or trends in the SAEs that could pose a risk to Lakeridge Health participants?** | | | | | | | | |
|  | Yes, please provide details and action taken below. | | | | | | | |
|  | | | | | | | |
|  | No | | | | | | | |

**Principal Investigator Declaration:** I confirm that during the course of the study, I have reviewed and reported any adverse events and/or any revisions to the study protocol, consent form, and impact on Lakeridge Health programs to the Research Ethics Board in a timely fashion. At this time, I am not aware of any new information that may affect the continuation of the study or require changes to the protocol. I will continue to report any future amendments, adverse events, protocol deviations, and privacy breaches.

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| Print Name | Signature of Principal Investigator or Designate | Date *(dd-mmm-yyyy)* |