|  |  |  |
| --- | --- | --- |
|  | RID No.:  |       |
|  | Contact Person:  |       |
|  | Submission Date:  |       |

**LHREB STUDY CLOSED TO ACCRUAL/CLOSURE 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.*

This Study Closed to Accrual/Closure Form is to be submitted to the REB for all studies that are terminated; i.e., studies that no longer require data collection, post-intervention follow-up, and data analysis or if this study is closed to accrual, but subjects are in “follow up”.

|  |  |
| --- | --- |
| **Full Study Title & Protocol No.:**  |       |
| **Principal Investigator:**  |       | **Email:** |       |
| **Start Date:** |       | **Termination Date:** |       |

**PLEASE CHECK ONE:**

|  |
| --- |
| [ ]  Closed to accrual ONLY[ ]  Completed as scheduled |
| [ ]  Premature termination of study due to: | [ ]  No Subjects |
| [ ]  Adverse Event(s) |
| [ ]  Other (*please specify*):       |

**STUDY RECRUITMENT INFORMATION:**

|  |  |  |
| --- | --- | --- |
| 1 |       | Number of participants originally planned |
| 2 |       | Number of participants in treatment *(only fill out if “closed to accrual” is checked off above)* |
| 3 |       | Number of participants in follow-up *(only fill out if “closed to accrual” is checked off above)* |
| 4 |       | Number of participants completed study |
| 5 |       | Number of participants withdrew consent |
| 6 |       | Number of participants transferred to another site |
| 7 |       | Number of participants screen failed |
| 8 |       | Number of participants expired |
| 9 |       | *Total number of participants enrolled in the study* ***(add lines 2-8 if closed to accrual only)*** *or* ***(add lines 4-8 if study is completed)*** *should equal line 9* |

Is there Intent to publish? [ ]  YES [ ]  NO [ ]  Unknown

Is there Intent to present? [ ]  YES [ ]  NO [ ]  Unknown

**SUMMARY OF CONCLUSIONS**: Attach a copy of the final report, if available.

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|       |

**Principal Investigator Declaration:** I confirm that throughout the course of the study, I have reviewed and reported any adverse events and/or any revisions to the study protocol, consent form, impact on Lakeridge Health programs and privacy breach to the Research Ethics Board in a timely fashion.

|  |  |  |
| --- | --- | --- |
|       |       |       |
| Print Name | Signature of Principal Investigator or Designate | Date |