**LHREB SAFETY & NOTIFICATION 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 form should be used when submitting the following documents: IBs, Safety Information, Data Safety Monitoring Board Letters, Dear Investigator Letters, Clarification Letters and any other Notification Letters that require acknowledgment from the Lakeridge Health REB.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **REB No.:** | **Contact Person:** | | **Submission Date:** *(dd-mmm-yyyy)* | |
|  |  | |  | |
| **Full Study Title:** | | | | |
|  | | | | |
| **LH Principal Investigator:** | | **Email:** | | |
|  | |  | | |
| **Items Received:** | | **Safety Implications** | | **Required Document Changes** |
|  | | Yes  No | | Yes  No |
|  | | Yes  No | | Yes  No |
|  | | Yes  No | | Yes  No |
|  | | Yes  No | | Yes  No |
|  | | Yes  No | | Yes  No |

**Principal Investigator Declaration:**

I acknowledge receipt of the documents listed above from the study sponsor. As the Principal Investigator, I have assessed the safety implications of the study at Lakeridge Health and confirm that any safety concerns and required documentation changes have been addressed by submitting an Amendment Form and/or Protocol Deviation Form for LH REB review and approval.

If no forms have been submitted, the reason is as follows:

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