**LHREB PROTOCOL DEVIATION 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.*

All studies in which there is a deviation from the approved protocol, consent form, impact on LH programs, and/or any other information pertaining to the study must be submitted by the PI to the REB for review and approval that the research remains scientifically and ethically sound before the study can continue at LH. Refer to *Guidelines for Reporting Protocol Deviations*.

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| --- | --- | --- |
| **REB No.:** | **Contact Person:** | **Submission Date:** *(dd-mmm-yyyy)* |
|  |  |  |
| **Full Study Title:**  |
|  |
| **LH Principal Investigator:** | **Email:** |
|  |  |

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| 1. | **Does the protocol deviation involve privacy (the theft, loss, or unauthorized *access, collection, use or disclosure of personal health information*)?**  |
|  | [ ]  Yes, then contact the LH Privacy Officer [ ]  No |
| 2. | **Describe the protocol deviation. Refer to the procedure from which the deviation occurred and indicate page number in the protocol.** |
|  | *Participant ID* | *Date of Protocol Deviation* | *Details* | *Protocol Page #* |
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| 3. | **Were study participant(s) adversely affected by the deviation?** |
|  | [ ]  Yes [ ]  No, explain and submit *Internal Serious Adverse Event (SAE) Report Form & Log.* |
| 4. | **Was study participant(s) informed of the deviation?** [ ]  Yes [ ]  No, explain:  |
|  |  |
| 5. | **How has this protocol deviation affected the safety or increased the risks to study participant(s)?** |
|  |  |
| 6. | **Describe corrective actions that will be taken to ensure that similar deviations do not occur in future.** |
|  |  |
| 7. | **Does the deviation affect the integrity of the study?** |
|  | [ ]  No [ ]  Yes, submit the *Amendment Form* |
| 8. | **Is there a deviation from the approved Impact Assessment on affected programs?** |
|  | [ ]  No [ ]  Yes, submit a new *Department Impact Assessment Form* and each respective *Fee Structure Form* to each identified program |

**Principal Investigator Declaration:** I attest that I am aware of the deviation and its safety implications, and that I have assessed the impact of the deviation on the study procedures. I have submitted an *Internal* *Serious Adverse Event (SAE) Report Form* & Log and/or *Amendment Form* when applicable.

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