**\*Refer to Policy REB-406 (Protocol Deviation) before completing this form.\***

|  |
| --- |
| **General Information:** |
| Holland Bloorview REB#: |
| Project Title: |
| Local Principal Investigator (LPI): |
| Today’s Date: Click here to enter a date. |
| Study Approval Expiry Date: Click here to enter a date. |

Primary protocol deviations must be reported to the REB using this form. **A protocol deviation is considered ‘primary’ if the answer to one or more of the following questions is ‘YES’**:

|  |  |  |
| --- | --- | --- |
| **Determination of Primary Protocol Deviations**  Did the protocol deviation: | **YES** | **NO** |
| Eliminate an immediate hazard(s) to participants or others? |  |  |
| Affect participant rights, welfare, or level of risk? |  |  |
| Impact the scientific integrity of the study? |  |  |
| Alter research participant eligibility? |  |  |
| Compromise the privacy of research participants or confidentiality of data? |  |  |

A protocol deviation is considered to be ‘secondary’ if the answer is ‘NO’ to all questions. If it is a secondary protocol deviation, do not submit this form to the REB. Instead, keep a ‘Protocol Deviation Log’ and refer to Standard Operating Procedure REB-406 for reporting requirements.

|  |  |
| --- | --- |
| Description of the Primary Protocol Deviation: | |
| Participant Study ID#: | |
| Date of protocol deviation:  Click here to enter a date. | Date of discovery:  Click here to enter a date. |
| Describe the primary protocol deviation in detail: | |
| Explain fully why the protocol deviation occurred: | |
| Describe the steps taken to correct/address any problems resulting from the protocol deviation: | |
| Describe the steps proposed to mitigate the risk of a similar protocol deviation in the future: | |
| Did (or could) the protocol deviation adversely affect the safety, welfare and/or well-being of research participants or others? If yes, please explain: | |
| Does (or could) the protocol deviation compromise the scientific integrity of the entire study? If yes, please explain: | |
| Is the protocol deviation repetitive in nature and affects the research participant’s safety, welfare or well-being or the scientific integrity of the entire study? If yes, please explain: | |

|  |  |  |
| --- | --- | --- |
| **Impact Assessment** | **YES** | **NO** |
| Does the protocol deviation result in permanent intentional action or process that revises/amends/modifies the approved protocol? If yes, submit an Amendment Request along with this Protocol Deviation Report Form as per Policy REB-409. |  |  |
| Does the protocol deviation require change(s) to the consent form(s)? If yes, submit an Amendment Request along with this Protocol Deviation Report Form as per Policy REB-409. |  |  |
| Did the protocol deviation result in an Adverse Event/Unanticipated Problem? If yes, submit an Adverse Event/Unanticipated Problem Report Form along with this Protocol Deviation Report Form as per Policy REB-407. |  |  |

***Local Principal Investigator Statement***

As Local Principal Investigator, I assume responsibility for the scientific and ethical conduct of this study. I agree to continue to conduct this study in compliance with the 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and, where required, in accordance with Health Canada regulations, Good Clinical Practices, and regulations in other jurisdictions.

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Signature Date (dd-mmm-yyyy)

**For REB Use Only**

Protocol Deviation Report reviewed and acknowledged as submitted.

Protocol Deviation Report requires revision and resubmission. The following additional information and/or revisions are required for REB review:

Study suspended pending further review

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Signature of REB Chair (or Designate)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date