***DEFINITIONS***

1. **Protocol Deviation:**

The term protocol deviation is not well defined by regulations or guidelines, but a deviation is any unplanned, unanticipated, or unintentional departure from the current HiREB-approved protocol, consent document, study addenda, or research activity. A deviation is different from an amendment in that it is generally applied to a single occurrence or participant, and is not intended at the time to modify the entire protocol.

Previously the term *protocol violation* was also used for certain situations. However, the terms *protocol deviation* and *protocol violation* may now be used interchangeably. The HiREB uses the term *protocol deviation* to refer to all such occurrences.

**NOTE: The only acceptable protocol deviation is when urgent action is required to eliminate an immediate hazard to a subject. This type of deviation must still be reported to the HiREB as outlined below.**

**The following protocol deviations are considered MINOR and need NOT be reported to the HiREB:**

a. Deviations that do not significantly affect the safety/well-being of the participant(s)

b. Deviations that do not increase the risk or decrease the benefit of the study

c. Deviations that do not significantly affect the integrity of the research data

**The Researcher MUST report to the HiREB any SIGNIFICANT deviations defined by the following criteria:**

a. Deviations that in the opinion of the Researcher jeopardize the safety of research participants, or that jeopardize

the research efficacy or data integrity

b. Any sponsor-approved waivers to the participant eligibility criteria

c. Any change in the approved process for obtaining consent

d. Any deviations that lead to an SAE or unanticipated problem

A protocol deviation must be reported to the HiREB **within 7 business days** of its discovery by using the HIREB **Protocol Deviation Report**. A copy of the sponsor protocol deviation or waiver form should be appended to the form. Other supporting documentation should be retained by the Researcher and be made available upon request.

1. **Waiver:**

An enrollment waiver that, in the opinion of the Researcher, is minimal risk, i.e., has no potential for negative

impact on the health and safety of the participant, may be implemented without **prior** HiREB approval. This waiver should still be reported to the HiREB within 7 business days of its occurrence.

**NOTE:** The HiREB will not give retroactive approval of a deviation.

***THE REPORT MUST BE TYPED—HANDWRITTEN COPIES WILL BE RETURNED***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| LOCAL PRINCIPAL INVESTIGATOR | | Click here to enter text. | | | |
| **STUDY TITLE AND REB NUMBER** | Click here to enter text. | | | | |
| What kind of Protocol Deviation is being reported?  **(See Instructions – Reporting Protocol Deviations & Waivers for definitions)** | | | Deviation | |  |
| Inclusion/Exclusion Waiver | |  |
| **Signature of Local Principal Investigator:** | | | | Date: | |
| DATE(S) WHEN THE PROTOCOL DEVIATION OCCURRED | | | Click here to enter text. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **1a** | In the opinion of the local principal investigator, does this deviation compromise the scientific integrity of the study? | YES |  |
| NO |  |
| **1b** | If YES, describe how this deviation will compromise the scientific integrity of the study.  Click here to enter text. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **2a** | In the opinion of the Local Principal Investigator, did the deviation increase the risk or decrease the benefit for the research participant(s)? | YES |  |
| NO |  |
| **2b** | If YES, discuss the increased risk or decreased benefit.  Click here to enter text. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **3a** | Was the protocol deviation the result of an error or incorrect action by the sponsor, investigator(s) and/or his/her staff? | YES |  |
| NO |  |
| **3b** | If YES, indicate what measures have been/will be taken to ensure this, or a similar problem, will not occur again.Click here to enter text. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **4a** | Was the protocol deviation caused by the research participant? | YES |  |
| NO |  |
| **4b** | If YES, indicate what measures have been/will be taken to ensure this, or a similar problem, will not occur again.Click here to enter text. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **5a** | Have you attached a copy of the Sponsor’s protocol deviation or waiver form? | YES |  |
| NO |  |
| NA |  |
| **5b** | If NO, provide a brief synopsis of the protocol deviation.  Click here to enter text. | | |

Submit one (1) **copy** of Report and supporting documents to the HiREB at the address noted below

***(DO NOT FAX OR EMAIL)***:

Hamilton Integrated Research Ethics Board

293 Wellington St. N., Ste 102

Hamilton, ON L8L 8E7

*For assistance contact the Research Ethics Officer at 905-521-2100 x 44574*

***(This box to be completed by the LPI)***

**REB Project #:** Click here to enter text.     **Local Principal Investigator:** Click here to enter text.

**Title of Study:** Click here to enter text.

**Event/Pt ID #:** Click here to enter text.      **and/or Date of Event:**  Click here to enter text.

**REVIEW OF PROTOCOL DEVIATION / WAIVER BY HiREB**

***(This box to be completed by the HiREB Chair only)***

**Further review is NOT required by the HiREB**

**Changes are required by the HiREB**

**Recommendations:** Click here to enter text.

**Protocol change:  YES  NO**

**Consent Form change:  YES  NO**

**Description of Changes Required:** Click here to enter text.

**Final Disposition by the HiREB:**

**Approved for continuation**

**Approved conditional on changes**

**Suspended pending further review**

**COMMENTS:** Click here to enter text.

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**Signature of Chair, HiREB (OR Designate) Date**