# William Osler Health System Logo

**Research Ethics Board**

William Osler Health System

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# PROTOCOL DEVIATION FORM

**The Osler Research Ethics Board serves as the Board of Record for Headwaters Health Care Centre and Home & Community Care Support Services Central West.**

Sites included in this review **(PLEASE CHECK ALL THAT APPLY)**:

**[ ]**  William Osler Health System **[ ]**  Headwaters (HHCC) **[ ]**  Home & Community Care Support Services CW

1. STUDY INFORMATION

|  |  |
| --- | --- |
| Name of Principal Investigator |       |
| Study Full Title: |       |
| Sponsor: |       |
| Osler REB# |       |

1. TYPE OF PROTOCOL DEVIATION

|  |  |
| --- | --- |
| [ ]  | Changes to study procedures |
| [ ]  | Enrollment of a participant who did not meet the inclusion/exclusion criteria |
| [ ]  | Over-enrollment exceeding the number of participants approved by the REB |
| [ ]  | Deviation on the consent form (i.e., missing documentation on the ICF, failure of obtain consent, used an unapproved or wrong consent form, etc.) |
| [ ]  | Performance of a study procedure not approved by the REB |
| [ ]  | Deviation on study procedure (i.e., failure to perform a study procedure that may affect patient safety, procedure or visit performed outside the time frame specified in the protocol, etc.  |
| [ ]  | Study drug or intervention errors (i.e., incorrect dosing) |
| [ ]  | Potential breach of confidentiality (i.e., missing documents, digital security breach, misplace of USB, etc.) |

1. PROTOCOL DEVIATION REPORTING

|  |  |
| --- | --- |
| Date of Protocol Deviation: (DD/MMM/YY) |       |
| Date Deviation Reported to REB:(DD/MMM/YY) |       |
| Date Deviation Reported to Sponsor:(DD/MMM/YY) |       |
| This report pertains to a single study subject?[ ]  No [ ]  Yes [ ]  N/AThis report pertains to more than one study subject?[ ]  No [ ]  Yes [ ]  N/A | Study Subject Number(s):

|  |
| --- |
|       |
|       |
|       |
|       |

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| Please provide description of the protocol deviation and attach relevant supporting documentation, including report filed with the study sponsor: |       |
| Were study subject(s) adversely affected by the deviation? | [ ]  No [ ]  YesIf Yes, please explain and submit a serious internal adverse event reporting form:       |
| Were study subject(s) informed of the deviation? | [ ]  No [ ]  Yes If No, please explain:       |
| How has this protocol deviation affected the safety/increased the risks to study subject(s) in the approved protocol? |       |
| Please describe any corrective actions that will be taken to ensure similar deviations do not occur in the future:Is a CAPA attached to this submission |      [ ]  No [ ]  Yes |
| In your opinion, does the deviation affect the integrity of the study data? | [ ]  No [ ]  Yes |
| Will a protocol amendment be submitted? | [ ]  No [ ]  Yes |

This signature attests that the PI is aware of the deviation and its safety implications and has assessed the impact of the deviation on the study procedures:

Principal Investigator:

 *Print Name Signature Date (DD/MMM/YY)*