# 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/A  This report pertains to more than one study subject?  No  Yes  N/A | Study Subject Number(s):   |  | | --- | |  | |  | |  | |  | |
| 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  Yes  If 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)*