# OVHLOGO_2CPOS_RGBOak Valley Health Research Ethics Board (REB)

# PROTOCOL DEVIATION FORM

**Please complete this form electronically (i.e., not handwritten) and submit one signed copy to the REB at** [**ResearchAdmin@msh.on.ca**](mailto:ResearchAdmin@msh.on.ca)

**Please note: Deviations must be reported to the REB within 15 calendar days of the Principal Investigator becoming aware of the protocol deviation. For more information, refer to the Oak Valley Health Reporting Protocol Deviations Guidelines**

|  |  |  |  |
| --- | --- | --- | --- |
| **I. STUDY INFORMATION** | | | |
| Date of Submission: |  | | |
| Site: | Markham Stouffville Hospital  Uxbridge Hospital | | |
| Study title: |  | | |
| Oak Valley Health REB #: |  | Study expiry date: |  |
| Principal Investigator (PI) | Name: | Email: | Telephone: |

|  |  |
| --- | --- |
| **II. TYPE OF PROTOCOL DEVIATION** | |
|  | Changes to study procedures(s) to eliminate immediate hazard to research participants |
|  | 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 to 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.) |
|  | Other (please specify): |

|  |  |
| --- | --- |
| **III. PROTOCOL DEVIATION REPORTING** | |
| Date of Protocol Deviation: | Click here to enter a date. |
| Date Deviation Reported to REB: | Click here to enter a date. |
| Date Deviation Reported to Sponsor: | Click here to enter a date.  N/A |
| Please provide description of the protocol deviation, reasoning for the protocol deviation, and attach relevant supporting documentation, including report filed with the study sponsor: |  |
| Does this report pertain to a single study participant?  Yes  No  N/A  Does this report pertain to more than one study participant?  Yes  No  N/A | If applicable, provide Study Participant Number(s): |
| Were the study participant(s) adversely affected by the deviation? | Yes  No  Unknown  If Yes, please explain and submit an internal serious adverse event (SAE) reporting form: |
| Were the study participant(s) informed of the deviation? | Yes  No  If No, please explain: |
| Was the participant withdrawn as a result of this protocol deviation? | Yes  No  If Yes, provide the date the participant was withdrawn: |
| How has this protocol deviation affected the safety/increased the risks to study participant(s) in the approved protocol? |  |
| Please describe any corrective/preventative actions that will be taken to ensure similar deviations do not occur in the future: |  |
| Is a CAPA attached to this submission? | Yes  No |
| In your opinion, does the deviation affect the integrity of the study data? | Yes  No |
| Will a protocol amendment be submitted to the REB for review and approval as a result of the deviation? | Yes  No |

**PRINCIPAL INVESTIGATOR ATTESTATION:** This signature attests that the Principal Investigator is aware of the deviation and its safety implications and has assessed the impact of the deviation on the study procedures:



**Print Name:**       **Signature**: **Date:**

# List of Attached Documents

Please submit any relevant supporting documentation for this protocol deviation. Provide clean and tracked (redlined) copies of revised study documents. Please ensure you provide updated version dates of revised documents. Add additional rows as needed.

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of document** | | **Name of Document** | **Version number/date** |
| **Clean** | **Tracked** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |