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| --- | --- | --- | --- |
|  | | | |
| **REB Study Number:**  **Pt\_ID:** | \_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_ \_\_\_\_\_\_\_ | **STUDY NAME:** |  |

**Has the participant had any Adverse Events during this study? *(If yes, please list all Adverse Events below)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Severity** | **Study Intervention Relationship** | **Action Taken Regarding Study Intervention** | **Outcome of AE** | **Expected** | **Serious** |
| 1 = Mild  2 = Moderate  3 = Severe | 1 = Definitely related  2 = Possibly related  3 = Not related | 1 = None  2 = Discontinued permanently  3 = Discontinued temporarily  4 = Reduced Dose  5 = Increased Dose  6 = Delayed Dose | 1 = Resolved, No Sequel  2 = AE still present- no treatment  3 = AE still present-being treated  4 = Residual effects present-not treated  5 = Residual effects present- treated  6 = Death  7 = Unknown | 1 = Yes  2 = No | 1 = Yes  2 = No  (If yes, complete SAE form) |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adverse Event | Start Date | Stop Date | Severity | Relationship to Study | Action Taken | Outcome  of AE | Expected? | Serious Adverse Event? | PI Initials |
| **1.** |  |  |  |  |  |  |  |  |  |
| **2.** |  |  |  |  |  |  |  |  |  |
| **3.** |  |  |  |  |  |  |  |  |  |

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| --- |
| Describe the Adverse Event(AE) / Unanticipated Problem *(including why it is considered an unanticipated problem; concomitant illness; past medical history; medications; relevant test results, etc.). \*attach the completed sponsor’s serious adverse event (SAE) form (if applicable).* |
| Describe the research team’s response to the event. |
| |  |  |  | | --- | --- | --- | | Does the Adverse Event(AE) / Unanticipated Problem *require change(s) to the study protocol*? *If yes, submit the changes using the ‘Amendment and Administrative Change Request Form’.* |  |  | | Does the Adverse Event(AE) / Unanticipated Problem *require change(s) to the consent form(s)? If yes, submit the changes using the ‘Amendment and Administrative Change Request Form’.* |  |  | | Should study participants be *notified* of this Adverse Event(AE) / Unanticipated Problem?  If no, please explain |  |  | | Is this a reportable Serious Unexpected-Adverse Drug Reaction (SU-ADR) to Health Canada? |  |  |   YES NO  Participant’s outcome of the event *(if known).* |

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| Principal Investigator / Study team comments: |

DECLARATION BY PRINCIPAL INVESTIGATOR / Co - INVESTIGATOR

I attest that I as the Principal Investigator (PI) or Co-Investigator (Co-I) have reviewed the Adverse Event(AE) / Unanticipated Problem and its safety implications, assessed the relationship of the Adverse Event(AE) / Unanticipated Problem to the research study and attest to the accuracy of this report.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Printed Name of Principal Investigator |  | Signature**\***  \*Original Ink or electronic/digital signature |  | Date |