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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)***

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| --- | --- | --- | --- | --- | --- |
| **Severity** | **Study Intervention Relationship** | **Action Taken Regarding Study Intervention** | **Outcome of AE** | **Expected** | **Serious** |
| 1 = Mild2 = Moderate3 = Severe | 1 = Definitely related2 = Possibly related 3 = Not related | 1 = None2 = Discontinued permanently3 = Discontinued temporarily4 = Reduced Dose5 = Increased Dose6 = Delayed Dose | 1 = Resolved, No Sequel2 = AE still present- no treatment3 = AE still present-being treated4 = Residual effects present-not treated5 = Residual effects present- treated6 = Death7 = Unknown | 1 = Yes2 = No | 1 = Yes2 = No(If yes, complete SAE form) |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adverse Event | Start Date | Stop Date | Severity | Relationship to Study  | Action Taken | Outcomeof 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. |
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| 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 NOParticipant’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.

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