

**Mount Sinai Hospital Research Ethics Board (MSH REB)**

**INTERNAL SERIOUS ADVERSE EVENT / UNANTICIPATED PROBLEM REPORTING FORM**

Do not leave any box blank. Submit a typed, hard copy of this form with **original signature** to the REB office for review. See *Guidelines for Reporting Serious Adverse Events/Unanticipated Problems* to the MSH REB for more information.

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| MSH Principal Investigator:      | MSH REB Number:       | Sponsor:       |
| Person Completing Form:       | Phone Number:       | Email Address:       |
| Study Title:       |
| Participant ID #:      | Date of Report:     (DD/MMM/YY) | Start Date of Event:     (DD/MMM/YY) | End Date of Event:     (DD/MMM/YY) |
|  |
| **MSH Investigator Assessment of INTERNAL (local) Serious Adverse Event (SAE)** | **YES** | **NO** |
| Is this adverse event/unanticipated problem *serious*? |  |  |
| Is this adverse event/unanticipated problem *unexpected*? |  |  |
| Is there a reasonable possibility\* that this adverse event/unanticipated problem may be *related* to the research? *(\* A reasonable possibility means that a causal relationship cannot be ruled out.)*  |  |  |
| **\*\*If you answer NO to any of the above questions, report submission to the MSH REB is not required\*\*** |
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| Type of Report: [ ] Initial [ ] Follow-up [ ] Final*If* ***follow-up*** *or* ***final*** *report, please indicate the REB submission date(s) of previous reports(s) (dd-mmm-yyyy)*    | Does the study have a DSMB: [ ]  Yes[ ]  No |
| Name of Adverse Event (AE)/Unanticipated Problem:  |
| Description of Adverse Event(AE)/Unanticipated Problem (including why it is considered an unanticipated problem; concomitant illness; past medical history; medications; relevant test results, etc. and an assessment as to whether the event reaction was mild, moderate or severe). |
| **SERIOUSNESS (outcome) of the Adverse Event (AE) / Unanticipated Problem:(check all that apply)** |
|  | Resulted in Death |
|  | Life Threatening |
|  | Required In-patient hospitalization or prolonged existing hospitalization |
|  | Resulted in persistent or significant disability/incapacity |
|  | Caused congenital malformation/birth defect |
|  | Based upon appropriate medical judgement, is an important medical event that may jeopardize the health of the research participant or may require medical intervention to prevent one of the outcomes listed above |
| **RESPONSE to Adverse Event (AE) / Unanticipated Problem** |
|  | None |
|  | Dose Adjusted |
|  | Discontinued from Study |
|  | Other (specify):  |
| **RELATEDNESS of the Adverse Event (AE) / Unanticipated Problem** |
|  | Related / Probably Related |  | Possibly Related |  | Unlikely |
| **MSH Investigator Impact Assessment of INTERNAL SAE/Unanticipated Problem** | YES | NO |
| Does this serious adverse event/unanticipated problem require a change *to the study protocol* and/or *consent form* and/or *require immediate notification* to research participants for safety reasons? |  |  |
| **\*\*If YES, submit the changes using the Amendment and/or Administrative Change Form\*\*** |
|  |
| **Comments:** |
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| **DECLARATION BY PRINCIPAL INVESTIGATOR** I attest that I as the Principal Investigator (PI) or MD Co-Investigator (Co-I) have reviewed the Adverse Event/ Unanticipated Problem and its safety implications, assessed the relationship of the Adverse Event/ Unanticipated Problem to the research study and attest to the accuracy of this report.I warrant that this study will continue to be conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans II (TCPS2), the Ontario Personal Health Information Protection Act (PHIPA) 2004, the other relevant laws, regulations or guidelines, [e.g., Health Canada Part C, Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations, Medical Devices Regulations, and ICH/GCP Consolidated Guideline E6].\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Printed Name of Signature of Date Signed (DD/MMM/YY)* *Principal Investigator Principal Investigator*  |