# OVHLOGO_2CPOS_RGBOak Valley Health Research Ethics Board (REB)

# EXTERNAL SERIOUS ADVERSE EVENT (SAE)/ UNANTICIPATED PROBLEM REPORTING FORM

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

Please note: External (non-local) SAE/unanticipated problems that requires change(s) and/or notification to participants must be reported to the REB within **3 calendar days** of the sponsor becoming aware of the event/report.

**Do not include this page with your submission.**

For more information, refer to the Oak Valley Health Guidelines: “**Reporting SAEs and Unanticipated Problems”** on ACORN REB page.

**DEFINITIONS:**

**Adverse Event (AE):** any unfavourable or unintended occurrence in the health or well-being of a research participant who is administered an investigational product (drug, natural health product, or device) or any other research procedure(s), which does not necessarily have a causal relationship with the investigational product/procedure. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of an investigational product, whether or not related to the investigational product.

**External (Non-local) Adverse Event:** An adverse event experienced by a research participant enrolled by the investigator(s) at other centres outside the jurisdiction of the REB. For example, the research participant is enrolled at an external site in a multi-centre trial in which Oak Valley Health is also a participating site.

**Serious Adverse Event (SAE) or Reaction:** any untoward medical occurrence that:

* Results in death;
* Is life-threatening;
* Requires inpatient hospitalization or prolongation of existing hospitalization;
* Results in persistent or significant disability/incapacity;
* Is a congenital anomaly/birth defect; and/or,
* Based on appropriate medical judgement, is an important medical event that may jeopardize the health of the study participant or may require medical intervention to prevent one of the outcomes listed above.

**Unanticipated Problem:** any incident, experience, or outcome that meets **ALL** of the following criteria:

* **Unexpected** (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents (e.g. the REB-approved research protocol and informed consent document, Investigator’s Brochure, and Product Monograph); and/or the characteristics of the research participant population being studied; AND
* **Related or possibly related** to participation in the research (i.e. at least a reasonable possibility exists that the incident, experience, or outcome may have been caused by the investigational product(s) or procedure(s) involved in the research; AND
* Suggests that the research **places research participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

**DO I NEED TO SUBMIT THIS FORM?**

1. Is this adverse event/unanticipated problem serious?
2. Is this adverse event/unanticipated problem unexpected?
3. 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)*

1. Does this adverse event/unanticipated problem require a change to study protocol, consent form, and/or require immediate notification to research participants for safety reasons? (*If yes, submit the changes using the Amendment and/or Change in Study Personnel Form)*

**If answered NO to any of the above questions, report submission to the Oak Valley Health REB is not required**

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| **I. STUDY INFORMATION**  |
| Date of Submission: |       |
| Oak Valley Health REB #: |       |
| Site: | **[ ]**  Markham Stouffville Hospital **[ ]**  Uxbridge Hospital  |
| Study title: |       |
| Initial approval date: |       | Study expiry date:  |       |
| Person Completing Form:  |       | Email & Phone:  |  |
| Principal Investigator (PI): |       | Sponsor: |       |
| Drug / Device / Intervention: |       | DSMB: | [ ]  Yes [ ]  No  |

# EXTERNAL SERIOUS ADVERSE EVENT (SAE)/ UNANTICIPATED PROBLEM REPORTING FORM

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| **I. SAE INFORMATION**  |
| **PI Initial & Date of Submission (dd-mm-yy)** | **SAE Serial # / IND Report #** | **Onset Date & Resolution Date of SAE** (respectively): | **Type:** | **Name or Medical Term of SAE**: | **Seriousness / Patient Outcome: (select all that apply)** | **Response to Event** | **Relationship to study at this site** | **Changes to protocol / consent form** |
| Same protocol | Same indication, different study | Different study, different indication |
|      Date:       |       | Date:      Date:       | [ ]  Initial[ ]  Follow-up[ ]  Final**If follow-up or final, indicate the REB submission date(s) of previous reports:**       |       | [ ]  Death[ ]  Life threatening [ ]  Hospitalization or prolonged existing hospitalization[ ]  Persistent or significant disability/incapacity[ ]  Caused congenital malformation / birth defect[ ]  Based on appropriate medical judgement, is an important medical event that may jeopardize the health of the study participant or require medical intervention to prevent one of the outcomes listed above. | [ ]  None[ ]  Dose Adjusted[ ]  Discontinued from Study[ ]  Other, specify:       | [ ]  | [ ]  | [ ]  | [ ]  Yes[ ]  No |

*(Add rows if needed)*

**Summary of Serious Adverse Event:**

*(e.g. Why it is considered an unanticipated problem; concomitant illness; past medical history; medications; relevant test results; assessment as to whether the event reaction was mild/moderate/severe; etc.)*

**PRINCIPAL INVESTIGATOR’S SIGNATURE:** This signature attests that the Principal Investigator has reviewed the SAE and its safety implications, assessed the relationship to the study intervention of the SAE, and attests to the accuracy of the form:

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