# OVHLOGO_2CPOS_RGB Oak Valley Health Research Ethics Board (REB)

# INTERNAL 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: Internal (local) SAE/unanticipated problems must be reported to the REB within **7 calendar days** of the PI becoming aware. If fatal of life-threatening, internal (local) SAE/unanticipated problems must be reported within **3 calendar days**.

**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.

**Internal (Local) Adverse Event:** An adverse event experienced by a research participant enrolled by the investigator(s) at one or more centres under the jurisdiction of the REB. In the context of a single-centre clinical trial, all adverse events would be considered internal (local) adverse events.

**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)*

**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 (if applicable): |       |
| Drug / Device/ Intervention:  |       | DSMB: | [ ]  Yes [ ]  No  |

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

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| --- |
| **I. SAE INFORMATION**  |
| **Subject Code:** | **Onset Date & Resolution Date of SAE** (respectively): | **Type:** | **Name or Medical Term of SAE**: | **Seriousness / Patient Outcome: (select all that apply)** | **Response to Event** | **Unexp-ected event** | **Relationship to Study Intervention** | **Study Action recommended** (If yes, go to \*) |
| Definitely/ Probably Related | Possibly Related | Unlikely Related | Unrelated |
|       | 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 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  Yes[ ]  No |

|  |  |  |
| --- | --- | --- |
| **(\*) Study action recommended by PI** 🡪 | **PI recommends changes to:** (*If requires change to study protocol, consent form, and/or immediate notification to research participants for safety reasons, must submit the changes using the Amendment and/or Change in Study Personnel Form)* | **Does this SAE meet the criteria for submission to Health Canada?** |
| **Protocol:**[ ]  Yes[ ]  No | **Consent Form:**[ ]  Yes[ ]  No | **IB:**[ ]  Yes[ ]  No | **Other Changes:**[ ]  Yes[ ]  No**If yes, specify:**       | [ ]  Yes – The PI attests that the SAE has been or will be submitted to Health Canada as required[ ]  No – The PI attests that the SAE does not require submission to Health Canada |

**Summary of Serious Adverse Event:**

**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:**