**Internal SERIOUS ADVERSE EVENT REPORTING FORM**

(Version Date: 16 April 2013)

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| Sites included in this review (**PLEASE CHECK ALL THAT APPLY**):[ ]  William Osler Health System [ ]  Headwaters Health Care Centre [ ]  Central West CCAC |

***Please refer to the WOHS REB Guidelines for SAE/Unanticipated Problems for reporting timelines: (***[***http://www.williamoslerhs.ca/research-and-education/research/research-ethics-board***](http://www.williamoslerhs.ca/research-and-education/research/research-ethics-board)***)***

| **Principal Investigator (PI):**      | **Person Completing Form****Name:****Phone Number:**  **Fax Number:**  |
| --- | --- |
| **PROTOCOL TITLE:**  | **Drug / Device / Intervention:**  | **Sponsor:**  | **DSMB** [ ]  **Yes**[ ]  **No** |
| **Date of Submission****(dd-mm-yy)** | **Subject Code** | **Onset Date & Resolution Date** **of SAE** | **Type** | **Name or Medical Term of SAE** | **Patient Outcome**1 = Death 2 = Hospitalization3 = Medical Intervention4 = Recovered5 = Other (specify) | **Response to Event**1 = None2 = Dose Adjusted3 = Discont’d from Study4 = Other (specify) | **Unexpected event** | **Relationship to Study Intervention** | **Study action recom-mended** **(**go to \*) |
| Definitely/Probably Related | Possibly Related | Unlikely/ Unrelated |
|       |       | **Date:** **Date:**  | [ ]  Initial[ ]  F/Up [ ]  Final |       |       |       | [ ]  Yes[ ]  No | [ ]  | [ ]  | [ ]  | [ ]  Yes[ ]  No |
| **(\*) Study action recommended by PI 🡪** | **PI recommends changes to:****Protocol Consent Form IB Other changes**[ ]  **Yes** [ ]  **Yes** [ ]  **Yes** [ ]  **Yes - Specify:** [ ]  **No** [ ]  **No** [ ]  **No** [ ]  **No** |

# **Summary of Serious Adverse Event:**