**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 = Hospitalization  3 = Medical Intervention  4 = Recovered  5 = Other (specify) | **Response to Event**  1 = None  2 = Dose Adjusted  3 = Discont’d from Study  4 = 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:**