**External SERIOUS AND UNEXPECTED 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 |

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| **Principal Investigator (PI):** Click or tap here to enter text. | **Person Completing Form:** Click or tap here to enter text.**Phone Number:** Click or tap here to enter text. | **Fax Number:** Click or tap here to enter text. |
| **PROTOCOL TITLE:** Click or tap here to enter text. | **Drug / Device / Intervention:** Click or tap here to enter text. | **Sponsor:** Click or tap here to enter text. | **DSMB**[ ]  **Yes**[ ]  **No** |
| **PI Initial****&**Date of Submission**(dd-mm-yy)** | **SAE Serial # / IND Report #**  | **Onset Date & Resolution Date** **of SAE** | **Type** | **Name or Medical Term of SAE** | **Patient Outcome**1 = Death2 = Hospitalization3 = Medical Intervention4 = Recovered5 = Other (specify) | **Response to Event**1 = None2 = Dose Adjusted3 = Discontinued from Study4 = Other (specify) | **Relationship to study at this site** | **Changes to****protocol/consent form** |
|  |  |  |  |  |  |  | Same protocol | Same indication, different study | Different Study, different indication |  |
| Click or tap here to enter text. | Click or tap here to enter text. | Date: Click or tap here to enter text.Date: Click or tap here to enter text. | [ ] Initial[ ] F/Up [ ] Final | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ] [ ]  [ ]  Yes [ ]  No |
| Click or tap here to enter text. | Click or tap here to enter text. | Date: Click or tap here to enter text.Date: Click or tap here to enter text. | [ ] Initial[ ] F/Up [ ] Final | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ] [ ]  [ ]  Yes [ ]  No |
| Click or tap here to enter text. | Click or tap here to enter text. | Date: Click or tap here to enter text.Date: Click or tap here to enter text. | [ ] Initial[ ] F/Up [ ] Final | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ] [ ]  [ ]  Yes [ ]  No |
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|  |  | Date: Click or tap here to enter text.Date: Click or tap here to enter text. | [ ] Initial[ ] F/Up [ ] Final | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ] [ ]  [ ]  Yes [ ]  No |

***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)***)***