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