**FORM 8.1B SERIOUS ADVERSE REPORT FORM**

For the purposes of this form, a serious adverse event is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, results in congenital anomalies/birth defects, or in the opinion of the investigators represents other significant hazards or potentially serious harm to research participants or others. A serious adverse event is considered unexpected if it is not described in the Package Insert or in the Investigator’s Brochure (for investigational agents), in the protocol, or in the informed consent document.

Date: (dd/mm/yy)

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| ***PROTOCOL TITLE:*** | |
| PRINCIPAL INVESTIGATOR: | Institution:  Phone: Email:…………………………. |
| Date became aware of SAE:  \_\_\_\_\_\_ /\_\_\_\_\_\_ /\_\_\_\_\_\_\_ | Type of Report: Initial.  Follow-up. |
| *Brief description of participant:* | SEX: M F AGE: (years) |
| Brief description of the nature of SAE, and sequence of events following onset of SAE (including diagnosis): | |
| Research involves a: DrugDevice  Procedure.  Is the drug/device investigational: Yes  No | Name of Drug, Device or Procedure: |
| Location of SAE: IDI Mulago  Kiswa Health Center | Severity of SAE (check only one):  Mild Moderate Severe but not fatal Fatal |
| Is the drug/device/procedure investigational:  Yes No | Causality:  Not related Unlikely  Possibly related Probably related Related Unknown |

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| ***Outcome of SAE* (check only one):**  Death (due to event)  Death (due to other causes) Hospitalization  Extended Hospitalization  Disability/incapacity  Requires intervention to prevent permanent impairment  Congenital Abnormality/ Birth defect  Recovered  Not yet recovered  Other (Specify) | | | | ***Relatedness of SAE to Research* (check only one):**  Not related (clearly not related to the research)  Unlikely (doubtfully related to the research)  Possible (may be related to the research)  Probable (likely related to the research)  Definite (clearly related to the research)  Undetermined | | |
| **Expectedness:** Expected Not expected | | | | **Recovery of Participant (check only one):**  Complete Moderate Minimal None Not yet resolved  Unknown | | |
| ***Have similar SAEs occurred on this protocol:*** Yes No  If “Yes”, how many? | | | | | | |
| ***What steps do you plan to take as a result of the SAE reported above (Check all that applies)?*** | | | No action required  Stop administration of study agent in the participant  Amend consent document  Amend protocol Inform current participants  Terminate or suspend protocol  Other (describe): | | | |
| **If changes are required to the protocol and/or consent form(s), state how soon the amended documents will be submitted to the IRB for approval:** | | | | | | Are being submitted now  Within 1 – 2 months |
| **If changes are not required, please explain as to why changes to the protocol /consent form are not necessarily based on the event:** | | | | | | |
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| **Report prepared by:** | |  | | | **Phone:**  **Email:** | |
| **Designation on the study:** |  |
|  |
| ***PI’S SIGNATURE:*** | | | | | ***DATE:*** | |