SANGATH INSTITUTIONAL REVIEW BOARD

**SERIOUS ADVERSE EVENTS REPORTING FORM (EXPEDITED REPORTING)**

All serious adverse events concerning a study approved by the Sangath Institutional Review Board should be reported to the Board. A serious adverse event may include Suspected Unexpected Serious Adverse Reactions (SUSARs) or violations/serious breaches of the protocol. A SUSAR is an unintended response to an intervention in a research study, which meets one of the following serious criteria: results in death, is life-threatening, requires hospitalisation or prolongation of an existing hospitalisation, results in persistent or significant disability or incapacity. Protocol violations are any deviations from the original protocol of a study that significantly affect the rights or interests of research participants, as well as impact the scientific validity of the study findings.

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| **1. Details of study** | |
| **1.1 Project Title** |  |
| **1.2 Name of Principal Investigator** |  |
| **1.3 Sangath IRB reference number** |  |
| **1.4 Date of submission** |  |
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| **2. Project summary (in brief)** | |
| 2.1 Date of event |  |
| 2.2 Date and time of first awareness of event |  |
| 2.3 Date of SAE form submission |  |

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| **3. Summary of the serious adverse event (including the nature, reasons for and consequences of the event on the participant/s, community, and the study)**  Please ensure that you do not exceed a maximum of 300 words. |
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| **4. Describe the impact on the study, including where temporary halt to activities took place.**  Please ensure that you do not exceed a maximum of 300 words. |
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| **5. Describe the management and follow-up of the serious adverse event.**  Please ensure that you do not exceed a maximum of 300 words. |
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| **6. Describe steps that will be taken to avoid recurrence of the serious adverse event (if possible).**  Please ensure that you do not exceed a maximum of 300 words. |
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