**Annexure-9**

**Serious Adverse Event Reporting Form**

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation
4. Date of EC approval:
5. Date of Start of study:
6. Participant details:

* Initials/ID:
* Age at the time of event
* Gender : Male/Female
* Weight (Kgs) :
* Height (cms) :

1. Suspected SAE Diagnosis:
2. Date of onset of SAE:
3. Describe the event:
4. Date of reporting SAE:
5. Details of suspected intervention causing SAE:
6. Report type: Initial/Follow-up/Final
7. If Follow-up report, state date initial report
8. Have any similar SAE occurred previously in this study? Yes/NO If yes, please provide details.
9. In case of a multi-centric study, have any of the other study sites reported similar SAEs ? (Please list number of cases with details if available)
10. Tick whichever is applicable for the SAE:
    * + Expected event/ Unexpected event
      + Hospitalization/ Increased Hospital Stay /Death /Congenital anomaly/birth defects/ Persistent or significant disability/incapacity/Event requiring intervention (surgical or medical) to prevent SAE/Event which poses threat to life/Others:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
11. In case of death, state probable cause of death:
12. Is there any permanent/ significant/ functional impairment : yes / no

If yes provide details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Details of Medical Management provided to Participant:
2. Details regarding compensation provided:
3. Outcome of SAE:

* Fatal
* Recovered
* Recovering
* Continuing
* Recovered with sequelae
* Not recovered
* Unknown

1. Provide any other relevant information that can facilitate assessment of the case such as medical history
2. Provide details about PI’s final assessment of SAE relatedness to research.

Signature of PI with date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_