Serious Adverse Event (SAE) Report Form

Protocol Title:
Protocol Number: **Site Number:** **Pt_ID:**

1. SAE Onset Date:

2. SAE Stop Date:

3. Location of serious adverse event (e.g. at study site or elsewhere):

4. Was this an unexpected adverse event?

   ☐ Yes ☐ No

5. Brief description of participant with no personal identifiers:

   Sex: ☐ Female ☐ Male Age:

6. Adverse Event Term:

7. Brief description of the nature of the serious adverse event (attach description if more space needed):

8. Category of the serious adverse event:

   ☐ death – date _____

   ☐ life-threatening

   ☐ hospitalization - initial or prolonged

   ☐ congenital anomaly / birth defect

   ☐ required intervention to prevent

   ☐ permanent impairment (Devices Only)

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☐ disability / incapacity ☐ important medical event

9. Intervention type:
   - ☐ Medication (Drug, Biological, Vaccine) or Nutritional Supplement: specify _____
   - ☐ Device: Specify: _____
   - ☐ Procedure/Surgery: Specify: _____
   - ☐ Behavioral/Life Style: Specify: _____
   - ☐ Radiation: Specify: _____
   - ☐ Genetic (gene transfer, stem cell, recombinant DNA): Specify: _____

10. Relationship of event to intervention:
   - ☐ Not Related (clearly not related to the intervention)
   - ☐ Possible (may be related to intervention)
   - ☐ Definite (clearly related to intervention)

11. Was study intervention discontinued due to event? ☐ Yes ☐ No

12. What medications or other steps were taken to treat serious adverse event?

13. List any relevant tests, laboratory data, history, including preexisting medical conditions

14. Type of report:
   - ☐ Initial
   - ☐ Follow-up
   - ☐ Final

Signature of Principal Investigator:_____ Date: