Serious Adverse Event (SAE) Report Form

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

1. SAE Onset Date: _____ (dd/mm/yyyy)

2. SAE Stop Date: _____(dd/mm/yyyy)

3. Location of serious adverse event: _____

4. Was this an unexpected adverse event? Yes ☐ No ☐

5. Brief description of participant(s) with no personal identifiers:
   Sex: F ☐ M ☐ Age: _____

   Diagnosis for study participation: _____

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

7. Category of the serious adverse event:

   ☐ death – date ☐☐/☐☐☐/☐☐☐☐(dd/mmm/yyyy)
   ☐ life-threatening
   ☐ hospitalization-initial or prolonged
   ☐ disability / incapacity
   ☐ congenital anomaly / birth defect
   ☐ required intervention to prevent permanent impairment
   ☐ other:_____

8. Intervention type:

   ☐ Medication or Nutritional Supplement: specify_____
   ☐ Device: Specify: _____
   ☐ Surgery: Specify: _____
   ☐ Behavioral/Life Style: Specify: _____

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9. Relationship of event to intervention:

- ☐ Unrelated (clearly not related to the intervention)
- ☐ Possible (may be related to intervention)
- ☐ Definite (clearly related to intervention)

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

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

_____

_____

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

_____

_____

13. Type of report:

- ☐ Initial
- ☐ Follow-up
- ☐ Final

Signature of Principal Investigator: _____ Date: _____