Serious Adverse Event Report Form

Protocol		**Site Number**	
Investigator		**Subject Number**	

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: _____
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: _____
9. <u>Relationship of event to intervention</u>:

   ☐ 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: _____