### Serious Adverse Event (SAE) Report Form

**STUDY NAME**

| Protocol Number: __________________________ | Date Participant Reported: __ __ / __ __ / __ __ __ __ |
| Site Name: __________________________ | d  d  m  m  m  y  y  y  y |
| Pt ID: __________________________ | __ __ / __ __ / __ __ __ __ |

1. SAE onset date: __ __ / __ __ / __ __ __ __ 
   d  d  m  m  m  y  y  y  y

2. SAE stop date: __ __ / __ __ / __ __ __ __ 
   d  d  m  m  m  y  y  y  y

3. Location of SAE: __________

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

5. Brief description of participants with no personal identifiers:
   Sex: □ F □ M  Age: ________
   Diagnosis for study participation: _________________________________

6. Brief description of the nature of the SAE (attach description if more space is needed):
   _________________________________________________________________

7. Category of the SAE:
   □ Date of death  __ __ / __ __ / __ __ (dd/mmm/yyyy)  □ Congenital anomaly/birth defect
   □ Life threatening  □ Required intervention to prevent permanent impairment
   □ Hospitalization – initial or prolonged  □ Other: _________________________________
   □ Disability/incapacity

8. Intervention type:
   □ Medication or nutritional supplement (specify): _________________________________
   □ Device (specify): _________________________________
   □ Surgery (specify): _________________________________
   □ Behavioral/lifestyle (specify): _________________________________
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 the SAE?
    
    ________________________________________________________________

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

13. Type of report:
   - Initial
   - Follow-up
   - Final

Signature of principal investigator: ________________________________ Date: __________________