1. SAE Onset Date: [enter SAE onset date] (dd/mmm/yyyy)
2. SAE Stop Date: [enter SAE stop date] (dd/mmm/yyyy)
3. Location of serious adverse event (e.g. at study site or elsewhere):
   1. [Enter location of SAE]
4. Brief description of participant with no personal identifiers:

Sex:  Female  Male Age: [Enter participant age]

1. Adverse Event Term(s): [Enter adverse event terms]
2. Brief description of the nature of the serious adverse event (attach description if more space needed):
   1. [Enter brief description of the nature of the SAE]
3. Category of the serious adverse event:

| death – date [Enter death date] (dd/mmm/yyyy) | congenital anomaly / birth defect |
| --- | --- |
| life-threatening | required intervention to prevent |
| hospitalization - initial or prolonged | permanent impairment |
| disability / incapacity | other: [other category of SAE] |

1. Intervention type:
   1. Medication or Nutritional Supplement: specify [specify text]
   2. Device: Specify: [specify text]
   3. Surgery: Specify: [specify text]
   4. Behavioral/Life Style: Specify: [specify text]
2. Relationship of event to intervention:
   1. Unrelated (clearly not related to the intervention)
   2. Possible (may be related to intervention)
   3. Definite (clearly related to intervention)
3. Was this an unexpected adverse event?
   1. Yes  No
4. Was study intervention discontinued due to event?
   1. Yes  No
5. What medications or other steps were taken to treat serious adverse event?
   1. [Medications or other steps were taken to treat SAE]
6. List any relevant tests, laboratory data, history, including preexisting medical conditions
   1. [Description]
7. Type of report:
   1. Initial
   2. Follow-up
   3. Final

Signature of Principal Investigator: [Signature of PI]

Date: [sign date] (dd/mmm/yyyy)