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)