| Protocol Title: [Enter protocol title] |
| --- |
| Protocol Number:[Enter protocol number] |
| Site Number: [Enter site number] |
| Pt\_ID: [Enter participant id] |
|  |

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):

[Enter location of SAE]

1. Was this an unexpected adverse event?

| [ ]  Yes | [ ]  No |
| --- | --- |

1. Brief description of participant with no personal identifiers:

| Sex: | [ ]  Female | [ ]  Male | Age: [Enter participant age] |
| --- | --- | --- | --- |

1. Adverse Event Term(s):

[Enter adverse event terms]

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

[Enter brief description of the nature of the SAE]

1. 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:

[ ]  Medication or Nutritional Supplement: specify [specify text]

[ ]  Device: Specify: [specify text]

[ ]  Surgery: Specify: [specify text]

[ ]  Behavioral/Life Style: Specify: [specify text]

1. Relationship of event to intervention:

[ ]  Unrelated (clearly not related to the intervention)

[ ]  Possible (may be related to intervention)

[ ]  Definite (clearly related to intervention)

| [ ]  Yes | [ ]  No |
| --- | --- |

1. Was study intervention discontinued due to event?
2. What medications or other steps were taken to treat serious adverse event?

[Medications or other steps were taken to treat SAE]

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

[List any relevant tests, lab data, history, including preexisting medical conditions]

1. Type of report:

[ ]  Initial

[ ]  Follow-up

[ ]  Final

Signature of Principal Investigator: [Signature of PI] Date: [sign date] (dd/mmm/yyyy)