| 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)