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| --- | --- | --- | --- |
| **Protocol Title:** | | | |
| **Protocol Number:**  **Site Number:**  **Pt\_ID:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  | | | |

1. SAE Onset Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (dd/mm/yyyy)
2. SAE Stop Date: \_\_\_\_\_\_\_\_\_\_(dd/mm/yyyy)
3. Location of serious adverse event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Was this an unexpected adverse event? Yes  No
5. Brief description of participant(s) with no personal identifiers:

Sex: F  M  Age: \_\_\_\_\_\_

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Category of the serious adverse event:

death – date \_\_/\_\_\_/\_\_\_(dd/mmm/yyyy)  congenital anomaly / birth defect

life-threatening  required intervention to prevent

hospitalization-initial or prolonged permanent impairment

disability / incapacity  other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Intervention type:

Medication or Nutritional Supplement: specify\_\_\_\_\_\_\_\_\_\_\_

Device: Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Surgery: Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Behavioral/Life Style: Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Relationship of event to intervention:

Unrelated (clearly not related to the intervention)

Possible (may be related to intervention)

Definite (clearly related to intervention)

1. Was study intervention discontinued due to event?  Yes  No
2. What medications or other steps were taken to treat serious adverse event?

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

1. Type of report:

Initial

Follow-up

Final

Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_