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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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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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: \_\_\_\_\_\_\_