

Serious Adverse Event (SAE) Report Form

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: _____

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

7. Category of the serious adverse event:

death – date __/__/__(dd/mmm/yyyy)

life-threatening

hospitalization-initial or prolonged

disability / incapacity

congenital anomaly / birth defect

required intervention to prevent permanent impairment

other: _____

8. Intervention type:

Medication or Nutritional Supplement: specify _____

Device: Specify: _____

Surgery: Specify: _____

Behavioral/Life Style: Specify: _____

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9. Relationship of event to intervention:

- Unrelated (clearly not related to the intervention)
- Possible (may be related to intervention)
- Definite (clearly related to intervention)

10. Was study intervention discontinued due to event? Yes No

11. What medications or other steps were taken to treat serious adverse event?

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

13. Type of report:

- Initial
- Follow-up
- Final

Signature of Principal Investigator: _____ Date: _____