



Serious Adverse Event (SAE) Report Form

STUDY NAME

Protocol Number: _____

Site Name: _____

Pt ID: _____

Date Participant Reported:

____/____/____
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1. SAE onset date: ____/____/____
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2. SAE stop date: ____/____/____
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3. Location of SAE: _____

4. Was this an unexpected adverse event? Yes No

5. Brief description of participants with no personal identifiers:

Sex: F M Age: _____

Diagnosis for study participation: _____

6. Brief description of the nature of the SAE (attach description if more space is needed):

7. Category of the SAE:

Date of death ____/____/____
(dd/mmm/yyyy)

Congenital anomaly/birth defect

Life threatening

Required intervention to prevent permanent impairment

Hospitalization – initial or prolonged

Other: _____

Disability/incapacity

8. Intervention type:

Medication or nutritional supplement (specify): _____

Device (specify): _____

Surgery (specify): _____

Behavioral/lifestyle (specify): _____

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 the SAE?

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

13. Type of report:

- Initial
- Follow-up
- Final

Signature of principal investigator: _____ Date: _____