Serious Adverse Event (SAE) Report Form

Protocol Title:

Protocol Number: _____

Site Number: _____

Pt_ID: _____

1. SAE Onset Date: _____ (dd/mmm/yyyy)
2. SAE Stop Date: _____ (dd/mmm/yyyy)
3. Location of serious adverse event (e.g. at study site or elsewhere):

   _____

4. Was this an unexpected adverse event? ☐ Yes ☐ No
5. Brief description of participant with no personal identifiers:

   Sex: ☐ Female ☐ Male Age: _____

6. Adverse Event Term(s):

   _____

   _____

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

   lkfdssdgdasg

   adglm'grekm

   _____

8. 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:_____

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9. Intervention type:

- ☐ Medication or Nutritional Supplement: specify_____
- ☐ Device: Specify: _____
- ☐ Surgery: Specify: _____
- ☐ Behavioral/Life Style: Specify: _____

10. Relationship of event to intervention:

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

11. Was study intervention discontinued due to event? ☐ Yes ☐ No

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

_____

_____

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

_____

_____

14. Type of report:

- ☐ Initial
- ☐ Follow-up
- ☐ Final

Signature of Principal Investigator: _____ Date: _____ (dd/mmm/yyyy)