National Center for Complementary and Integrative Health

Serious Adverse Event (SAE) Report Form

STUDY NAME

Protocol Number:_____

Site Name:_____

Pt ID:_____

Date Participant Reported:

__ __ / __ __ __ / __ __ __ __
d d m m m y y y y

1. SAE onset date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   d d m m m y y y y

2. SAE stop date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   d d m m m y y y y

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)
   ☐ 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/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: _____