Completion Date: __/__/____ Staff ID: ________________

A. EVENT INFORMATION – Completed at the HSCHS/SOL Field Center

1. Contract No.: HHSN ________________

2. Principal Investigator: ________________

3. Field Center: ________________

4. Date SAE occurred: __/__/____

5. Reported to: Principal Investigator
   Yes If Yes, date reported: __/__/____
   No
   Field Center IRB
   Yes If Yes, date reported: __/__/____
   No

6. Serious adverse episode affecting:
   a. Pregnant study participant
   b. Fetus
   c. Neonate
   d. Other: ________________________________

7. Category of the Serious Adverse Event
   a. Death
   b. Life-threatening
   c. Requires hospitalization
   d. Associated with disability/incapacity
   e. Likely associated with congenital anomaly / birth defect
   f. Required intervention to prevent permanent impairment
   g. Other: ________________________________
8. Describe the event (*Enter in a notelog on DMS.*)

9. Indicate whether the event is:  
   - 1 Ongoing
   - 2 Resolved

10. Describe what action was taken (*Enter in a notelog on DMS.*)

11.Likelihood of relationship to participation in HCHS/SOL:
   - 1- Unrelated (clearly not related)
   - 2- Unlikely (doubtful related)
   - 3- Possible (may be related)
   - 4- Probable (likely related)
   - 5- Definite (clearly related)

B. ACTIONS TAKEN BY INVESTIGATORS - Completed by the HCHS/SOL Coordinating Center

12. Reported to: NHLBI  OSMB

13. Was a change to the protocol made because of this SAE?
   - Yes  
     If Yes, date changed: 
   - No

14. Were any other actions taken by the investigators in response to this SAE?
   - Yes  
     If Yes, date actions taken: 
   - No

15. If yes to either of the above questions, please specify: ____________________________

16. Completion Date:  

CSCC Staff ID: