Administrative Information

0a. Completion Date: (m m / d d / y y y y )
0b. Staff ID: __________

Instructions: This form should be completed within 24 hours of an serious adverse event. An adverse event is serious if it affected a pregnant study participant, a fetus or a newborn, or if it results in any of the following outcomes: Death, A threat to life, Requires (inpatient) hospitalization, Likely causes persistent or significant disability or incapacity, Likely associated with a congenital anomaly or birth defect, Requires treatment to prevent one of the outcomes listed above, other than for pre-existing conditions detected as a result of participation in HCHS/SOL, its tests and examination protocol. Serious adverse events (SAEs) are therefore unanticipated and unexpected, whether study related or otherwise.

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

1. Contract No.:
   HHSN __________

2. Principal Investigator:

3. Field Center:

4. Date SAE occurred: (m m / d d / y y y y )

5. Reported to:
   Principal Investigator No 0 □
   Yes 1 □ date reported: __________
   Field Center IRB No 0 □
   Yes 1 □ date reported: __________

6. Serious adverse episode affecting:
   Pregnant study participant 1 □
   Fetus 2 □
   Neonate 3 □
   Other 4 □
   Specify: ______________________

7. Category of the Serious Adverse Event
   Death 1 □
   Life-threatening 2 □
   Requires hospitalization 3 □
   Associated with disability / incapacity 4 □
   Likely associated with congenital anomaly / birth defect 5 □
   Required intervention to prevent permanent impairment 6 □
   Other 7 □
   Specify: ______________________

SAE Serious Adverse Event Form -7-2-2014.doc
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:
   - Unrelated (clearly not related)  ☐ 1
   - Unlikely (doubtful related)  ☐ 2
   - Possible (may be related)  ☐ 3
   - Probable (likely related)  ☐ 4
   - Definite (clearly related)  ☐ 5

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?
   - No  0 ☐
   - Yes  1 ☐ If Yes, date changed:  ☐

14. Were any other actions taken by the investigators in response to this SAE?
   - No  0 ☐
   - Yes  1 ☐ If Yes, date action taken:  ☐

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

16. Completion Date:  ☐  ☐  ☐  CSCC Staff ID:  ☐  ☐  ☐