HCHS/SOL Serious Adverse Event Form Visit 2

Administrative Information

0a. Completion Date: [dd/mm/yyyy]

0b. Staff ID: [blank]

Instructions: This form should be completed within 24 hours of a 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] [blank]

2. Principal Investigator: [blank]

3. Field Center: [blank]

4. Date SAE occurred: [dd/mm/yyyy]

5. Reported to:
   Principal Investigator No [ ]
   Yes [ ] date reported: [dd/mm/yyyy]
   Field Center IRB No [ ]
   Yes [ ] date reported: [dd/mm/yyyy]

6. Serious adverse episode affecting:
   Pregnant study participant [ ]
   Fetus [ ]
   Neonate [ ]
   Other [ ]
   Specify: ____________________________

7. Category of the Serious Adverse Event
   Death [ ]
   Life-threatening [ ]
   Requires hospitalization [ ]
   Associated with disability / incapacity [ ]
   Likely associated with congenital anomaly / birth defect [ ]
   Required intervention to prevent permanent impairment [ ]
   Other [ ]
   Specify: ____________________________
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: □□□□