HCHS /SOL Serious Adverse Event Form

ID NUMBER:									FORM CODE: SAE VERSION: A 07/09/2010	Contact Occasion:	0	1	SEQ #	0	0

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.*

Completion Date: ☐☐/☐☐/☐☐☐☐ Staff ID: ☐☐☐
mm / dd / yyyy

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 ☐ 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: ________________________________

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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: ☐☐☐