HCHS /SOL Serious Adverse Event Form Visit 2		
ID NUMBER:FORM CODE: SAE VERSION: 1, 7/2/2014Contact Occasion:03SEQ #00		
Administrative Information		
0a. Completion Date: / / / / 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: $(mm / d d / y y y y)$		
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 Neonate 0ther 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:	_

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8. Describe the event (<i>Enter in a notelog on DMS.</i>)
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
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: ////////////////////////////////////