

HCHS /SOL Serious Adverse Event Form Visit 2

NU	ID FORM CODE: SAE Contact VERSION: 1, 7/2/2014 Occasion: 0 3 SEQ # 0 0	
Administrative Information		
0a.	Completion Date:/	
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.		
Α. Ι	EVENT INFORMATION – Completed at the HSCHS/SOL Field Center	
	Contract No.: HHSN	
2.	Principal Investigator:	
3. I	Field Center:	
<i>4.</i> [Date SAE occurred:	
5. I	(m m / d d / y y y y) 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	
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:	

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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:		
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 / 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:		