Hispanic	SOL HCHS	SOL Serious Adve	erse Event Form	Visit 2	
N	ID JMBER:	FORM CODE: SAE VERSION: 1, 7/2/2014	Contact Occasion: 0 2	SEQ # 0 0	
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.					
Α.	EVENT INFORMATION – Co	mpleted at the HSCHS/S	OL Field Center		
	Contract No.: HHSN				
2.	Principal Investigator:				
3.	Field Center:				
4.	Date SAE occurred:	//			
5.	Reported to: Principal Investigator	No 0 Yes 1 date reported	I:///		
	Field Center IRB	No 0 🗌 Yes 1 🗌 date reported	I://[
6.	Serious adverse episode affectir Pregnant study participant Fetus Neonate Other Specify:	g: 1 2 3 4			
7.	Category of the Serious Adverse Death Life-threatening Requires hospitalization Associated with disability / in Likely associated with conge Required intervention to prev Other Specify:	capacity nital anomaly / birth defect	1		

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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				
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: ////////////////////////////////////				