

HCHS /SOL Unanticipated Problem Form Visit 2

ID NUMBER: FORM CODE: UPR VERSION: 1, 06/29/2015	Contact Occasion: 0 2 SEQ#	
Administrative Information		
0a. Completion Date: m m / d d / y y y y)	0b. Staff ID:	
<u>Instructions:</u> This form should be completed within 48 hours of an Unanticipated Problem (UP). UPs include any experience or outcome that is unexpected, and related or possibly related to participation in SOL, and Suggestive that the research places subjects or others at a greater physical, psychological, economic, or social risk or harm than was previously known		
A. EVENT INFORMATION – Completed at the HSCHS/SC)L Field Center	
1. Contract No.: HHSN		
2. Principal Investigator:		
3. Field Center:		
4. Date UP occurred:		
(m m / 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. Source of the event: Interview with study participant 1		
7. Describe the event (inflit to 250 words of less)		

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8	3. Indicate whether the event is: Ongoing 1 Resolved 2
ξ	9. Describe what action was taken (limit to 250 words or less)
B. <i>A</i>	ACTIONS TAKEN - Completed by the HCHS/SOL Coordinating Center
10.	Reported to: NHLBI
11.	Was a change to the protocol made because of this UP?
	Yes 1 If Yes, date changed:///
12.	Were any other actions taken by the investigators in response to this UP? No 0
	Yes 1 If Yes, date action taken:
13.	If yes to either of the above questions, please specify:
14.	Completion Date: CSCC Staff ID: