HCHS /SOL Unanticipated Problem Form Visit 2

Administrative Information

0a. Completion Date: [ mm/dd/yyyy ]
0b. Staff ID: [ ]

Instructions: 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/SOL Field Center

1. Contract No.:
   HHSN

2. Principal Investigator:

3. Field Center:

4. Date UP occurred: [ mm/dd/yyyy ]

5. Reported to:
   - Principal Investigator: No [ ] Yes [ ]
     date reported: [ mm/dd/yyyy ]
   - Field Center IRB: No [ ] Yes [ ]
     date reported: [ mm/dd/yyyy ]

6. Source of the event:
   - Interview with study participant [ ]
   - Blood draw [ ]
   - Glucose load [ ]
   - Echocardiography scan [ ]
   - Other physical examination or tests [ ]
   - Other [ ]
   Specify: ___________________________

7. Describe the event (limit to 250 words or less)

______________________________
______________________________
______________________________
______________________________
______________________________
______________________________
______________________________
______________________________
8. Indicate whether the event is: Ongoing □ Resolved □

9. Describe what action was taken (limit to 250 words or less)

B. ACTIONS TAKEN - Completed by the HCHS/SOL Coordinating Center

10. Reported to: NHLBI □ OSMB □

11. Was a change to the protocol made because of this UP?
    No □
    Yes □ If Yes, date changed: □/□/□

12. Were any other actions taken by the investigators in response to this UP?
    No □
    Yes □ If Yes, date action taken: □/□/□

13. If yes to either of the above questions, please specify: ____________________________

14. Completion Date: □/□/□ CSCC Staff ID: □/□/□