HCHS /SOL Minor Adverse Event Form Visit 2

Instructions: This form should be completed within 7 days of a minor adverse event. An event is minor if it DOES NOT affect a pregnant study participant, a fetus or a newborn, or if it DOES NOT result 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. Minor adverse events (MAEs) are anticipated and expected to occur as stated risks in the study protocol, whether study related or otherwise.

A. EVENT INFORMATION – Completed at the HCHS/SOL Field Center

1. Contract No.: HHSN

2. Principal Investigator:

3. Field Center:

4. Date MAE 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 □
   Blood draw 2 □
   Glucose load 3 □
   Echocardiography scan 4 □
   Other physical examination or tests 5 □
   Other 6 □
   Specify: ______________________________

7. Describe the event (Enter in a notelog on DMS.)


ID NUMBER: ___________________________ FORM CODE: MAE VERSION: 1, 07/01/2014 Contact Occasion: 0 2 SEQ # __________
8. Indicate whether the event is: Ongoing 1 □ Resolved 2 □

9. Describe what action was taken (Enter in a notelog on DMS.)

10. Is this type of event foreseen in the Informed Consent or study MOP?
    No 0 □ Yes 1 □ (Go to End) Don’t know 9 □

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 □□/□□/□□

13. Was a change to the protocol made because of this MAE?
    No 0 □
    Yes 1 □ If Yes, date changed: □□/□□/□□

14. Were any other actions taken by the investigators in response to this MAE?
    No 0 □
    Yes 1 □ If Yes, date action taken: □□/□□/□□

15. If yes to either of the above questions, please specify: ________________________________

16. Completion Date: □□/□□/□□□□ CSOC Staff ID: □□□□