HCHS/SOL – Minor Adverse Event (MAE)

[Administrative Information]

0a. Completion Date (mm/dd/yyyy): date
0b. Staff ID: number

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; or 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: name

3. Exam Site/Field Center: location

4. Date MAE occurred: date

5. Reported to:
   a. Principal Investigator No 0
      Yes 1 a1. date reported: date
   b. Field Center IRB No 0
      Yes 1 b1. date reported: date

6. Source of the event:
   - Interview with study participant 1
   - Blood draw 2
   - Glucose load 3
   - DEXA scan 4
   - MRI scan 5
   - CT scan 6
Other physical examination or tests 7
Other source 8

a. If Other source, specify: ________________________________

7. Describe the event (Enter a note in CDART):

8. Indicate whether the event is: Ongoing 1 Resolved 2

9. Describe what action was taken (Enter in a note in CDART):

10. Was this type of event foreseen in the Informed Consent or study MOP?
    No 0 Yes 1 [END FORM] Don’t Know 9

11. Likelihood of relationship to participation in HCHS/SOL [Answered by site Principal Investigator only]:
    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 Coordinating Center

12. Reported to: a. NHLBI b. OSMB

13. Was a change to the protocol made because of this MAE?
    No 0
    Yes 1

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

15. If Yes to either Question 13 or 14, please specify: ________________________________

16. a. Completion Date: b. CSCC Staff ID: 

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