HCHS/SOL – Minor Adverse Event (MAE)

ID NUMBER:									FORM CODE: MAE VERSION: 2, 8/22/2019	Contact Occasion:	0	3	SEQ #		

ADMINISTRATIVE INFORMATION

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

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: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

3. Exam Site/ Field Center: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

4. Date MAE occurred: ☐☐/☐☐/☐☐☐☐ [MM/DD/YYYY]

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

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: ☐☐☐