

HCHS/SOL – Minor Adverse Event (MAE)

ID FORM CODE: MAE Contact VERSION: 2, 8/22/2019 Occasion: 0 3 SEQ #
ADMINISTRATIVE INFORMATION
0a. Completion Date (mm/dd/yyyy)://
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 Ves 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

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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
13. Was a change to the protocol made because of this MAE?
No 0
14. If Yes, date changed://
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: D. CSCC Staff ID: D. CSC