

HCHS /SOL Minor Adverse Event Form Visit 2

ID NUMBER: FORM CODE: MAE Contact VERSION: 1, 07/01/2014 Occasion: 0 2 SEQ#
Administrative Information
0a. Completion Date: (m m / d d / y y y y) 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, 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 HSCHS/SOL Field Center
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Contract No.: HHSN
2. Principal Investigator:
3. Field Center:
4. Date MAE occurred:
5. Reported to: Principal Investigator Yes 1 date reported:
Field Center IRB No 0
6. Source of the event:
Interview with study participant Blood draw Clucose load Echocardiography scan Other physical examination or tests Other Specify: 7. Describe the event (Enter in a notelog on DMS.)

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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 Definite (clearly related)
B. ACTIONS TAKEN BY INVESTIGATORS - Completed by the HCHS/SOL Coordinating Center
12. Reported to: NHLBI OSMB / OSMB
13. Was a change to the protocol made because of this MAE?
No 0
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: CSCC Staff ID: