



HCHS /SOL Minor Adverse Event Form Visit 2

ID NUMBER:

FORM CODE: MAE
VERSION: 1, 07/01/2014

Contact Occasion:

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 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 <input type="checkbox"/>
Blood draw	2 <input type="checkbox"/>
Glucose load	3 <input type="checkbox"/>
Echocardiography scan	4 <input type="checkbox"/>
Other physical examination or tests	5 <input type="checkbox"/>
Other	6 <input type="checkbox"/>

Specify: _____

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

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8. Indicate whether the event is: Ongoing Resolved

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 Yes (Go to End) Don't know

11. Likelihood of relationship to participation in HCHS/SOL:

- Unrelated (clearly not related)
- Unlikely (doubtful related)
- Possible (may be related)
- Probable (likely related)
- Definite (clearly related)

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
Yes If Yes, date changed: / /

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

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

16. Completion Date: / / CSCC Staff ID:
