

ID NUMBER:

FORM CODE: MAE
VERSION: 2, 8/22/2019

Contact Occasion: 01

SEQ #

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: