

ID NUMBER:

FORM CODE: MAE
VERSION: A 07/09/2010

Contact Occasion:

SEQ #

8. Indicate whether the event is: 1 Ongoing 2 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 ?

Yes (Go to End) No Don't know

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

- 1- Unrelated (clearly not related)
- 2- Unlikely (doubtful related)
- 3- Possible (may be related)
- 4- Probable (likely related)
- 5- 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?

Yes No
If Yes, date changed: / /

14. Were any other actions taken by the investigators in response to this MAE?

Yes No
If Yes, date actions taken: / /

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

16. Completion Date: / / CSCC Staff ID:
