

ID NUMBER:								
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FORM CODE: MAE
VERSION: 1, 7/01/2014

Contact Occasion:	0	2
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SEQ #		
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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.)

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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 ☐

B. ACTIONS TAKEN BY INVESTIGATORS - Completed by the HCHS/SOL Coordinating Center

12. Reported to: NHLBI

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 OSMB

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13. Was a change to the protocol made because of this MAE?

No 0 ☐

Yes 1 ☐ If Yes, date changed:

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

No 0 ☐

Yes 1 ☐ If Yes, date action taken:

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

16. Completion Date:

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 CSCC Staff ID:

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