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.

Completion Date: mm/dd/yyyy

A. EVENT INFORMATION – Completed at the HSCHS/SOL Field Center

1. Contract No.: HHSN

2. Principal Investigator:

3. Field Center:

4. Date MAE occurred: mm/dd/yyyy

5. Reported to:
   Principal Investigator
   Field Center IRB

6. Source of the event:
   a. Interview with study participant
   b. Blood draw
   c. Glucose load
   d. Lung function testing
   e. Other physical examination tests
   f. Other ____________________________

7. Describe the event (Enter in a notelog on DMS.)
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  
      - If Yes, date changed:
    - [ ] No

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

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

16. Completion Date:  
   - [ ] CSCC Staff ID:  