ADMINISTRATIVE INFORMATION

0a. Completion Date: __/__/____ 0b. Staff ID: __ __ __

Instructions: This form should be completed within 48 hours of a serious adverse event. An adverse event is serious if it results 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 ARIC, its tests and examination protocol. Serious adverse events (SAEs) are therefore unanticipated and unexpected, whether study related or otherwise.

A. EVENT INFORMATION – Completed at the ARIC Field Center

1. Contract No.: ____________________________________________________________

2. Principal Investigator: ________________________________________________

3. Field Center: __________________________________________________________

4. Did the participant have more than one event during their visit? ☐ YES or NO (Y or N)

5. If Yes, which event number is this: ☐ (1 through 9)

6. Date SAE occurred: __/__/____

7. Reported to: Principal Investigator ☐ Y Yes ☐ N No
   If Yes, date reported: __/__/____
   Field Center IRB ☐ Y Yes ☐ N No
   If Yes, date reported: __/__/____

8. Category of the Serious Adverse Event ☐
   Death...........................................................................................................A
   Life-threatening..........................................................................................B
   Requires hospitalization...........................................................................C
   Associated with disability/incapacity .......................................................D
   Likely associated with congenital anomaly / birth defect......................E
   Required intervention to prevent permanent impairment....................F
   Other: ........................................................................................................G
   Specify: ____________________________________________________________________
9. Describe the event:


10. Indicate whether the event is:  

   [ ] Ongoing  
   [x] Resolved

11. Describe what action was taken:


12. Likelihood of relationship to participation in ARIC:  

   [ ]
   Unrelated (clearly not related) .........................A
   Unlikely (doubtful related) ..............................B
   Possible (may be related) ..............................C
   Probable (likely related) .............................D
   Definite (clearly related) ............................E