SERIOUS ADVERSE EVENT FORM

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: S A E DATE: 04/01/2016 Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month Day Year) 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: ☐☐/☐☐/☐☐☐☐ (Month Day Year)

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: ☐O Ongoing
☐R 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