MINOR ADVERSE EVENT FORM

ID NUMBER: ___________________________ FORM CODE: MAE DATE: 04/01/2016 Version 1.0

ADMINISTRATIVE INFORMATION

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

Instructions: This form should be completed within 7 days of a minor adverse event. An event is minor 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 ARIC, 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.

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? ☐ Y Yes ☐ N No

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

6. Date MAE occurred: __/__/____

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

MAE- Minor Adverse Event Form
8. Source of the event: 

- Interview with study participant ................................ A
- Blood draw ....................................................... B
- Other physical examination tests .......................... D
- Other ....................................................................... E

Specify: _______________________________________

9. Describe the event:


10. Indicate whether the event is:  

☐ Ongoing

☐ Resolved

11. Describe what action was taken:


12. Is this type of event foreseen in the Informed Consent or study MOP  

☐ Y Yes (Go to End)

☐ N No

13. 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