MINOR ADVERSE EVENT FORM

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: M 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 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: ☐☐/☐☐/☐☐☐☐ (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. 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: ☐O Ongoing
☐R 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

INSTRUCTIONS FOR THE MINOR ADVERSE EVENTS FORM (MAE)

I. General Instructions

The Minor Adverse Events form is designed to track any adverse event considered minor that affects a study participant, whether or not it is related to his/her participation in ARIC. The form must be completed in CDART within 7 days of a minor adverse event.

See the ARIC Manual 2 Participant Safety section for a definition of adverse events and their classification as serious (or minor), expected (vs. unexpected), and study-related (vs. possibly study-related, or not study-related). That information is critical to an appropriate classification of adverse events and unanticipated problems, and must be considered before selecting this form to record and document a MAE.

Once the study participant's safety and comfort have been addressed following a Minor Adverse Event a MAE form is entered into CDART. The ARIC field center staff entering the SMAE form in the DMS then notifies the coordinating center by sending an email with the study participant ID to arichelp@unc.edu. These actions result in a review of the event by coordinating center personnel and a report of the MAE to the NHLBI by the Coordinating Center. No direct notification of an adverse event to NHLBI is required from the field center unless additional information is requested. Field centers also follow their Institution's protocol that may require notification of the study PI and the IRB.

All minor adverse events are entered into the data management system (CDART) and are periodically reported to NHLBI and the ARIC OSMB. The study participant does not need to be present when this form is completed.

This form may be accessed more than once, since information may not be complete at the time of initial entry about actions taken by the field center concerning the adverse event. Similarly, updates may be needed once more information related to the MAE becomes available. Arichelp@unc.edu should be notified if a MAE for is updated or reclassified.

II. Specific Instructions

Obtain as much information about the adverse event as possible before beginning to enter the MAE into CDART.

Items 1 through 3. Select the correct drop-down menu choice for each item. The Contract No. corresponds to the number of the federal contract that funds ARIC at the field center's institution. This number is available from the Study Coordinator or administrative staff.

Item 4. Record whether there was more than one minor adverse event for the participant during this visit.

Item 5. Record the event number.

Item 6. Enter the date when the adverse event occurred.

Item 7 – 7c. Enter whether the adverse event was reported to the Principal Investigator, the date reported, whether the adverse event was reported to the local IRB, and the date reported.

Item 8. Select the category from the dropdown menu.

Item 9. Describe the occurrence, the circumstances surrounding the event, and their sequence. Enter as much detail about the adverse event as possible to assist reviewers get an accurate picture of what occurred and of the setting.

Item 10. Indicate whether the event has been resolved or is still ongoing.

Item 11. Describe what action(s) were taken by the field center staff and/or the Principal Investigator. Indicate whether medically trained personnel was present or contacted, the timing of various actions taken in response to the event, the study participant's response, and the resolution of the event.

Item 12. Select whether the event was foreseen (Yes) or not (No) from the drop-down menu based on information from the Informed Consent, MOP, or other source.

Item 13. Select the likelihood choice of response from the drop-down menu, based on information from the Principal Investigator and other sources.

This form may be filled in consultation with a supervisor or medically trained personnel. It may also be updated after review by the medical director or ARIC principal investigator.