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

INSTRUCTIONS FOR THE SERIOUS ADVERSE EVENTS FORM (SAE)

I. General Instructions

The Serious Adverse Events form is designed to record and track any adverse event considered serious that affects a study participant, whether or not it is related to his/her participation in ARIC. The SAE form must be completed in CDART within 48 hours of a serious adverse event and the Arichelp must be notified (by email) of the occurrence of the event (see below).

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 SAE.

Once the study participant's safety and comfort have been addressed following a Serious Adverse Event a SAE form is entered into CDART. The ARIC field center staff entering the SAE 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 SAE to the NHLBI by the Coordinating Center, within 72 hours. 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.

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 SAE becomes available. If the adverse event has been defined as SAE because it resulted in an admission to an ER or hospital, it is important for the field center personnel to find out whether the ARIC participant was admitted for 24 hours or more. If the participant was discharged in less than 24 hours the event is classified as a minor adverse event (MAE) instead. The original SAE form is then deleted from CDART and the adverse event is recorded in CDART as a MAE. Once this done arichelp@unc.edu is notified of the reclassification.

The study participant does not need to be present when this form is completed.

II. Specific Instructions

Before filling the SAE form obtain as much information about the adverse event as possible before beginning to enter the SAE into CDART. Information summarizing the event and its circumstances, such as triggering factors, signs and symptoms experienced by the study participant, the duration of the condition, and the apparent causes are informative in documenting the event and assist reviewers.

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 serious adverse event for the participant during this visit.

Item 5. Record the event number.

Item 6. Enter the date when the serious 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. The form may be accessed more than once if meaningful updates to this information become available; arichelp@unc.edu should be notified if the form is updated.

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 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 the ARIC principal investigator.