



# SERIOUS ADVERSE EVENT FORM

ID NUMBER:

FORM CODE:  S  A  E

DATE: 06/01/2011  
Version 1.0

## ADMINISTRATIVE INFORMATION

0a. Completion Date: / /   
Month Day Year

0b. Staff ID:

**Instructions:** This form should be completed within 24 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  Yes If Yes, date reported: / /   
 No Month Day Year

Field Center IRB  Yes If Yes, date reported: / /   
 No Month Day Year

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

9. Describe the event :

10. Indicate whether the event is:  Ongoing  
 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 track any adverse event considered major that affects a study participant, whether or not it is related to his/her participation in ARIC. The SAE form must be completed in the DMS within 24 hours of a serious adverse event and the ARIC coordinating center must be notified of the occurrence of the event (see below).

An adverse event is considered serious if it results in any of the following: Death, a threat to life, requires (inpatient) hospitalization, will likely cause persistent or significant disability or incapacity, is likely associated with risk of a congenital anomaly or birth defect, or requires treatment to prevent one of the outcomes previously listed. Pre-existing conditions detected as a result of participation in ARIC, its tests and examination protocols do not by themselves constitute an adverse event. By definition, a serious adverse event is unanticipated and unexpected, whether study-related or otherwise.

Once the study participant's safety and comfort have been attended to following a Serious Adverse Event (see MOP 2) a SAE form is entered into the data management system. 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](mailto:arichelp@unc.edu). This results in 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 of the field center unless additional information is needed. Field centers also follow their Institution's protocol that may require notification of the study PI and/or the IRB.

This form may be accessed more than once, since information may not be complete at the time of initial entry about action(s) taken by the field center and/or the Principal Investigator concerning the adverse event. Similarly, there may be a short delay before the local IRB is notified. Consequently, field center staff should determine whether a SAE form for the event was previously entered in the DMS before attempting to enter a new form.

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

### II. Specific Instructions

Obtain as much information about the adverse event as possible before beginning to enter the SAE into the data management system.

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 their 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. Enter as much detail about the adverse event as possible.

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.

Item 12. Select the likelihood choice of response from the drop-down menu, based on information from the Principal Investigator and other sources.