



OMB#: 0925-0281

Exp 3/31/2014

MINOR ADVERSE EVENT FORM

ID NUMBER:

FORM CODE:

M	A	E
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DATE: 06/01/2011
Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date:

		/			/				
Month			Day			Year			

0b. Staff ID:

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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? YES or NO (Y or N)

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

6. Date MAE occurred:

		/			/				
Month			Day			Year			

7. Reported to:
Principal Investigator Yes, If Yes, date reported:

		/			/				
Month			Day			Year			

 No

Field Center IRB Yes, If Yes, date reported:

		/			/				
Month			Day			Year			

 No

8. Source of the event:

- Interview with study participant.....A
- Blood drawB
- Lung function testingC
- Other physical examination tests.....D
- Other _____.....E

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

- Yes (Go to End)
- 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 within seven days of a minor adverse event.

An adverse event is considered minor if it **does not** result 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 a congenital anomaly or birth defect, or requires treatment to prevent one of the outcomes previously listed. Minor adverse events are anticipated, and expected to occur as risks stated in the informed or the study protocol, whether study-related or otherwise. Pre-existing conditions detected as a result of participation in ARIC, its tests and examination protocols do not by themselves constitute an adverse event.

When a Minor Adverse Event form is entered into the data management system, it triggers a series of actions at the Coordinating Center: 1) A report is generated containing the information reported by the field center; 2) the contents of that report are reviewed at the Coordinating Center; and, 3) NHLBI is notified within three months. Coordination between the CC and the field center may be required, either to obtain additional information or to follow-up on specific action(s) taken by the field center.

This form may be accessed more than once, since adverse event information may not be complete at the time of initial entry and action(s) taken by the field center and/or the Principal Investigator may not be complete or accomplished at the time of initial data entry. Similarly, there may be a short delay before the local IRB is notified. Consequently, field center staff should determine whether a MAE form for the occurrence 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. The information required is gathered at the time of the study visit.

II. Specific Instructions

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